The Impact of Health Literacy on the Attitudes toward Pharmacological Treatment in Patients with Schizophrenia Spectrum Disorder

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The Impact of Health Literacy on the Attitudes toward Pharmacological Treatment in Patients with Schizophrenia Spectrum Disorder

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Background

Problem statement:
There are racial disparities in relation to the diagnosis and treatment of patients with schizophrenia spectrum disorders (SSD). These disparities can be attributed to several factors, including cultural incompetence, stigma in regard to mental health disorders, access to care barriers, inadequate social support, and poor health literacy. This study aims to investigate health equity by increasing health literacy using inpatient educational resources in patients diagnosed with SSD.

Introduction:
Mental health disorders are underdiagnosed, and therefore insufficiently treated in marginalized communities [1-3]. While the most common disorders are anxiety and depression related, a large number of people are greatly affected by psychotic disorders, including schizophrenia spectrum disorders (SSD). Worldwide, there are approximately 24 million people living with schizophrenia [4]. Schizophrenia is a neurocognitive disorder involving excess dopamine in the brain [5]. This chemical imbalance leads to a spectrum of positive symptoms (hallucinations, delusions, disorganized speech and behavior) and negative symptoms (apathy, flat affect, speech poverty, lack of motivation, and social isolation). Individuals with schizophrenia can also have concomitant bipolar spectrum disorders (BPSD), which can further complicate and delay diagnosis and treatment. Given the progressively worsening nature of SSD, symptoms can become severely debilitating.

Research has shown discrepancies in the rate of diagnosis and pharmacological treatment in Caucasians compared to ethnically marginalized communities. Even when presenting with the same symptoms, African Americans (AA) are 2.4 to 5 times more likely to be diagnosed with schizophrenia than White Americans, and White Americans are more likely to be diagnosed with Bipolar Spectrum Disorder [6, 7]. When examining the discrepancies in detection and treatment between ethnic minorities and White Americans, it is important to consider social and cultural influences as potential driving factors for the expansion of the health equity gap. In order to make appropriate and effective treatment guidelines for SSD in African Americans and other ethnically marginalized communities, several factors must be investigated and addressed.

The stigmatization of mental health disorders plays a direct role in delaying diagnosis and treatment, as individuals with mental health illnesses are less likely to seek help [8]. In addition to this, many ethnic minorities are hesitant to participate in medical studies or even

seek medical attention for mental and physical illnesses due to a general mistrust of the healthcare system [9-11]. The negative beliefs surrounding medical care are a direct result of the historically unethical experimentation (HeLa cells, gynecological exploration), intentional neglect (Tuskegee Syphilis Study), and mistreatment of ethnic minorities and incarcerated populations (unethical sterilization) [12-16]. Dismantling this stigma and mistrust requires strategically intentional interventions in such populations and developing culturally competent healthcare providers is paramount.

Access to medical care should also be examined, as it plays a large role in healthcare outcomes. Burra et al. highlighted how housing status was associated with resources at the time of discharge in patients on an inpatient psychiatric unit [17]. In comparison to housed individuals, homeless individuals had less resources and support and were less likely to have outpatient follow-up, case management, and coverage for prescription medications at time of discharge. Access can be influenced by several factors, including health literacy, socioeconomic status (SES), access to consistently reliable transportation and medical resources, distance to healthcare facilities, healthcare provider-to-patient ratios, access to childcare, and financial and social ability to take time away from work in order to receive consistent follow up, including psychotherapy and medication management. In areas where virtual treatment options are offered, access to reliable resources (equipment, internet access, software, etc.) is necessary for adequate patient follow-up.

Given that ethnic minorities often make up the majority of lower SES populations, it can also be postulated that their decreased understanding of disease processes, treatment options, and handling of adverse side effects is a barrier to seeking and establishing care, as well as receiving continuity of care. Several studies have shown an association between low SES and higher risk of hospitalization and mortality in patients with schizophrenia when compared to individuals with higher SES [18, 19]. Further, poor health literacy regarding mental health is associated with lower SES [20].

Several studies have examined the associations between knowledge, medication adherence, and the use of educational programs in patients with schizophrenia [21,22,23]. The Knowledge About Schizophrenia Test (KAST) is a validated 18-item, multiple- choice test developed to assess knowledge about schizophrenia for research purposes [24]. While this test assessed knowledge in lay community members, caregivers of people with schizophrenia, police officers, and healthcare professionals, another study by Chan et al. used a modified version of the KAST specifically in patients diagnosed with schizophrenia spectrum disorders to investigate the association between patient knowledge, insight into illness, and medication adherence [25]. This study found that patients with higher KAST scores and more insight were more adherent to treatment. Other studies have focused on utilizing educational tools to improve quality of life and discovering which medium of educational resources is the most promising for enhancing knowledge in patients with schizophrenia [26,27,28]. Although such studies are significant in continuing the conversation about the impact of health literacy on medication adherence and overall quality of life in patients with mental illness, there is still a need for effective, easily accessible educational resources that can be used nationwide to assess and improve the healthcare literacy of patients with SSD. Further, most of the studies investigating educational interventions are carried out in the outpatient setting on presumably well-stabilized individuals. This study will evaluate the effects of providing these interventions to patients as they are recovering from acute exacerbations in the inpatient

setting. Our study aims to develop a multimedia educational approach that involves a dedicated space for clinicians to identify and fill health literacy gaps, for the purposes of improving attitudes toward treatment and adherence. We plan to carry out a prospective study examining the effect of providing culturally sensitive educational resources on the health literacy and attitude toward pharmacological treatment in patients with a new or prior diagnosis of schizophrenia spectrum disorder at University Medical Center in New Orleans, Louisiana.

Health literacy will be assessed using the Knowledge About Schizophrenia Test (KAST). An assessment for attitudes toward treatment will be developed specifically for this study, with guidance from the Drug Attitude Inventory (DAI) and the Attitudes towards Neuroleptic Treatment (ANT), which was found to be useful in the quantitative assessment of attitudes before and after initiation of neuroleptic medication [29]. The National Alliance on Mental Illness (NAMI) will be used to guide the development of inpatient educational resources.

We hypothesize that health literacy scores and attitude towards treatment will improve following educational intervention. A possible limitation of this study is the effect of concomitant intellectual disability (ID) on an individual's ability to comprehend the provided educational resources. Therefore, we plan to exclude patients with a documented history of intellectual disability and patients suspected to have intellectual disability based on clinical interactions. We also plan to follow up with participants monthly, where we will utilize tools such as the Medication Adherence Rating Scale (MARS) to provide further insight into adherence to treatment plans [30,31].

We believe the information provided from this study can be of great significance in strengthening the patient-provider relationship, building a community, and dissolving the stigma around mental health, while simultaneously empowering and encouraging patients to get more involved in their care. Due to the contribution of mental health literacy on healthcare outcomes, we believe such an intervention can prove to be unequivocal in decreasing the health equity gap in mental health disorders and beyond. At the minimum, it will provide necessary insight into the needs of this underserved and highly vulnerable population and guidance on navigating their treatment.

Study Aims/Objectives

a. Assess health literacy level as it relates to schizophrenia before and after provision of educational resources.
b. Assess the attitude toward treatment of each patient before and after provision of educational resources.
c. Create and provide inpatient educational resources in the form of audiovisual and textual infographics developed by the Louisiana State University Health Sciences Center- New Orleans, Department of Psychiatry.
d. Collect and analyze patient- centered data, including age, gender, ethnicities, and highest level of education, to identify any trends in healthcare literacy as measured by the KAST across these demographics.

Primary endpoints: Post- intervention KAST and ATT scores
Secondary endpoints: MARS scores, KAST and ATT scores in relation to demographics (age,

gender, ethnicity, highest level of education) collected

Study Design

Inclusion Criteria

i. Patients admitted to the University Medical Center-New Orleans (UMCNO) inpatient behavioral health unit ages 18 and older with a new or previous diagnosis of schizophrenia spectrum disorder outside of substance use disorders
ii. Patients must be proficient in English.
iii. Patients must have a government issued social security number (required for reimbursement through the university).

Exclusion Criteria

i. Patients at UMCNO that are ages 17 or younger
ii. Patients with SSD and concomitant intellectual disability, as evidenced by prior documented history on chart review or patients suspected to have intellectual disability or impairment based on clinical interactions
iii. Patients with concomitant substance use and documentation of psychosis being resolved after a period of washout and without the use of psychotropic medications
iv. Patients unable to complete health literacy assessments, attitude towards treatment assessments, and IQ testing due to severity of symptoms during hospitalization
v. Patients that are not proficient in English
vi. Patients that do not have a government issued social security number

Study Assessments and Outcome Questionnaires

The Knowledge about Schizophrenia Test (KAST):
The KAST [24] is an 18-item multiple-choice test designed to measure knowledge about schizophrenia. The questions focus on knowledge of development, symptoms, treatments, and supporting information about schizophrenia.

Attitudes towards Neuroleptic Treatment (ANT):
The ANT [29] is a 12-item questionnaire assessing attitudes using a visual analogue scale form in which participants note their opinions on a scale of 0-100 for each statement.

Drug Attitude Inventory (DAI):
The Drug Attitude Inventory is a 30-item questionnaire assessing attitudes toward medication using a true-false format.

Medication Adherence Rating Scale (MARS):
The Medication Adherence Rating Scale [30] is a measurement tool for eliciting patients' reports of nonadherence. This study will use a 10-item version of the MARS [31].

Study Methods

Phase 1: Development of Educational Intervention Materials

The LSU- Ochsner Department of Psychiatry, including staff, residents, and trainees will work collectively to develop the attitudes toward treatment questionnaire and the interventional educational resources that will be provided to the patients during Phase 3. Extensive efforts will be made to produce culturally sensitive and appropriate materials. In general, educational

materials will be developed using language that is inclusive, clear to understand and avoids stigmatizing terms. When visual aids are used, they will reflect the diversity of the population served, in a respectful manner. Further, the language and visuals utilized in NAMI educational videos and online readings will be used as guidance on creating such material.

The attitudes toward treatment (ATT) questionnaire will include approximately 20 items and will be developed using guidance from the Drug Attitude Inventory (DAI-10) and the Attitudes toward Neuroleptic Treatment (ANT) assessment. The educational video will be approximately 5- 10 minutes, and the script will be developed using guidance from the National Alliance on Mental Illness (NAMI) and the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V). The contents of the video will include the pathophysiology of SSD, as well as common symptoms along the spectrum, natural history, available treatment options and frequently associated adverse side effects. The educational pamphlet will be produced with guidance from NAMI and include similar content, reiterated in written form.

Phase 2: Implementation of Educational Intervention

Medical charts will be reviewed for patients in the UMCNO inpatient behavioral health unit that may qualify based on incoming symptom presentation. Once on the behavioral health unit, patients will receive the standard of care, including any necessary testing, medications, and therapeutic interventions. This will be provided regardless of insurance status. If patients have insurance, their insurance will be utilized to pay for costs associated with their hospitalization and they will be responsible for any applicable co-pays. For those patients who do not have insurance, case management staff will assist them in applying for insurance while in the hospital. If not approved, patients will be sent a bill for the charges associated with their hospitalization. It is also the standard of care to provide patients with at least a one-month supply of their medications prior to discharge. For uninsured patients, there are several charity programs staff will utilize to obtain these medications at little to no cost to the patients.

Once stabilized on the inpatient unit, patients will be approached for participation in the study, and consent will be obtained. Then, the clinician will approach the patient to assess participation in the educational portion of the study. If amenable, the clinician will then describe the process of the educational intervention phase, which is further described below. The patient will also be informed of the follow-up protocol at this time. If the patient is amenable, the clinician will take the patient to one of the quiet rooms on the inpatient units so that he or she may complete the required components. Participants will be given an assessment examining attitude toward treatment, as described in Phase 1. The Knowledge about Schizophrenia Test (KAST) will be administered to obtain a baseline health literacy score. This will represent Day 1 of the study. On Day 2 of the study, patients will sit with a healthcare provider one-on-one, and watch an educational video about SSD, as previously described in Phase 1. During this time, the healthcare provider will answer any questions. On Day 3, the educational pamphlet will be provided to the patient prior to the second psychoeducational meeting. On Day 4, attitude toward treatment and health literacy scores will be reassessed using the initial pre-intervention questionnaires. Please see the chart below for a schematic representation of the approximate timeline of events.

These days are subject to change given the course of the patient's hospitalization and any patient-specific barriers that prevent the collection of data. If a patient is unavailable or experiences an exacerbation or decompensation of their condition, the assessment or

intervention will be postponed until the patient is able to participate. If a patient experiences suicidal ideation or thoughts of self-harm, this will be fully investigated by the healthcare provider to determine if intent and plan are present. Every effort will be made to protect patients from self-harm while on the unit. Depending on the severity (passive versus active), the educational resources or assessments may be postponed until the patient is able to resume participation.

Of note, patients will be selected to carry out the KAST and ATT randomly by either of the resident physicians using a randomization tool. There will be 4 resident physicians carrying out the patient questionnaires and educational sessions. They will be assigned a number 1-4, which an excel- integrated tool will use to randomize which physician will administer the KAST and ATT questionnaires. The resident that will complete the next task will be the one assigned the next chronological number, and so on. For example, resident #2 is randomly selected to do the KAST and ATT questionnaires. Then, the resident assigned #3 will carry out the first educational session. This is to ensure the patient does not interact with a resident physician more than once while on the inpatient unit. Follow up calls will be carried out by either resident physician. Patient identities will be concealed from the individuals analyzing the data by using numerical identifiers.

Patients will act as their own control, as their initial KAST and ATT questionnaires will serve as a baseline for which to compare future KAST and ATT questionnaires. At the end of each phase, the clinician will transfer the patient's answers electronically into the dataset. Patients will be paid $50 through Clincards issued by the research team upon discharge from the hospital. Assessments and questionnaires will be carried out on paper, while the educational resources will be provided electronically via tablet.

Procedures	Day 1	Day 2	Day 3	Day 4	Months 1 -12
KAST	X			X	
ATT (ANT + DAI)	X			X	
Video		X			
Psychoeducational Meeting 1		X			
Educational Brochure			X		
Psychoeducational meeting 2			X		
Monthly follow up phone calls with MARS					X

Phase 3: Data Extraction

This project will require approval from both the Louisiana Health Sciences Center-New Orleans Institutional Review Board and the University Medical Center- New Orleans Office of Research. A formal data request will be made to UMCNO with the needed information for data abstraction. Data metrics will be pulled from the UMCNO electronic medical record

(EMR). Information that will be extracted from the electronic health record includes race, gender, ethnicity, age, mental health diagnosis, number of hospital admissions and Emergency room presentations, pharmaceutical agents prescribed, type of insurance, if any, housing status, and highest level of education achieved. This will occur once patients have been stabilized and consented to participate in the study.

For further clarification on the proposed timeline:

a. a. Recruitment: This will be an ongoing task from the start of the study, where prospective patients will be identified from the Behavioral Health Emergency Room (BHER) and BH inpatient units. Consent will be obtained when patients are stable.
b. Administration of questionnaires, completion of educational interventions: Please see the proposed timeline table in the protocol. An exact timeline cannot be given, as events are contingent upon the patient's ability to participate and thus will be different between individuals.
c. Data collection will be ongoing and will last until the final follow-up data from the last patient is obtained.

Follow up

Patients will receive monthly follow-up calls that last approximately 5-10 minutes each. During these calls, they will be asked questions about medications, symptom control, and follow-up. A sample of questions is listed below. In addition, they will also be asked to provide answers to the questions listed on a modified version of the Medication Adherence Rating Scale (MARS).

1. Are you taking any medications to manage your symptoms: yes/ no?
2. How has that medication affected your symptoms: better/ worse/ no change?
3. If you are no longer taking your medications, what is the reason: ASE/ unable to pay for prescription/ unable to pick up prescription?
4. If applicable, have you been going to the scheduled follow up visits with your behavioral health provider: yes/ no?
5. If you answered no to the previous question, what is the reason: transportation/ time conflict/ forgot?
6. Have you been admitted to a psychiatric facility since your last follow up call: yes/ no?
7. If so how many times: 1-3/ 3+?

Table 1: 10-item medication adherence rating scale (MARS)

No.	Questionnaire	Question Answer
1.	Do you ever forget to take your medication?	Yes/No
2.	Are you careless at times about taking your medication?	Yes/No
3.	When you feel better, do you sometimes stop taking your medication?	Yes/No
4.	Sometimes if you feel worse when you take the medication, do you stop taking it?	Yes/No
5.	I take my medication only when I am sick	Yes/No
6.	It is unnatural for my mind and body to be controlled by medication	Yes/No
7.	My thoughts are clearer on medication	Yes/No
8.	By staying on medication, I can prevent getting sick.	Yes/No
9.	I feel weird, like a "zombie" on medication	Yes/No
10.	Medication makes me feel tired and sluggish	Yes/No

Adverse Events

This study does not anticipate adverse events beyond psychological discomfort as it relates to the awareness and processing of a newly diagnosed or established diagnosis of a mental health condition. However, all adverse events will be collected and reported in accordance with the safety event and quality reporting as outlined by Janssen. This will include adverse events (AE), serious adverse events (SAE) including lack of effect of pharmacological intervention, reports of drug exposure during pregnancy, and abnormal pregnancy outcomes. Definitions of adverse events and contact information are listed below:

Adverse Event (AE)

Any untoward medical event in a patient administered a pharmaceutical product which does not necessarily have to have a causal relationship with the treatment. An adverse event can be any unfavourable and unintended sign (including abnormal finding or lack of expected pharmacological action), symptom, or disease temporarily associated with the use of a medicinal (investigational or non-investigational) product, whether or not related to that (investigational or non-investigational) product.

This includes any occurrence that is new in onset or aggravated in severity from the baseline condition, or abnormal results of any diagnostic procedures, including laboratory test abnormalities.

Adverse Event of Special interest

Adverse events of special interest are events that the Company is actively monitoring as a result of a previously identified signal (even if non-serious). There are no required Adverse events of special interest of paliperidone to be reported to the Company. In case of any amendments to the AESI list, Company will notify the Investigator. Investigator will ensure that these changes are updated in the protocol as soon as practical.

Serious Adverse Event (SAE)

Any adverse event occurring that:

- Results in death
- Is life-threatening
- Requires in-patient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect
- Any suspected transmission of any infectious agent via administration of a medicinal product
- Is considered medically significant*

*Any untoward medical occurrence that is considered medically significant. Medical and scientific judgment should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not result in death, be life-threatening or require hospitalization but may be considered a serious adverse drug experience when, based on appropriate medical judgement, that may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the other outcomes listed in the bulleted list above. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in hospitalization, or development of drug dependency or drug abuse or malignancy.

Hospitalization

For reports of hospitalization, it is the sign, symptom or diagnosis which led to hospitalization that is the serious event for which details must be provided. Any event requiring hospitalization or prolongation of hospitalization that occurs during a study must be reported as a serious adverse event, except hospitalizations for the following:

- Hospitalizations not intended to treat an acute illness or adverse event (e.g., social reasons such as pending placement in long-term care facility)
- Surgery or procedure planned before entry into a study. [Note: Hospitalizations that were planned before the signing of ICF and where the underlying condition for which the hospitalization was planned has not worsened will not be considered serious adverse events. Any adverse event that results in a prolongation of the originally planned hospitalization is to be reported as a new serious adverse event.]

Special Situations

The following special situations must be reported to Company with or without an associated serious adverse event (SAE):

- Drug exposure during pregnancy (paternal, maternal)
- Suspected transmission of any infectious agent via administration of a Janssen Product(s) under study.

These safety events may not meet the definition of an adverse event; however, the Parties agree that for reporting purposes, they are deemed to be adverse events.

Product Quality Complaints

A PQC may have an impact on the safety and efficacy of a Company product. Timely, accurate, and complete reporting and analysis of PQC information from studies are crucial for the protection of patients, investigators, and the Company, and are mandated by regulatory agencies worldwide. The Company has established procedures in conformity with regulatory requirements worldwide to ensure

appropriate reporting of PQC information. The Institution agrees that Lot and/or Batch #s shall be collected, when available, for all PQC reports, including reports of failure of expected pharmacological action (i.e., lack of effect) of a Janssen Medicinal Product. A sample of the suspected product shall be maintained for further investigation if requested by the Company. Any complaint that indicates a potential quality issue during manufacturing, packaging, release testing, stability monitoring, dose preparation, storage or distribution of the product or delivery system is considered a PQC. Not all PQCs involve a patient.

Examples of PQC include but are not limited to:

Mislabelling or misbranding
Information concerning microbial contamination, including a suspected transmission of any infectious agent by a product
Any significant chemical, physical, or other changes that indicate deterioration in the distributed product
Any foreign matter reported to be in the product
Mixed product, e.g., two drugs are mixed-up in the packaging process
Incorrect tablet sequence (e.g., oral contraceptive tablets)
Insecure closure with serious medical consequences, e.g., cytotoxics, child-resistant containers, potent drugs
Suspected counterfeit or tampered product
Adverse Device Effects including any adverse event resulting from insufficiencies or inadequacies in the instructions for use, the deployment, implantation, installation, operation, or any malfunction of a medical device or combination product. This also includes any event that is a result of a use error or intentional misuse and dosing device malfunctions (e.g., auto-injector button not working, needle detaching from syringe, etc.)
Physical defect (e.g., abnormal product odor, broken or crushed tablets, etc.)

"Extraordinary" correspondence

Correspondence with a regulatory authority or ethics committee regarding a safety issue that may impact the safety or benefit-risk balance of the Janssen Product(s) Under Study, and/or may impact patients or public health. Examples include:

Safety issues relating to a quality defect
Major safety issues identified with changes in the nature, severity or frequency of known serious adverse reactions which are medically significant or the detection of new risk factors for the development of a known adverse reaction or a new serious adverse reaction.
Major safety issues identified in the context of ongoing or newly completed post-marketing studies e.g., an unexpected increased rate of fatal or life-threatening adverse events.

Type of report	**Timelines**	**How to report**
Serious Adverse Event	Within 15 calendar days of becoming aware of the event(s)	By a secure means, as agreed by the Parties, on a Serious Adverse Event Form.
Adverse Events of Special Interest (AESI)	Within 15 calendar days of becoming aware of the event(s)	By a secure means, as agreed by the Parties, on a Serious Adverse Event Form.

Reports of drug exposure during pregnancy (maternal and paternal), with or without SAE.	Within 15 calendar days of becoming aware of the event(s)	By a secure means, as agreed by the Parties, on a Serious Adverse Event Form.
Reports of Suspected transmission of any infectious agent via administration of a Janssen Product, with or without an SAE	Within 15 calendar days of becoming aware of the event(s)	By a secure means, as agreed by the Parties, on a Serious Adverse Event Form.
Abnormal Pregnancy Outcomes (e.g. spontaneous abortion, fetal death, stillbirth, congenital anomaly, ectopic pregnancy)	Within 15 calendar days of becoming aware of the event(s)	By a secure means, as agreed by the Parties, on a Serious Adverse Event Form.
Lack of Effect (with or without a suspected adverse reaction), must be reported as an SAE.	Within 15 calendar days of becoming aware of the event(s).	By a secure means, as agreed by the Parties, on a Serious Adverse Event Form.
Product Quality Complaints	Within 3 business days of becoming aware of the event(s)	By a secure means, as agreed by the Parties.
Non-Serious Adverse Event* (*Not meeting other listed 3 business day reporting criteria e.g. AESI)	Annually and in final study report.	Recorded in CRF and reported annually and in final study report.
Follow-up information	Transmitted within the same timeframes as above i.e. if initial report was required to be submitted within 15 calendar days, follow-up information shall be submitted within the same timeframe.	Transmitted via same method as above i.e. if initial method of transmission was on an SAE form, follow-up information shall be transmitted in the same manner.

Janssen SAE/Pregnancy Notifications	TO: GMS_AE_Inbo@its.jnj.com Please note the underscores (_) in the email name this is critical to highlight as if its missing then the SAE will fail to transmit. CC: Janssen SRS/SRP and Clinical Project Scientist

Janssen PQC:	DL-DPYIE-Globalcontacts-NIS@its.jnj.com CC: Janssen SRP/CPS
Janssen Fax:	1-215-293-9955

Statistical analysis

A power analysis resulted in the two possible sample sizes as shown below:

> *An a priori power analysis was performed using g*power to estimate sample size for a paired sample t-test. Using a small effect size (d=.2), power of 80% (alpha of .05), the desired sample size is 199.*
> *An a prior power analysis was performed using g*power to estimate sample size for a paired sample t-test. Using a medium effect size (d=.5), power of 80% (alpha of .05), the desired sample size is 34.*

Per literature review, studies with educational interventions in patients with SSD had sample sizes ranging from 20s to several hundreds. None of the studies provided information on power analysis calculations or how sample size was obtained. Given that we will not have access to 200 patients with schizophrenia spectrum disorders at the study site within the time frame of the study, we have chosen to use the former power analysis.

To assess changes in knowledge and attitudes, a paired samples t-test will be completed on pre-intervention and post-intervention scores for the KAST and ATT. Demographic data will be analyzed using regression analysis.

Data Collection and Storage

Each study participant will be given an arbitrary study identification number. The study ID number will be used on all data collected for the purposes of this study. All assessments and questionnaires for this study will be entered using a tablet into the REDCAP system, a secure and HIPAA compliant web-based system provided through LSUHSC- New Orleans for data collection. Permission to access the project's Research Electronic Data Capture (REDCAP) program must be approved by an investigator or study coordinator. Participants and linking study identification numbers will be kept in a database outside of the REDCAP system on the LSUHSC-NO secure network drive in a folder that can only be accessed by individuals given permission by the primary investigator and study coordinator. This information will also be protected by a password only known to the study personnel. Informed consent forms will be kept in individual participant files which will be in locked file cabinets in a locked door.

Data extracted from the medical records will also be given an arbitrary study ID. This data will be collected using the REDCAP system. To track patient data that has been retrieved, a separate database will be kept on the LSUHSC-NO network drive linking the patient's medical

requisition number with the arbitrary study ID. This database will also be protected by a password only known to study personnel.

After the data has been analyzed and the study closed, data will be destroyed in compliance with LSUHSC-NO Institutional Review Board requirements.

Citations

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