

Improving Medication Adherence in Individuals with Psychiatric Illnesses

Meghann Alcala

Rutgers, The State University of New Jersey-School of Nursing

DNP Chair: Barbara A. Caldwell, PhD, APN-C

DNP Team Member: Mamilda Robinson, DNP, APN, PMHNP-BC

Date of Submission: March 14, 2020

Table of Contents

Abstract	5
Introduction	6
Background and Significance	8
Needs Assessment	13
Problem/Purpose Statement	16
Clinical Question	18
Aims and Objectives	19
Review of the Literature	19
Theoretical Framework/Conceptual Framework	35
Methodology	37
Project Design	37
Setting	38
Study Population	38
Subject Recruitment	38
Consent Procedure	41
Risks/Harm/Ethics	41
Subject Costs and Compensation	43
Study Interventions	43
Outcome Measures	48

IMPROVING MEDICATION ADHERENCE

	3
Project Timeline	51
Resources Needed	51
Evaluation Plan	52
Data Analysis Plan	52
Maintenance and Security	53
Results	54
Discussion	61
Implications/Recommendations	69
Clinical Practice	69
Healthcare Policy Implications	70
Implications on Quality/Safety	71
Implications on Education	72
Implications on Economic/Cost Benefits of Project	73
Other Implications as Related to the Project	74
Sustainability	74
Plans for Dissemination and Professional Reporting	75
Summary	76
References	77
Appendix A – Site Approval	87

IMPROVING MEDICATION ADHERENCE

	4
Appendix B – Theoretical Framework.....	88
Appendix C – Table of Evidence	92
Appendix D – Recruitment Flyer	103
Appendix E – Participant Consent Form	103
Appendix F – Budget	111
Appendix G – Medication Adherence Rating Scale	111
Appendix H – Educational Materials	112
Appendix I – How To Use the Medisafe Cell-Phone App.....	112
Appendix J – Weekly Medication Adherence Log	114
Appendix K – Mobile Device App Satisfaction.....	115
Appendix L – Common Psychotropic Medication Side Effects and Ways to Deal.....	115
Appendix M – Community Resources in New Jersey – Peer Support Groups.....	116
Appendix N – Medisafe App	120
Appendix O – Clinical Global Impressions (CGI) Tool	120
Appendix P – Provider Consent Form	122
Appendix Q – Schedule for Psychoeducation Group	127
Appendix R – Participant Demographics, Surveys, and Code Book	127

Abstract

Schizophrenia and schizoaffective disorder are chronic, serious mental health illnesses that can impact an individual's well-being and result in severe symptoms. Psychiatric medications are a necessary treatment for people with these disorders; yet, many patients do not take their medications as prescribed. Medication nonadherence often results inadequate symptom reduction, poor psychosocial functioning, arrests, substance use, and high rates of relapse and hospitalizations. The **purpose** of this quality improvement project was to use a *psychoeducation program and mobile device application (app), Medisafe, to improve medication adherence from baseline medication adherence in adult psychiatric outpatients with schizophrenia or schizoaffective disorder*. **Methodology** included improving medication adherence using a quality improvement approach, implementation of a psychoeducation program over a series of four weekly approximate one-hour sessions once a week; and implementation of Medisafe. The Medication Adherence Rating Scale (MARS) was administered pre-post- and post-intervention. The Mobile Device App Satisfaction Survey (MDASS), and Clinical Global Impressions Scale (CGI) were administered pre- and post-intervention to measure the study outcome. Also, weekly adherence percentage reports were evaluated on participants' mobile device apps. **Results** were that MARS and MDASS results were not statistically significant, while CGI results were statistically significant post-intervention. **Implications** are that the app can continue to be used in the mental health population, yet further research is needed.

Keywords: medication adherence, medication compliance, schizophrenia, schizoaffective, schizophrenia spectrum and other psychotic disorders, psychosis, psychoeducation, mobile applications, mHealth, smartphone, mobile app, cell phone, android, mobile, and iPhone.

Introduction

Schizophrenia is a severe public health concern as well as a main disability in the United States (Fitch, Kosuke, and Villa, 2014). It is a chronic and serious mental illness that can affect social functioning and quality of life (Cetin & Aylaz, 2018). Another similar and chronic disorder, schizoaffective disorder, can result in severe symptoms and have negative long-term effects on individuals (Mayo Clinic, 2019a). The World Health Organization (2013, p. 10) in their Mental Health Action Plan 2013-2020, emphasizes that healthcare facilities should provide “comprehensive, integrated, and responsive mental health and social care services in community-based settings.” These services include education such as listening to and acknowledging patients’ understanding of their illness and finding ways to assist them in recovery, which may aid this population in adhering to needed treatment. A necessary treatment for people with serious mental illnesses like schizophrenia or schizoaffective disorder is psychotropic medications; but, many patients with these disorders do not directly take their medications (Haddad, Brain, and Scott, 2014). Psychotropic medications, in this case, antipsychotic medications, must be taken on a regular basis as prescribed to reduce and control psychiatric symptoms long-term (U.S. Department of Veterans Affairs, n.d.). The study to be conducted by the principal investigator will determine the benefits of psychoeducation and the use of Medisafe, a mobile device application, in improving baseline medication adherence in mental health outpatients with schizophrenia or schizoaffective disorder.

Medication adherence refers to the “extent to which patients take medication as prescribed by their doctors (U.S. Food & Drug Administration, 2018, “Are You Taking Your Medications as Prescribed?” para. 1). Adherence includes remembering to take medications in a

timely manner, understanding directions, and getting prescriptions filled. Psychoeducation is described as providing information and education to people participating in or seeking mental health services. Such individuals include those diagnosed with mental health conditions and their families (Bauml, et al., 2006). Additionally, patients are considered adherent if they take their prescribed medications 80% of the time (American Medical Association, 2019). A medication cell-phone application, Medisafe (Please see Appendix N), is a tool that helps patients to track their medications with specific schedules and alarms and may improve patients' baseline medication adherence.

Worldwide, risk factors for psychotropic medication non-adherence in schizophrenia include lack of illness awareness (having insight into illness, and also perceived beliefs and attitudes about the nature of the illness), the consequences of symptoms (depression, cognitive problems, and positive and negative symptoms), lack of social support, comorbid substance abuse, stigma, and the inconsistencies in mental health services (Haddad, Brain, and Scott, 2014). Risk factors for nonadherence to medications in outpatients with schizophrenia who live in the community may include intolerable side effects, lack of insight into mental illness or need for medications, substance abuse issues, ongoing symptoms, and lack of a therapeutic alliance with patients' providers. (Levin et al., 2014). The focus of the quality improvement project was to improve patients' abilities to take medications at designated times.

Project Site

A non-profit organization emphasizes recovery-focused, comprehensive primary care, mental health care, rehabilitation, and substance abuse services. Outpatient services are voluntarily offered to adults and children at 49 sites, which include three outpatient centers, 10

residential houses, office locations at three hospitals, and seven community offices. The partial care program includes specialized services such as psycho-educational and skills building groups and medication monitoring and education. Residential services include health and medication monitoring along with treatment as needed, among many others.

The organization benefitted from a program to increase patient medication adherence. Patients who attend the partial care program did not have a system in place to measure proper medication adherence in the community and residential settings. In addition, patients with schizophrenia and schizoaffective disorder, as well as the nurse practitioner involved in providing care for these patients, had reported problems with patients adhering to their prescribed medications. The lack of a proper system to monitor medication adherence and the reports from both provider and patients emphasizing problems with adhering to medication regimen suggested that implementation of the mentioned psychoeducation program and mobile device application, Medisafe, would improve adherence in this population.

Background and Significance

Schizophrenia is a severe mental illness that deals with thorough disruptions in thinking, language, sense of self, and individual perception. It is a treatable illness that affects over 21 million people worldwide (WHO, 2019). In addition, worldwide, it is considered one of the top 15 primary causes of disability. Approximately 4% of individuals with schizophrenia commit suicide, which is a rate that is significantly greater than the general population at 0.0126% (WHO, 2019; National Center for Injury Prevention and Control, 2015). People with the illness have an increased risk of early mortality than the general population and in the U.S., 28.5 years is the average potential life lost in those with schizophrenia (National Institute of Mental Health,

2018). Early mortality in the schizophrenia population may stem from suicide, homicide, accidental deaths, cardiovascular illness, respiratory illness, and other natural causes. Additionally, factors such as economic problems, negative health behaviors, and trouble adhering to medical treatments contribute to early mortality in the mental health disorder (Olfson, Gerhard, and Huang, 2015). Also, direct and indirect financial costs linked to schizophrenia are significantly greater than other chronic and physical health problems with indirect costs including social service needs, productivity loss, high risk of criminal activity, and other factors (National Institute of Mental Health, 2018). Annual U.S. costs for schizophrenia treatment range from \$94 million to \$102 billion with indirect costs contributing 50-85% of total illness costs. The economic strain of the disorder ranges from 0.02-1.65% of the gross domestic product and the great economic burden suggests a lack of adequate health care services to these patients; and, unfortunately, one in two people living with schizophrenia does not receive proper care for the disorder including treatment with medications, psychosocial therapy, or hospitalizations (Chong, et al., 2016; MayoClinic, 2019b; and WHO, 2019;). Nonadherence to needed medications contributes to the statistics, which emphasize a negative impact on patients' health and functioning, as well as a negative financial strain on society (Higashi, et al., 2013).

Individuals with the diagnosis of schizophrenia often experience psychotic episodes, including delusions and/or hallucinations, disorganized speech, disorganized or catatonic (unaware) behavior, or decreased emotional expression. These symptoms can negatively affect one or more of the primary areas of functioning including work, self-care, or social relations (American Psychiatric Association, 2013). To expand, the negative impact of the illness and the symptoms may result in violence/impulsivity, self-injury, social isolation, or homelessness (Sadock, Sadock, and Ruiz, 2015). People diagnosed with schizophrenia and related disorders

schizophreniform and schizoaffective illnesses comprise about 60-70% of the mental health population served by community psychiatric services (Chien, Mui, Cheung, & Gray, 2015).

Schizoaffective disorder, which is similar to schizophrenia, is a serious mental health condition involving symptoms of schizophrenia and a mood disorder (abnormally heightened mood or depression) (U.S. National Library of Medicine, 2019). It is seen in approximately 0.3% of the U.S. population and has lifetime prevalence rates of about 0.32% with a 0.5-0.8 range (National Alliance on Mental Health, 2019-a; Yogeswary, 2014). Further epidemiological information and cost information on schizoaffective disorder is not available, possibly because it is difficult to differentiate from other conditions since it includes a mood component. For example, clients with schizoaffective disorder are frequently incorrectly diagnosed with bipolar disorder, a mental illness consisting of at least one abnormally heightened mood episode followed by major depressive episodes (National Alliance on Mental Health, 2019; Sadock, et al., 2015). In contrast to bipolar disorder, patients with schizoaffective disorder, similar to patients with schizophrenia, may experience symptoms of hallucinations/delusions or disorganized thinking. In addition, though, and in contrast with patients who solely have the diagnosis of schizophrenia, the mood components of major depression or abnormally heightened mood (mania) would also be experienced in schizoaffective disorder (National Alliance on Mental Illness, 2019).

Nonadherence to psychotropic medications is a common problem in individuals diagnosed with schizophrenia or schizoaffective disorder, thus resulting in issues such as inadequate symptom reduction, poor psychosocial functioning, and high rates of relapse. Worldwide, approximate nonadherence rates in schizophrenia are around 50% (Velligan, et al.,

2014). Research worldwide indicate that there is a great need to assess the reasons for nonadherence and to implement effective interventions to improve medication adherence in this population (Chien, et al., 2015). With increased patient adherence, there may be reduced patient suffering and improved overall functioning, as well as a decrease in annual costs related to the disorders (Chong, et al., 2016).

A study that determined the informational needs considered most important by psychiatric outpatients showed that the need for and the side effects of medications were thought of as the most important aspects of treatment information (Perreault, Katerelos, Tardif, & Pawliuk, 2006). Furthermore, 65% of patients rated ‘signs to identify treatment progress’ as very important. Therefore, educating patients about aspects of their treatment that they find most helpful or important to them, may assist them in adhering to needed medications. Studies indicate the benefits of psychoeducation in improving medication adherence and motivating patients to remain adherent with needed treatment (Bäumli, et al., 2016; Cetin & Aylaz, 2018; and Chien et al., 2015).

Mindfulness-based psychoeducation and adherence therapy are two types of patient education that are shown to be effective in enhancing patient adherence to medications. Mindfulness-based education emphasizes focusing on an individual’s feelings in the present moment. It can be used to aid patients with psychiatric disorders to gain clinical insight into their illnesses, including insight into the importance of medication adherence. Adherence therapy, on the other hand, involves a combination of therapies that involve motivational interviewing, cognitive behavioral therapy, and psychoeducation (Cetin & Aylaz, 2018; Chien et al., 2015). For clarification purposes, motivational interviewing is a form of therapy that focuses on aiding

patients in overcoming ambivalence and increasing their desire to change (Hettema, 2009). On the other hand, cognitive behavioral therapy is a type of treatment that focuses on changing patterns of thinking; therefore, helping individuals to gain understanding and insight into their behavior (American Psychological Association, 2019). Psychoeducation, as explained earlier, refers to providing education to those seeking knowledge/treatment to mental illnesses (GoodTherapy, 2019). Adherence therapy, encompassing the different treatment modalities of motivational interviewing, cognitive behavioral therapy, and psychoeducation, may work to assist patients with schizophrenia/schizoaffective disorder to become adherent with needed treatment (medications) and to gain a better understanding into their conditions (Chien, et al., 2015).

Studies also indicate the benefits of technology such as smart-pill containers and cell-phone applications in creating medication profiles and setting alarms to assist patients in properly taking their medications at due times (Shadare, Williamitis, Hanisch, & Webb, 2017; Velligan, et. al., 2013). The technology mentioned that includes alarms and notifications to prompt patients to take scheduled medications, favor the formation of a habit, which may be helpful for patients who are ambivalent about medication adherence or who forget to take prescribed medications at correct times. The benefits of the prompts or alarms regarding medication adherence are apparent in the research along with the evidence indicating that cellular phones are personal, inexpensive, and accessible (Cole-Lewis and Kershaw, 2010). Although studies regarding psychiatric patients and use of Medisafe were not available, the application was ranked number one among advanced reminder applications via the Mobile Adherence Rating Score (MARS) survey and portrayed effectiveness in non-randomized studies involving other chronic conditions such as hypertension (Medisafe, 2019; Santo, et al., 2016).

This suggests that the Medisafe mobile device application may be an accessible and efficient tool for patients in the partial care program to use to improve their baseline medication adherence.

Increased medication adherence from patients' baselines using the mobile device prompts and alarms may result in decreased economic costs, reduced in-patient hospitalizations further leading to decreased costs, and improved over-all patient functioning (as discussed earlier).

Improved medication adherence may also indicate an improvement in patients' insights regarding the importance of adherence. In addition, mobile devices may support treatment engagement and sense of being able to manage schizophrenia/schizoaffective disorder (Swendsen et al., 2011; Palmier-Claus et al., 2012).

Needs Assessment

Problems occur when mental health outpatients at the partial care hospitalization program would incorrectly take their medications or miss medication dosages, placing them at greater risk for relapse, rehospitalization, decreased quality of life, and harm to self. Nationally, the mean rate of nonadherence to medication in patients with schizophrenia is 41%. When the definition of adherence entailed taking prescribed medications at least 75% of the time, nonadherence in this population increased to 50% in the U.S. (Haddad, et al., 2014).

In the United States, emergency department (ED) visits related to schizophrenia in the adult population in ages 18-64 from 2009-2011 were 382,000 with ED visit rates of 20.1 per 10,000 individuals, which is most likely due to medication nonadherence (Centers for Disease Control and Prevention [CDC], 2015). The ED visit rate in men with schizophrenia was 26.5 per 10,000 compared to the rate of 13.8 per 10,000 for women. One-half of ED schizophrenia visits resulted in either a hospital admission (32.7%) or transfer to a mental health hospital (16.7%).

The prior percentages mentioned were higher than percentages for ED visits that were not schizophrenia related (CDC, 2015).

Crude rates of hospital admissions of patients with mental health and behavioral disorders in NJ in 2016 was 68,391 (New Jersey State Health Assessment Data, 2019). The number of individuals with mental health disorders in the population in NJ in 2016 was 8,944,469 and crude rates per 10,000 individuals was 76.5. Additionally, data in NJ from 2014 indicate the population in the state receiving treatment for a mental health disorder with Mercer, Camden, and Cumberland counties at 12.1-13.5%; Ocean, Gloucester, Warren, and Morris counties at 10.7-12.1%; Atlantic, Monmouth, Somerset, Hunterdon, Bergen, and Passaic at 9.2-10.7%; and Sussex, Essex, Hudson, Middlesex, Burlington, Salem, Cape May, and Union at 6.8-9.2% (New Jersey State Health Assessment Data, 2019).

The number of hospitalizations in NJ of patients with schizophrenia spectrum disorders F20-F29 in 2016 was 13,798, which was most likely due to medication nonadherence and symptom exacerbation (New Jersey State Health Assessment Data, 2019). Although medication nonadherence rates in patients with schizophrenia/schizoaffective disorder in the state of NJ are not clear, occurrences of psychiatric hospitalizations, utilizing emergency psychiatric services, arrests, and substance use are all associated with medication nonadherence in patients with schizophrenia (Haddad, et al., 2014). In the facility, there is currently no system to monitor patients in the community for medication adherence, but such a system may be helpful for case management of the patients.

In 2016, state hospital readmission rates most likely related to psychiatric medication nonadherence in civil “non-Forensic” clients in the U.S. within 30 days was 7,715; 6.1% in NJ;

and 8.8% in the U.S. State hospital readmissions within 180 days was 17,365; 17.9% in NJ; and 19.7% in the U.S. In the U.S. in 2012, patients with schizophrenia had 383,000 inpatient hospital stays with the average length of stay being 10.4 days. During the same year, readmission rates in patients with schizophrenia was 15.7% with the average initial hospital stay being \$8,800 and readmissions with the same diagnosis costing the same amount (Agency for Healthcare Research and Quality [AHRQ], 2015; New Jersey 2016 Mental Health National Outcome Measures (NOMS): SAMHSA Uniform Reporting System, 2016).

In working with patients in a partial hospitalization program, the patients had described forgetting to take medications on time, both in the morning and in the evening. This resulted in either missed medication dosages or late administration of medication. One patient described taking another patient's medications by accident because she was in the habit of not checking her prescribed medications before taking them, while she was in the group home. Patients also reported that they were unsure of medication effects in relation to their illness. Also, although reports in the partial care program regarding medication nonadherence rates were not available, the nurse practitioner in the program had reported that particular patients with schizophrenia/schizoaffective disorder needed assistance with maintaining adherence to their medications since they forgot to take their medications at specific times of the day, both in the morning and in the evening.

Additionally, the Quality Assurance Department at the facility reported that there had been issues with patients in the residences taking their medications correctly (M. Alcala, personal communication, February 11, 2019). Patients with schizophrenia/schizoaffective disorders who live in the group homes at the facility are responsible for independently taking

their medications in a timely manner when the medications are delivered to them by staff from the program. Although the rate of nonadherence to medications is not known, reports indicated that the medication counts were off when staff checked the remaining pills left in each patient's possession weekly, indicating that the patients were not independently taking medications as prescribed. Oftentimes, there were more pills left in the patients' possessions than should be present after one week. As evident, patient nonadherence was a frequent problem in the particular partial hospitalization outpatient program mentioned above. The current services in the facility regarding medication monitoring and education were reassessed.

Problem/Purpose Statement

Studies have shown that nonadherence to pharmacological treatment is a common problem in outpatients diagnosed with schizophrenia and schizoaffective disorders, thus resulting in issues such as poor psychotic symptom reduction, poor overall patient functioning, and high rates of relapse, among other issues (Chien et al., 2015; Chien, Bressington, & Karatzias, 2017; El-Mallakh & Findlay, 2015).

In spite of research around the problem of medication nonadherence in psychiatric outpatients, researchers suggest that there is still much to discover. Interventions, such as psychoeducation and implementation of a medication adherence phone application to improve medication adherence in patients with mental health problems, including schizophrenia, were shown to be beneficial in increasing adherence in this population; yet, more studies are needed. Studies emphasizing mindfulness-based psychoeducation programs, motivational interviewing, and adherence therapy demonstrated improvements in medication adherence in Asian patients with psychosis, but trials with patients from other ethnic and sociodemographic groups are

needed (Chien et al., 2017; Chien et al., 2015). Also, the longer-term benefits of mindfulness-based education must also be considered (Chien et al., 2017). Furthermore, research in technological applications in assisting with medication adherence may also be beneficial.

Contemporary researchers are emphasizing research in three key areas of this problem: the importance of adhering to pharmacological treatment in mental health patients with schizophrenia and schizoaffective disorder; the reasons for nonadherence in the mental health population with these disorders, including the effects of nonadherence; and the benefits of psychoeducation and digital medication reminders related to medication adherence (El-Mallakh & Findlay, 2015; Pompili, et al., 2007; Chien et al., 2015; Chien et al., 2017; Cetin & Aylaz, 2018; Bäuml, et al., 2016; and Shadare, et al., 2017).

Research has demonstrated the benefits of a four-session, one hour per week, psychoeducation program in increasing baseline medication adherence in patients with schizophrenia/schizoaffective disorder. The program covered four topics: the symptoms of mental health illness (schizophrenia or schizoaffective disorders), the link between psychiatric illness and stress, the main effects and side effects of antipsychotic medications, and how patients can live in the community with their illness (Matsuda and Kohn, 2016).

In addition, research has also indicated the efficacy of educational 15-minute video presentations containing education regarding patients' diagnosis and the importance of medication adherence in the population with schizophrenia/schizoaffective disorder in improving baseline medication adherence. The intervention of the video presentations was conducted once a week over a four-week period and was effective in improving baseline medication adherence (McIlroy, 2018). Also, the benefits of using a mobile device alarm reminder app monitored

biweekly (to ensure that it was functioning correctly) over an eight-week period was shown to improve baseline medication adherence in the schizophrenia population (Shadare, et al., 2017).

In considering the research, a four-week, approximate one hour per week, psychoeducation program consisting of the four topics mentioned (one topic per week) with corresponding evidence-based video presentations on the specific topics (including illness and the benefits of medication adherence) have demonstrated to result in improved baseline medication adherence in the outpatient schizophrenia/schizoaffective disorder population. Also, the mobile device alarm reminder app was monitored weekly during each visit to assess functionality and to obtain patients' adherence percentage reports, as opposed to biweekly during an eight-week period, as mentioned in a previous study.

The purpose of the quality improvement project that was conducted by the PI was to determine whether a four-week, approximate one hour per week, psychoeducation program, including the use of Medisafe (a medication reminder app), conducted by the PI would improve medication adherence rates (compared to baseline medication adherence rates via the MARS scale) in patients diagnosed with schizophrenia or schizoaffective disorder. The study involved adult psychiatric outpatients diagnosed with either disorder who attend a partial hospitalization program in NJ.

Clinical Question

In adult psychiatric outpatients diagnosed with schizophrenia or schizoaffective disorder, will a four-week, approximate one hour per week, psychoeducation program including the education and utilization of the mobile device application, Medisafe, result in improved medication adherence compared to baseline medication adherence?

Aims and Objectives

The project's foundation was based on previous research that psychoeducation was beneficial in improving baseline medication adherence in patients with schizophrenia or schizoaffective disorder (Bauml, et al., 2016; Cetin & Aylaz, 2018). The aim of this quality improvement project was to use a psychoeducation program, including the use of the mobile device application, Medisafe, to improve medication adherence from baseline medication adherence in adult psychiatric outpatients with schizophrenia or schizoaffective disorder. Objectives included improving medication adherence from baseline adherence in psychiatric adult outpatients with schizophrenia/schizoaffective disorder in four weeks; implementation of a psychoeducation program in adult psychiatric outpatients over a series of four weekly approximate one-hour sessions, once a week to improve patient understanding of illness, problem-solving, and medication education; implementation of Medisafe, a cellular device application as a self-report measure for improved baseline medication adherence during a four-week span; and implementation of a weekly medication log to assess weekly medication adherence/nonadherence and reasons for non-adherence

Review of the Literature

The search of the literature conducted in February of 2019 by the co-investigator included a review of the impact of psychoeducation or mobile device applications on medication adherence in patients with schizophrenia/schizoaffective disorder in order to analyze current research regarding the clinical question. The question was "In adult psychiatric outpatients diagnosed with schizophrenia or schizoaffective disorder, will a four-week, approximate one hour per week, psychoeducation program including the education and utilization of a mobile

device application result in improved medication adherence compared to baseline medication adherence?” Databases and sites searched for the following literature review included the Cumulative Index of Nursing and Allied Health Literature (CINAHL), PubMed, Scopus, and PsycINFO. To facilitate a more extensive search of the key terms, the subject headings function in CINAHL, the MeSH terms function in Pubmed, and the map terms function in PsycINFO were utilized.

Keywords used were “Medication Adherence,” “medication adherence,” “medication compliance,” “schizophrenia,” “schizoaffective,” “schizophrenia spectrum and other psychotic disorders,” “psychosis,” “psychoeducation,” “mobile applications,” “mHealth,” “smartphone,” “mobile app,” “cell phone,” “android,” “mobile,” and “iPhone.” The applicable terms in each database within each key term class were connected using the Boolean term “OR.” Combinations of key term classes (i.e. schizophrenia and mobile applications) were used with the Boolean term “AND.” In addition, psychoeducation and mobile applications were used in separate searches to yield specific information on each intervention. Each database will be further discussed to investigate the search strategy that led to the final review of pieces used in the table of evidence (see Appendix C).

Inclusion criteria were original research studies, systematic reviews in peer-reviewed journals, or expert opinion non-research pieces that examined the effects of psychoeducation or mobile device reminder apps in medication adherence in adult patients with schizophrenia or schizoaffective disorders. Exclusion criteria included research used before 2012 (relevant and necessary information was found in a 2012 study) to include more recent information, bipolar disorder to focus on schizophrenia/schizoaffective disorder, and patients <18 years of age to

focus on adult patients. Studies remaining after exclusion criteria were applied in each database will be explained in detail.

In CINAHL, an initial search of “medication adherence,” “schizophrenia,” and “mobile device applications” yielded a total of four results, with two relevant pieces, which were added to the table of evidence. Afterwards, the search resumed with three key term classes including (MH “Medication Compliance” OR “medication adherence” OR “medication compliance”) AND (MH “Schizophrenia” OR MH “Schizoaffective Disorder”...), AND (MH “Mobile Applications”...). 12 results were obtained and two pieces were retrieved and added to the table for relevance. A search of “psychoeducation,” “medication adherence,” and “schizophrenia or schizoaffective disorder” yielded 26 results, with two pieces of relevance added to the table of evidence.

Using PubMed, three key term classes with further information including (“Medication Adherence” [MeSH] OR medication adherence...) AND “Schizophrenia Spectrum and Other Psychotic Disorders” [MeSH]...) AND (“Mobile Applications... OR mHealth”...) yielded 42 results with one relative study added to the table of evidence after exclusion criteria were applied. A search of psychoeducation using key-words mentioned in the CINAHL database search yielded 126 results, which was further narrowed to 43 results when exclusion criteria mentioned prior was applied with further filtering of “time frame of five years” and “human subjects only.” One piece of relevance was added to the table.

In Scopus, a search using the three key term classes described for the PubMed search strategy regarding mobile applications yielded 36 results and one piece of relevance was added to the table. An initial search of “psychoeducation” and “schizophrenia” yielded 1,303 results. A

search within the results including “medication adherence” and the years 2015-2019 were applied, resulting in 99 results. A specification of Open Access yielded the final 22 results with one piece of relevance added to the table.

In PsycINFO, eight searches were conducted with each individual search saved before the following one took place. An initial search of (“medication adherence” or “medication compliance”) resulted in 4,810 results, while a second search of “exp schizophrenia” yielded 86,154 results. A third search combining “schizophrenia or schizoaffective or psychosis” resulted in 155,344 results. A fourth search combining the prior second and third searches using the term “OR” resulted in 155,374 results. A fifth search of “exp Mobile Devices” resulted in 2,167 results, while a sixth search including various terms relating to “cell phone” resulted in 18,237 results. For the seventh search, combining searches five and six resulted in 18,237 results. For the eighth search, combining searches one, four, and seven ended with 18 results and two pieces of relevance were added to the table after exclusion criteria were applied.

The conducted searches resulted in studies emphasizing the consequences of medication nonadherence in the schizophrenia population and the benefits of psychoeducation and/or electronic reminders on medication adherence. Study limitations were also apparent and will be discussed.

Consequences of Medication Nonadherence

Acosta, Hernandez, Pereira, Herrera, and Rodriguez (2012) emphasized the impact of the high prevalence of medication non-adherence in the population diagnosed with schizophrenia and schizoaffective disorders and the importance of medication adherence-promoting strategies. Consequences of medication non-adherence include hospitalization, higher suicide risk, poorer

prognosis of illness, longer remission time regarding schizophrenic symptoms, drug and alcohol use, psychiatric emergencies, poor mental performance, dangerous behaviors leading to violence and arrest, and low life satisfaction. Additionally, psychotic relapse in patients with both disorders increases by five times after five years at 81.9%. Also, 40% of costs associated with the treatment of patients with schizophrenia/schizoaffective disorders are attributed to medication non-adherence. To further support the mentioned evidence, Haddad, Brain, and Scott (2014) discuss how medication nonadherence in patients with schizophrenia increases the patients' risks of harming themselves, readmission into hospitals, relapse, hospitalization costs, and lowers patients' quality of life. Additionally, the National Council Medical Director Institute (2018) reports that medication nonadherence in schizophrenia results in a 75% risk of relapse and 33-70% chance of hospitalizations.

The Benefits of Psychoeducation on Medication Adherence

Bauml, et al. (2016) conducted a study portraying that psychoeducation resulted in improved medication baseline adherence in adult patients with schizophrenia or schizoaffective disorders. After a seven-year follow-up, patients in the intervention group (IG) receiving psychoeducation, compared to patients in the control group (CG) receiving treatment as usual (TAU), had lesser number of days spent in the hospital. This suggests the benefits of psychoeducation in improving medication adherence from patients' baselines, as indicated by the reduced psychiatric hospitalizations at 74.7 days (IG) compared to 243.4 days (CG) ($p < .05$). Education focused on the effects of biological factors and psychosocial stress on psychosis and how medication management is a necessary treatment.

Similarly, Cetin and Aylaz (2018) conducted a true experimental design including pre- and post-test control groups with a study population of 369 patients with schizophrenia attending community mental health centers. The two study hypotheses were that psychoeducation would result in higher insight in the experimental group, as well as higher medication adherence in that same group. The intervention applied consisted of a psychoeducation program for the experimental group. Education focused on mindfulness therapy which increases insight into illness and medication adherence. Exercises included body and breath mindfulness movement, body scanning, and a three-minute respiration exercise. Questionnaires post-test included the Medication Adherence Rating Scale (MARS) (a comprehensible test in assessing adherence to medication), the Beck Cognitive Insight Scale (reliability and validity study that measures insight into illness and consists of a Likert scale), and the Descriptive Information Form (11-question form made by the study researcher consisting of questions regarding sociodemographic information and medical history). Results showed that the mean post-test Beck Cognitive Insight Scale was 4.89 ± 6.05 in the experimental group, 1.68 ± 5.67 in the control group and the difference between the two mean scores was statistically significant at $p < 0.05$. Similarly, the mean post-test MARS score was 1.76 ± 0.42 in the experimental group, 1.50 ± 0.50 in the control group and the difference between the two mean scores was statistically significant at $p < 0.05$. Results indicate that psychoeducation indeed resulted in higher cognitive insight and increased medication adherence in the experimental group.

Also, Chien et al. (2017) conducted a study testing three interventions: mindfulness-based psychoeducation group (MBPEG), a conventional psychoeducation group (CPEG), and treatment as usual (TAU). Patients with schizophrenia-spectrum disorders who attended six community treatment centers were randomly assigned to each intervention group. Education

focused on lack of insight into illness in patients with psychosis and the importance of increasing insight into mental illness and increasing motivation regarding treatment. The outcome involved changes in the length of re-hospitalizations. The MBPEG group had decreased lengths of re-hospitalizations compared to the patients in the other intervention groups at $F_{2,330} = 5.23$, $p = 0.005$.

The different studies mentioned portray the benefits of psychoeducation on improved baseline medication adherence. Two studies indicate improvement in patients regarding decreased length of re-hospitalizations, while one study discussed improved higher cognitive insight and medication adherence. Because psychoeducation in patients with schizophrenia was shown to be beneficial in these studies, the intervention may be feasible to the schizophrenia outpatient population in the partial care hospitalization program.

Psychoeducation and Electronic Reminders/Monitoring on Medication Adherence

Haddad, et al., (2014) discussed interventions to improve medication adherence in patients with schizophrenia. These interventions included both psychoeducation and electronic reminders, such as alarms to assist in taking medications at certain times. It was suggested that although psychoeducation improved knowledge about medications, it was not enough to affect adherence behavior. Furthermore, “practical” learning exercises, behavioral reinforcement, and/or cognitive modifications were shown to be beneficial regarding improved medication adherence. Therefore, psychoeducation and the behavioral reinforcement of cell phone medication alarms, together, were combined and were effective in improving medication adherence in psychiatric outpatients. To further support the efficacy of electronic reminders, the study mentioned a systematic review about the effectiveness of electronic reminders (SMS,

audiovisual, and pager messages) in improving medication adherence in patients with long-term physical health disorders. Also, a randomized control trial in stable outpatients with schizophrenia showed that daily electronic reminders sent to them over a three-month span improved patient-rated adherence with medications when compared to a control group (Montes, et al., 2012).

Electronic Reminders/Monitoring on Medication Adherence

Acosta, et al. (2012) discussed how patient-related interventions included improving insight into illness for patients with schizophrenia/schizoaffective disorder with little to no awareness into their illness and reducing negative attitudes toward medications. Also, electronic monitoring, the Micro-Electro-Mechanical Systems (MEMS) device was discussed, which records the time and occurrence of each medication bottle opening. The study emphasized that the MEMS device is considered the most efficient way to monitor adherence.

Similarly, Velligan, et al. (2013) conducted a study in which patients with schizophrenia at a community mental health center were randomly assigned to one of three treatments: PharmCAT (alarms, pill containers, signs, and checklists included in-home visits occurring weekly); Med-eMonitor (MM) (an electronic monitor that prompts medication use or warns patients when they are about to take the wrong medication at incorrect times); or treatment as usual (TAU). Repeated measures analyses of variance for mixed models showed that medication adherence was significantly greater in both active interventions than TAU at $p < 0.0001$. Furthermore, medication adherence in the active interventions was in the 90-92% range compared to 73% in TAU.

Additionally, Ben-Zeev, et al. (2013) conducted a study where patients (with diagnoses of schizophrenia or schizoaffective disorder) and providers at a large community-based rehabilitation agency completed a survey regarding their interest in mobile health (mHealth) services. Survey results indicated that out of 904 participants, 570 (63%) of participants carried a mobile device and many were interested in mHealth services. These services included reminders about appointments and medication times (44%), check-ins with providers (38%), and psychoeducation, treatments, and services information (31%). All eight practitioners thought that participants could benefit from and learn to use an mHealth application. From the results, a multidisciplinary team designed a mobile device application (FOCUS) targeting medication adherence, sleep, social functioning, mood regulation, and symptom coping. Usability testing was completed and from the results, the application was updated to favor participant needs and preferences. In support of rehabilitation in patients with schizophrenia, a mobile device illness self-management system was developed and may be feasible for patient evaluation in different psychiatric conditions including outpatients with schizophrenia or schizoaffective disorder.

Also, Santo, et al. (2016) completed a systematic review, identifying high-quality cell-phone applications (apps) to improve medication adherence. A total of 272 medication reminder apps were evaluated with 152 apps found in Google Play, 87 available in iTunes, 33 available in both Google Play and iTunes. 109 apps were available for free, which included Medisafe. The Mobile Adherence Rating Scale (MARS) (a scale to detect the quality of mobile health apps) was used to identify high-quality apps that were considered very engaging, entertaining, very interactive, easy to operate, and carrying high-quality information with visual appeal. Medisafe was ranked number one regarding the advanced medication reminder apps. Furthermore, it was

the highest-ranking app out of 10 apps via the MARS tool and was found to carry the features mentioned.

Additionally, Shadare, et al. (2017) conducted a study portraying how a mobile device app reminder alarm could aid adult outpatients with disorders that fell under the schizophrenia spectrum to take medications at prescribed times. The results supported an increase in medication adherence. The intervention of a mobile app phone alarm was statistically significant in improving medication adherence with a p-value of <0.00001 , compared to the null hypothesis of no significant difference. Relapse (return of schizophrenia symptoms including delusions or hallucinations) showed a significant reduction at 42.95% post-intervention.

To further support the evidence, Treisman, et al. (2016) completed non-research work in which a panel of experts including psychiatrists, medical technology innovator, family caregiver, mental health advocate, health policy maker, and third-party payer discussed the uses, benefits, and limitations of electronic health, including digital technologies and mobile devices, and the ability to provide more integrated care, monitor the status of patients, and improve medication adherence in patients with schizophrenia. The evidence explained that pharmacologic medications and psychosocial therapies are the main treatment options to support patients with schizophrenia, yet nonadherence rates to treatment remain high. The implementation of innovative health technologies may assist in improving patients' access to services, provide monitoring of patients remotely, and may strengthen behavioral therapy. Regarding medication adherence, technology adherence approaches described in the literature included electronic prescribing systems and medication monitoring databases, SMS text messages, electronic diaries with alarms, and microelectromechanical systems (technology that records data when a patient

opens a pill container). The literature emphasized how different strategies may increase patients' medication adherence in the schizophrenia population. Because this piece of evidence was non-research, research limitations were not described. The discussion contributed to the benefits of using technology, including alarms from mobile devices, in improving baseline medication adherence in the population with schizophrenia.

Lastly, the National Council Medical Director Institute (2018) included a diverse group of administrators, clinicians, policymakers, advocates, researchers, innovators, educators, peer specialists, and payers of a two-day meeting who focused on analysis and review of non-adherence to medications. Considerations to improve medication nonadherence in the population with schizophrenia included technology such as alarms to remind patients to take medications at specific times, pill implants, and compatible devices. Because this piece was also non-research, research limitations were not described. The discussion further contributed to the benefits of using technology in improving baseline medication adherence in the schizophrenia population.

In summary, it is apparent that technology including mobile device reminder applications, has contributed to improving baseline medication adherence in patients with schizophrenia and schizoaffective disorder. Studies indicated that individuals were interested in using mobile device apps. The particular mobile device app, Medisafe, was considered appealing, user-friendly, useful, and informative compared to other apps, indicating that it would be an ideal intervention to improve schizophrenia patients' baseline medication adherence. The studies' research limitations will be described.

Study Limitations Regarding Psychoeducation and Adherence

Studies involving psychoeducation and medication adherence have had limitations, which are important to assess in order to consider the possible limitations affecting the quality improvement project that will be conducted. Since the project took place in an outpatient partial hospitalization program, it is important to examine the study constraints related to location, measurement tests, the characteristics of the study group, level of patient functioning, and the psychiatric medications that the patients are taking.

Cetin and Aylaz (2018) describe that study limitations included different community mental health center study locations and the post-test measurement occurring once with the inability to follow-up afterward. Also, the findings pertain to the particular study group involved, which questions applicability to different schizophrenic populations. Also, in a separate study, Chien et al., (2017) discuss that study limitations were that the patients were motivated to participate and were aware of the different interventions, which may result in an expectation bias; patients had a shorter duration of illness with schizophrenia (2.5-2.7 years), which may not accurately represent the greater schizophrenia population such as those with chronic schizophrenia or co-occurring substance abuse disorders; the study was also conducted by advanced practice nurses who had intensive training which may interfere with the intervention's applicability; and the positive outcomes specifically dealt with Chinese culture-specific situations, suggesting that it may be more applicable to Chinese patients. Although the limitations were present, MBPEG was shown to reduce psychotic symptoms and length of re-hospitalizations, indicating improved functioning and insight into illness in outpatients with schizophrenia.

Bauml et al., (2013) elaborated on study limitations, which included that the sample size four years post-discharge was small in both groups and selection bias of healthier, more motivated patients could not be excluded. The specific medications taken by the patients were not documented during a 6.5-year period and it was only during the six months prior to follow-up that the medications were evaluated. Patients in the IG group had a higher rate of atypical antipsychotics use (second generation medication with fewer side effects), which may have influenced the better study outcome compared to the CG. Also, unknown confounders could have influenced group outcomes. In summary, despite the different study limitations mentioned, it is important to consider further research which has shown the benefits of psychoeducation in improving baseline medication adherence in adult psychiatric patients with diagnoses of schizophrenia or schizoaffective disorders.

Study Limitations Regarding Psychoeducation, Electronic Reminders, and Adherence

Haddad, et al. (2014) describe limitations regarding psychoeducation to include that although it has been assumed that increased knowledge through medication or illness education in patients with schizophrenia helps patients with mental illness to cope with their illness more effectively, evidence for its efficacy is limited. Another limitation is that medication adherence using family psychoeducation therapies, apart from one trial, has shown to have mixed benefits for patients. Limitations regarding electronic reminders include “message fatigue” where patients receive reminders regardless of whether they are adherent with medications or not, resulting in the favorable effect of the reminder to wear off (Haddad, et al., 2014). Overall, despite the study limitations and as mentioned earlier, psychoeducation and electronic reminders used together

have improved medication adherence in psychiatric outpatients with schizophrenia or schizoaffective disorders.

Study Limitations Regarding Electronic Monitoring and Adherence

Acosta, et al., (2012) explained that study limitations included the MEMS device being expensive and that opening of the bottle does not necessarily mean that the patient actually took the medication. This circumstance is similar to the Medisafe cell-phone app, which is used as a self-report measure with the patient indicating on the app when their medications were taken. There is the limitation and chance that although the patient indicates the medication is taken on the app, that it was not actually consumed. As mentioned earlier, despite these limitations, it is important to consider that studies have shown that electronic monitoring has assisted patients in increasing their medication baseline adherence.

Velligan, et al., (2013) described that study limitations included the great number of individuals approached to participate who were not interested and others who dropped out of the study after one month; the high baseline adherence in patients before the intervention took place; and a higher rate of dropout in the MM group. The study, despite the limitations, further prove that baseline medication adherence can improve with the use of an electronic device in patients in the community with a diagnosis of schizophrenia.

Ben-Zeev, et al., (2013) also discussed study limitations regarding the FOCUS application. The limitations included the small number of practitioners involved and the difficulties that came with the first usability cycle, such as participants having difficulty comprehending abbreviations and longer words including “meds” and “transitions.” Also, the font on the application was small and the buttons were close together, making it difficult for

participants to select the correct option or resulting in them skipping screens. To address the concerns, the second usability cycle portrayed changes that catered to the patients' difficulties. Despite the prior limitations, the study emphasized the significant role that technology (especially mobile device applications) can play in improving medication adherence in patients with schizophrenia.

Santo, et al., (2016) additionally described the limitations to include that the search was conducted in the Australian app store, which may have limited the results of the review. Also, the eligibility criteria may have excluded certain good-quality medication app reminders that may be useful for certain patient groups. Next, the researchers were not able to assess and download all of the apps that were reviewed; and, at the time the study took place, there was no evidence of app effectiveness in improving medication adherence. Despite these limitations, it is important to consider the appeal of the Medisafe app to patients. Because the app was considered high-quality, patients with schizophrenia/schizoaffective disorder were willing to utilize the app in improving their baseline medication adherence. Also, recent research has shown that Medisafe has been effective in improving medication adherence in patients with hypertension (Medisafe, 2019).

Lastly, as per Shadare, et al., (2017), limitations in this study were evident such as the project conducted did have a small sample size and the results may not be applicable to a large outpatient psychiatric facility. In addition, other psychiatric illnesses that the patients may have had were not mentioned, the type of medications was not mentioned, the insight that patients had into their illness was not mentioned, and there was no specification of the schizophrenia spectrum disorder that the patients were diagnosed with. However, these findings must be

evaluated in the context of further research which has shown the benefits of using technology and alarm systems in improving medication adherence in different populations, including outpatients with schizophrenia/schizoaffective disorders.

Synthesis of the Literature

The studies mentioned have described the negative consequences of medication nonadherence in patients with schizophrenia or schizoaffective disorder including relapse and re-hospitalizations; higher suicide risk; dangerous behavior involving arrests and violence; and alcohol and drug use (Acosta, et al., 2012; Haddad, Brian, and Scott, 2014; The National Council Medical Director Institute, 2018). In addition, the benefits of utilizing psychoeducation and technology including mobile device applications with alarms in improving baseline medication adherence have been greatly discussed in detail. Study results have indicated that psychoeducation and use of electronic reminders and mobile device applications have greatly assisted patients in adhering to needed medications, resulting in reduced schizophrenic symptoms (hallucinations and delusions) and reduced occurrence and length of psychiatric hospitalizations (Acosta, et al., 2012; Shadare et al., 2017; Treisman et al., 2016; Velligan et al., 2013). Other beneficial electronic prescribing systems and medication monitoring databases to improve baseline medication adherence include the MEMs device, SMS text messages, electronic diaries with alarms, and microelectromechanical systems (Acosta et al., 2012; Treisman et al., 2016).

Medisafe, a particular mobile device application to improve medication adherence, has been shown to have high system quality and an appeal to users (Santo, et al., 2016). Evidence pointed towards the benefits of the implementation of a psychoeducational group which included

utilization of the mobile device application, Medisafe, to assist patients with schizophrenia or schizoaffective disorder to take medications at due prescribed times and improve baseline medication adherence.

Theoretical Framework/Conceptual Framework

A Quality Improvement (QI) framework was used for the project and included the Plan-Do-Study-Act (PDSA) model (see Appendix B), which is a four-step cycle that allowed implementation of change, problem-solving, and process improvement. Created by Walter Shewhart and Edward Deming, the PDSA model focuses on systemic process improvement and is commonly used in healthcare settings (Coury, et al., 2017; White, Dudley-Brown, and Terhaar, 2016). The Model is utilized for education and change and is frequently used to enhance the quality of care resulting in safer, efficient, effective, and patient-centered healthcare (Donnelly and Kirk, 2015).

The PDSA model consisted of four key components. In the first component, “planning,” objectives were set based on patient and service needs. Key points at this time included the goal that the investigator is trying to achieve, the problem, and an explanation of the solution is formed. In the second component, “doing,” the intervention was carried out and results were recorded with attention placed on patterns in the data (Donnelly and Kirk, 2015). It was important to determine problems, developments, and unexpected considerations during this second stage. The third component, “studying,” was essentially focused on analyzing the data obtained and the actual process itself. During this time, the investigator could determine whether the outcome was close to the prediction and what the lessons learned are. In the last component, “acting,” measurements and agendas were considered to ensure that the solution remained

efficient. During this time, modifications and the state of readiness to implement changes to make the systemic improvement more effective were considered (Donnelly and Kirk, 2015). The components of the PDSA model in relation to the co-investigator's QI project were as follows:

Plan

Identify an evidence-based psychoeducational program and mobile device application that could be implemented to improve baseline medication adherence in outpatients with schizophrenia or schizoaffective disorder. Also, engage stakeholders (Quality Assurance, Director of Residency Program, Director of Partial Care) for feedback on potential flyers, recruitment strategies, running a four-week psychoeducational group and identifying patients with smartphones who meet inclusion criteria. Then, develop a questionnaire to assess outpatients with schizophrenia/schizoaffective disorders' interests in attending a medication education program including mobile device application education will be devised. The last step of planning would include the evaluation of the efficacy of the Medication Adherence Rating Scale (MARS) tool and weekly adherence percentage rating reports via the mobile device application regarding improvement in baseline medication adherence for upcoming implementation.

Do

Recruitment flyers were distributed after weekly announcements during partial care meetings to ensure visibility by patients who meet inclusion criteria. . Information sessions were held to discuss purpose, benefits, and length of program. Information was also given to the NP regarding the project and consent form. He agreed to filled out the CGI pre-and post-intervention. Also, implementation of the program occurred and include weekly education with

topics covering schizophrenia/schizoaffective disorder symptoms including the importance of taking medications, the link between mental illness and stress, the main effects/side effects of the top three antipsychotic medications that the participants are using, and community resources for individuals with mental illness. Also, education about Medisafe, a mobile device application used to improve baseline medication adherence., was provided. Patients' concerns were addressed and questions were answered.

Study

Adherence reports were analyzed on patients' mobile devices to assess improvement in baseline medication adherence. Additionally, before the study began, at the end of four weeks, and during the one-month follow-up, the self-report questionnaire, MARS, was completed by patients pre-, post-, and post-intervention to assess perceived improvement in baseline medication adherence. Additionally, the MDASS and CGI were administered pre- and post-intervention to analyze improved medication adherence.

Act

The last stage of the cycle included the evaluation of outcomes and identification of areas of improvement to the psychoeducation program, including the education and monitoring of the Medisafe app.

Methodology

Project Design

The study used a quality QI approach with the MARS survey administered before implementation, four weeks after implementation, and during the one month follow-up of the

psychoeducation program, along with the co-investigator's evaluation of patients' weekly adherence percentage reports on their mobile device applications. Additionally, as mentioned, the MDASS and CGI scales were administered pre- and post-intervention.

Setting

The setting for this project was an adult partial hospitalization outpatient program. The patients who attend the program are primarily Caucasian, but include African American and Hispanic populations, as well. The partial hospitalization program currently sees approximately 117 patients, who primarily are insured by Medicaid.

Study Population

The project included a purposive sample of men and women in New Jersey from an outpatient partial hospitalization program who were diagnosed with either schizophrenia or schizoaffective disorder. Inclusion criteria were English-speaking men and women who were 18-years-old or over with the diagnosis of either schizophrenia or schizoaffective disorder, attended the outpatient program, were prescribed psychiatric medication(s), were willing to attend all group sessions, and had a smartphone. Exclusion criteria included men and women with bipolar disorder, major depressive disorder, or other mental illnesses, to focus primarily on schizophrenia and schizoaffective disorders. Utilizing Raosoft, Inc. (2004) for a priori power analysis app to determine the sample size needed for the project with a 5% margin of error and 95% confidence interval, the necessary sample size was 45 patients. Considering feedback from the QA department, the attrition percentage for QI projects is approximately 10%. As a result, five patients will be added, bringing the total needed sample size to 50 patients.

Subject Recruitment

The DNP student took over the pre-selected “Technology Information” group at the facility, which occurs twice per week and has partial care hospitalization clients already listed to attend. In the “Technology Information” scheduled group, participants usually conduct different activities on the facilities’ available IPADS, which involve different games and websites that they are interested in.

The DNP student evaluated the pre-selected participant list for the “Technology Information” group and then confirmed participants’ study inclusion criteria via chart reviews and confirmed with the nurse practitioner about the need for improvement in baseline medication adherence in the possible participants. Participants in the group who did not meet inclusion criteria were encouraged to participate in a separate technology exercise during the time the group occurred, in a separate group room, run by a case manager.

Following confirmation of potential participants’ inclusion criteria, the DNP student met with the nurse practitioner (NP), discussion of benefits and length of psychoeducation program took place and the DNP student went through the consent form for clinicians to complete (please see Appendix P). The CGI questionnaire was shown and explained to the NP and that he would rate each client’s improvement in functioning pre- and post-intervention via the CGI questionnaire with the pre-intervention CGI for each participant handed to him for completion after the initial participant group meeting.

The initial group meeting with potential participants who met inclusion criteria was in a scheduled group room at the site (during their scheduled “Technology Information” group time) prior to the first group study (Week 1); explained the study purpose, goals, and objectives of the study; thoroughly discussed and went through the consent form while verifying participant

understanding via asking participants to describe the study topics in their own words; and discussed the benefits and length of the psychoeducation program including the usage of a smartphone app. The participants who did not meet inclusion criteria during this group time were to participate in a technology activity (on the IPAD) with a case manager in a separate group room. For those who met inclusion criteria, instructions were provided on how to access the Terms and Conditions and Privacy Policy of the app. Information about psychoeducation and utilization of a mobile device app to improve baseline medication adherence were shared via information flyers (please see Appendix D), which were handed out during the initial meeting during participants' group time one week before "Week 1" study intervention began. Participants who met inclusion criteria and were interested in participating in the study signed a client consent form during this time with a copy given to each individual participant and one kept for the student's files. A group schedule was also given (please see Appendix Q). Groups took place in scheduled group rooms at the facility with "Week 1" interventions starting the following week during scheduled group times. Total time during the initial meeting with the participants prior to the study interventions took approximately 15 minutes.

Efforts to recruit participants also took place via an announcement from the co-investigator during weekly client meetings. Clients were informed about the study (by the co-investigator) during the meeting and were encouraged to participate if they met inclusion criteria. A list of the clients who met inclusion criteria and were interested in participating were collected by the co-investigator. The clients were then informed about attending an information session in group room 71 afterwards, where information flyers were handed out by the co-investigator and explained and participant consent forms were signed. Total time during this meeting was around 15-20 minutes.

Participants did not receive compensation. Total recruitment time took place in approximately two months (verifying the inclusion criteria of clients in the pre-selected list prior to the initial first meeting). Potential participants were informed that their participation in the program was a voluntary, supplemental, service and did not impact their treatment as usual.

Consent Procedure

The participants had schizophrenia/schizoaffective disorder. Initial participant interviews during recruitment included the explanation that participation is completely voluntary. The consent process included the consent form for participants to sign with a full description of all of the elements of the form explained to the participants by the DNP student (refer to Appendix E). Questions were encouraged after each section of the form and at the end of the consent form. One copy of the consent form was given to the participant and one was kept with the DNP student.

The CGI was reviewed with the NP, who was asked to repeat key parts of the consent form, verifying understanding. One copy of the consent form was given to the NP and one was kept with the DNP student. After signing the consent form, and after the first initial participant group meeting occurs, the NP was given the pre-intervention CGI to complete for each participant.

Risks/Harm/Ethics

Potential risks. Participation in this study poses minimal risk. The principal participant risks were: breach of confidentiality, study burden, distress associated with psychoeducation and utilization of mobile device app. In regards to the breach of confidentiality, there was the possibility that personal health information may be inadvertently shared by participating in the

project. There was also a small risk of the medication list on patients' mobile device apps being hacked. Regarding study burden, the participants were asked to commit an approximate total of four hours and 10-15 minutes in the span of four weeks to participate in the study with a total of 10 minutes committed to pre- and post-intervention surveys and approximately one hour weekly committed to psychoeducation groups. A five-minute group was scheduled one month later to assess continued use of the app. Regarding distress associated with the psychoeducation received, select potential participants may have experienced distress from receiving information on diagnosis and medications. Regarding distress associated with using a mobile device app, mild-moderate anxiety may be experienced from the education participants receive on utilizing a mobile device app if the participants were not familiar with app-use.

Provisions to minimize the breach of confidentiality. The patients' initials, ethnicity, age, gender, education level, psychiatric medication list, and diagnosis were collected and assigned a number, allowing data to be viewed without directly being linked to patients' names. Only the co-investigator had access to the information linking the patients' names with the number associated. Regarding the risk of the participants' mobile device apps being hacked, security risks were addressed by teaching patients' how to update their phone system; clean up apps; lock their phones; be wary of public Wi-Fi, giving out their personal phone numbers, and wary of links in unusual text messages/emails; and how to reset a lost/stolen phone.

Provisions to minimize burden. During the initial interview during recruitment, participants were made aware of the time required during the study to complete the pre-and post-intervention surveys and the psychoeducation groups, giving participants the opportunity to opt out. The 10-question surveys were easily accessible, with each participant given a copy to fill

out. There were no financial burdens related to study participation. If participants showed nonadherence to prescribed psychotropic medications via weekly adherence percentage reports on their mobile device apps of less than 80% (during the second and third weeks) and lack of adherence via weekly medication logs (and verbalize that they have not been adherent with medications), they were referred to their provider to discuss their medication concerns. Concerns were addressed for the remainder of the project and documented.

Provisions to minimize distress. Regarding possible distress associated with psychoeducation received regarding diagnosis and medications and distress from utilizing a mobile device app, the information was discussed in an initial meeting for study participation with each candidate, allowing participants to opt out of further participating in the study. All concerns and questions were addressed. They were reassured that that DNP student would be there to assist them. Participants were encouraged to speak with their therapist/psychiatrist/nurse practitioner in the facility if they experienced distress.

Additionally, participants were informed of the option to uninstall the Medisafe app on their cellphones and refrain from using the service without penalty. Participants were also informed of any new findings that may affect their decisions to take part in the study. Overall, there was a less than minimal risk to patients' rights, dignity, welfare, and privacy by participating in the study.

Subject Costs and Compensation

There was no cost to participate in the study. Participants did not receive monetary compensation for project participation. Participants were not coerced to participate in any way.

Study Interventions

Following recruit and consent procedures, participants began the four-week, approximate one hour per week, psychoeducation groups which include education on utilizing the mobile device app, Medisafe, to improve their baseline medication adherence.

Week One. After consent was obtained, introductions were made, information was re-iterated about voluntary study participation and the option to opt out at any time, and the purpose of the study was re-iterated, including information about the Medisafe phone app. The MARS was handed to each individual to be completed within five minutes and then handed back to the co-investigator. Next, the co-investigator provided information about security risks and protecting cell-phones, including education on updating participants' phone systems (Android and iPhone); maintaining control of the mobile device physically; cleaning up apps; locking phones for security; being wary of public Wi-Fi, links in unusual text messages/emails, and giving out cell-phone numbers; and resetting a lost/stolen phone (United States Computer Emergency Readiness Team, 2011).

Following the security risk education, the co-investigator downloaded Medisafe app onto each participant's phone and input their daily psychiatric medication schedules onto the app. The co-investigator then completed a demonstration of how to navigate the app with instructions, which were verbalized while the co-investigator navigated through her downloaded app at the same time (please see Appendix I). In addition, each participant was given the information in a take-home handout entitled "How to Use the Medisafe Cell-Phone App" with step-by-step instructions on using the app. They were encouraged to bring the card during each weekly session (Appendix I). Navigation instructions included details on how to set alarm notifications for when each psychiatric medication is due and an explanation that there will be three alarms

and three push notifications which will appear on participants' screens at the due times, reminding them to take their medications. They were instructed on which buttons to press to document medication-taking. An individualized return demonstration on documenting medication-taking was provided by each participant during this time and any questions or concerns (including any reasons for medication non-adherence in the past) were answered.

Next, a discussion of symptoms of schizophrenia and schizoaffective disorders was reviewed with information taken from NAMI (2019). A YouTube video was shown regarding symptoms of schizophrenia from the Schizophrenia Society of Alberta (SSA) https://www.youtube.com/watch?time_continue=398&v=fGaj2l_mVVk. Participants were then instructed to record medication adherence throughout the week via the mobile device app until the next group. They were each given a handout of a weekly medication log (please see Appendix J) with each of their individual medications displayed with prescribed times during each day of the week. They were instructed to check off (using a pen) which medications they took during the times that the medications were due. They were to bring the weekly log to the next meeting to show the co-investigator which medications were taken. This documentation was used to show the co-investigator which medications were taken in case the participants forgot to utilize the Medisafe app at any time throughout the week. A five-minute mindfulness breathing and relaxation exercise was led by the co-investigator with information from Foundation for a Mindful Society (2019) (please see Appendix H).

Week Two. In the beginning the group, the co-investigator viewed the “weekly adherence” report on each participant’s mobile device and documented the individual percentages. For the participants who forgot to utilize the app at times throughout the week but

were able to write down the times taken for each of their psychiatric medications, the information was manually put into their app by the co-investigator to update their weekly adherence log. The difference was noted regarding patient use of the app versus manually self-recording their medication log via pen and paper. Questions and concerns (including any reasons for medication non-adherence) were addressed after the adherence reports were recorded. Participants were encouraged to report how they felt about using the app. The following satisfaction survey was given to them to assess their thoughts towards the app (Please see Appendix K) (Survicate, 2019).

Following questions and concerns, a discussion on the link between mental illness and stress (including ways to reduce stress) took place with information from the NAMI (2019) website (please see Appendix H). A five-minute mindfulness breathing and relaxation exercise was led by the co-investigator with information from Foundation for a Mindful Society (2019) (please see Appendix H). Participants were then given a new medication adherence weekly log to check off and will be reminded to record their medication adherence on their Medisafe apps for evaluation the following week.

Week Three. The co-investigator viewed each participant's "weekly adherence" report and document individual percentages. Questions and concerns (including any reasons for medication non-adherence) were addressed and participants were encouraged to verbalize their concerns; comments were written down regarding participants' verbalizations on how the app is going. Next, a discussion regarding the main effects and side effects of the top three antipsychotic medications that the participants are using will take place with information provided by NAMI (2019-b) and an educational video from NAMI Austin (2018) was provided

with information about how psychiatric medications work:

<https://www.youtube.com/watch?v=hwuiE6-17AA>. The main psychotropic medication side effects of weight gain (including risk for hyperglycemia and increased lipid levels) sleep disturbances, risk for infections, and anticholinergic side effects were explained with intervention strategies and a handout given (please see Appendix L) (National Institute of Mental Health [NIMH]-b, n.d.). Next, as previously mentioned, instructions were provided on recording weekly medication adherence via the Medisafe app and writing checking off medications that were taken at specific times throughout the week, on their medication logs, as well. A five-minute mindfulness breathing and relaxation exercise will be led by the co-investigator with information from Foundation for a Mindful Society (2019) (please see Appendix H).

Week Four. The co-investigator recorded weekly adherence reports for each participant. Next, information from NAMI was provided to participants via a printed copy of the resources listed on the website regarding peer community resources for individuals with mental illness (NAMI New Jersey, 2018) (please see Appendix M). Participants were also informed about community resources available in NJ that are recommended by the [REDACTED] case managers and NP (please see Appendix M). The participants were given a survey asking how they thought the Medisafe app was for them over the past weeks (please see Appendix K). They were asked how taking their medications on a regular basis, while using the app, was for them. Their comments and feelings about the app were documented. Questions and concerns were answered and the participants were thanked for their time. The MARS was distributed to each individual, answered within five minutes, and handed back to the co-investigator. The participants were encouraged to continue to use Medisafe if they feel it has helped them with their medication adherence. A five-minute mindfulness breathing and relaxation exercise was led by the co-investigator with

information from Foundation for a Mindful Society (2019) (please see Appendix H). The group then ended (Please see Appendix H for all educational interventions).

An additional five-10-minute scheduled group took place one month post-intervention with the administration of the MARS to assess continued use of the app. Percentage reports were recorded. The NP completed a post-intervention CGI scale for each participant at this time.

Outcome Measures

The patient-rated scales regarding medication adherence and medication app satisfaction included the Medication Adherence Rating Scale (MARS) and the Mobile Device App Satisfaction Survey (MDASS), respectively. The Medisafe app was another patient-rated measure to assess weekly changes in baseline medication adherence. A fourth patient-rated measure included the weekly written medication log. The provider-rated scale included the CGI scale. Each outcome measure, including patient demographics, will be further explained.

The first outcome measure was the MARS, a dichotomous (yes or no) 10-question survey used to assess baseline self-rated medication adherence pre-intervention and medication adherence post-intervention (see Appendix G). The scale included questions regarding perceived adherence to psychiatric medications during the past week. Participants circled the “yes” or “no” survey answer which described their behavior or attitudes towards their medications (Thompson, et al., 2000). Each survey had identifying codes to distinguish whether it was a pre- or post-test survey. Information from participants’ charts including initials, ethnicity, gender, age, and diagnosis were gathered to assess descriptive characteristics and assigned a number, allowing the data to be visible without being directly linked to participants’ names. Patients’ psychiatric medication lists were gathered and assigned the same number, but were only used to input into

patients' mobile device apps. Only information on these surveys, the descriptive characteristics, and percentages reported from the mobile device app were participant identifiers and in no way will they be attached to any personal participant information. Once data was transcribed and verified, all information from patients' charts which were assigned numbers, surveys and percentage reports held by the co-investigator were destroyed according to Rutgers University guidelines.

The MARS is a 10-item self-reporting tool that describes three areas: medication adherence behavior (questions 1-4); attitude towards medication-taking (questions 5-8); and negative side effects and attitudes towards psychotropic medications (questions 9-10). Each question has a yes or no response. Scores were obtained by adding the items within each area. A non-adherence response had a score of 0, while an adherent response had a score of 1. Total scores range from 0-10 with higher scores showing better medication adherence. A score of 6 and above indicates adherence, while scores 5 and below indicate nonadherence (Owie, Olotu, and James, 2018). The reliability and validity of the MARS were evaluated in relation to its psychometric properties in schizophrenia facilities. The reliability of the MARS in patients with schizophrenia portrayed good reliability at Cronbach's alpha 0.76. The scale was constructed with three factors: medication adherence behavior, attitude to taking medications, and negative side effects and attitude to psychotropic medications. The MARS demonstrated significant, yet weak external validity to psychopathology ($p < 0.001$) and insight ($p < 0.001$). The factor of medication adherence displayed good internal consistency at $\alpha=0.80$ with six items that could be considered a reliable proxy measure of medication adherence instead of the MARS. Overall, the MARS was useful in assessing medication adherence in the schizophrenia population (Owie, Olotu, and James, 2018).

A second outcome measure was the Mobile Device App Satisfaction Survey (Appendix K) includes questions from Survicate (2019) assessing mobile device app satisfaction for users. Questions included assess the user's feelings about the design of the app, ease of use, efficacy in helping the user achieve goals, thoughts about recommendation, and rating the app overall. Survicate is a leading company in collecting constructive feedback and insights from customers. The company has received "High Performer" awards in Fall and Spring of 2018, as well as a "Users Love Us" award. Users of the service are located in 152 countries and in 2018, users collected over 70,000,000 answers from customers (Survicate, 2019). The survey was administered during weeks two and four during the intervention phase with encouraged questions/concerns to assess the participants' feelings towards the app. Feedback was considered and changes were implemented if needed. Survey results were included in the discussion.

A third outcome measure was the medication adherence percentage reports on the Medisafe app which were viewed on participants' mobile devices and documented, utilizing the individualized assigned numbers used to document descriptive statistics for each participant. There were no patient identifiers. Medisafe is ranked number one in regard to advanced medication reminder apps. The Mobile Adherence Rating Scale (MARS), used to detect mobile health app quality, was used to assess Medisafe and the app was considered easy to operate, carrying high-quality information, entertaining, interactive, engaging, and visually appealing (Santo et al., 2016).

A fourth outcome measure was the co-Investigator's Medication Log which had each participant's psychiatric medication list and possible reasons for medication non-adherence (if applicable). Possible reasons for medication non-adherence were encouraged to be verbalized

during group sessions weeks 1-3 via open-ended questioning. Answers were recorded and placed into “reasons for non-adherence” section of log (Please see Appendix R). A fifth outcome measure was participant demographics including ethnicity, age, gender, diagnosis, education level, and occupation (also available in Appendix R).

A sixth outcome measure was the Clinical Global Impression (CGI) tool (see Appendix O). CGI has proved to be a measure of efficacy in various clinical drug trials and is simple and quick to administer if the provider knows the patient well. The CGI is a 3-item observer-rated scale that measures illness severity (CGIS), global improvement or change (CGIC), and therapeutic response (Guy, 1976). The tool is rated on a seven-point scale, with the illness severity using a range of responses from one (normal) to seven (amongst the most severely ill patients). CGI-C scores range from one (very much improved) through to seven (very much worse).. The different sections of the tool must show a score change of 2-points to indicate a reliable change (Guy, 1976). The first two items of the CGI was completed by the NP pre- and post-intervention.

Project Timeline

Project Timeline			Period												
Activity	Plan Start	Plan Duration	May-19	June-19	July-19	Aug-19	Sept-19	Oct-19	Nov-2019	Dec-19	Jan-20	Feb-20	Mar-20	Apr-20	May-20
Presentation of Proposal to Team	5/19	1													
IRB Submission	5/19	3													
Participant Recruitment	8/19	1													
Project Implementation	9/19	2													
Data Collection	11/19	2													
Data Analysis	1/20	1													
Evaluation/Writing	2/20	2													
Presentation of Final Project	4/20	1													
Graduation	5/20	1													

Resources Needed

The co-investigator was solely responsible for costs associated with this project. Anticipated costs included recruitment materials and research expenses. Educational program materials had no cost. An anticipated budget was located in Appendix F.

Evaluation Plan

The PDSA framework was used to assess project evaluation including facilitators/barriers/unintended consequences that were experienced throughout project implementation. Project “planning” included identifying an evidence-based psychoeducational program and mobile device application that could be used to improve baseline medication adherence in outpatients with schizophrenia/schizoaffective disorder; engaging stakeholders for feedback on running the four-week psychoeducational group; identifying patients who met inclusion criteria with smartphones; and evaluating the efficacy of the MARS tool and weekly adherence percentage reports in regards to improving patients’ baseline medication adherence. Implementation “doing” consisted of recruiting participants, conducting informative sessions with potential candidate, and implementation of the four-week psychoeducation program/utilization of Medisafe app. Additionally, an information session was held with the NP. “Studying” consisted of assessing weekly adherence reports on the mobile device apps and comparing MARS, MDASS, and CGI scores. “Act” included evaluating the outcomes and determining improvement areas to the psychoeducation program and to the monitoring utilization of the Medisafe app. The PDSA sequence was repeated to ensure that all of the activities and outcomes directly coincided with the original problem statement. Each of the goals and aims mentioned were addressed in the evaluation plan, as well.

Data Analysis Plan

The sample of participants were described using descriptive statistics regarding ethnicity, age, gender, and diagnosis. Analytical statics were used to evaluate the efficacy of the interventions. Pre- and post-intervention scores (dichotomous data) were collected regarding patient perceived medication adherence. In addition, weekly medication adherence percentage reports were collected from the mobile device app to evaluate changes in participants' medication adherence. The statistical software package SPSS was used to completely analyze the data.

Non-parametric statistics, Cochran's Q Test, McNemar's Test, Cohen's Kappa, and the Wilcoxon Rank Sum were used for data analysis. Regarding patients with schizophrenia or schizoaffective disorder, the MARS was administered pre-, post- and post-intervention with Cochran's Q computed. McNemar's test was used to calculate questions one through four of the MDASS and question five was computed using Cohen's Kappa. The Wilcoxon Rank Sum was used to calculate CGI scores.

Maintenance and Security

Following recruitment procedures, participants did not contact the co-investigator via phone or email, and so participants' contact information were not available to the co-investigator.

All information provided was completely confidential and there was no personally identifying information tied to the data that was collected. Participants were provided with a randomized ID number by the co-investigator, which was used on both private health information data collection, the MARS rating scales, the MDASS, the CGIs, and the weekly adherence percentages collected from the Medisafe app.

Medisafe has technical, administrative, and physical safeguards in place to prevent unauthorized access/disclosure of personal health information. Private health information was stored on secure servers and was not available publicly (Medisafe, 2019). Full information is available on the Privacy Policy is viewable at [medisafe.com](https://www.medisafe.com/privacy-policy) (Medisafe, 2019).

Upon project completion, IRB closure, and final manuscript documentation, all data will be destroyed according to Rutgers University guidelines. Hard copies of consents and aggregate data were kept securely at Rutgers University.

Results

This section presents the results of data analysis, including quantitative survey results and medication percentage reports. Demographics are described and key findings are discussed. Participant recruitment occurred from September 2019- October 2019. Psychoeducational groups including surveys and Medisafe reports were implemented weekly during two groups for four weeks. The dates were October 28- November 3, 2019, October 29- November 5, 2019; November 4-November 11, 2019, November 5- November 12, 2019; November 11- November 18, 2019, November 12- November 19, 2019; November 18- November 25, 2019, November 19- November 26, 2019. Follow-up groups with surveys given to participants were conducted on December 9 and December 10, 2019. In addition, follow-up surveys for the nurse practitioner in the form of post-intervention CGIs were given on those same dates, as well.

A total of 16 patient participants with either schizophrenia ($n = 6$)/schizoaffective disorder ($n = 10$) attended the four weekly group sessions with one hundred percent of participants completing the MARS and MDASS scales. Participants' ages ranged from 22 to 60

years with a mean age of 44.45 years ($SD = 12.45$). Over half of the participants (63%) had a diagnosis of schizoaffective disorder and under half (38%) had a diagnosis of schizophrenia (Figure 1). Regarding gender, less than half of the participants were female (31%) and over half (69%) were male. Regarding ethnicity, over half (63%) were white; under half (25%) were Hispanic; and (13%) were Black. Over half (56%) had the highest grade level of high school; under half (13%) completed up to the first year of college; under half (13%) held an associates' degree; under half (13%) completed their bachelor's degree; one participant (6%) dropped out of 9th grade. Over half (82%) of participants were unemployed; under half (13%) worked in a café; and one (6%) was employed at a workshop. There was one NP who evaluated each participant.

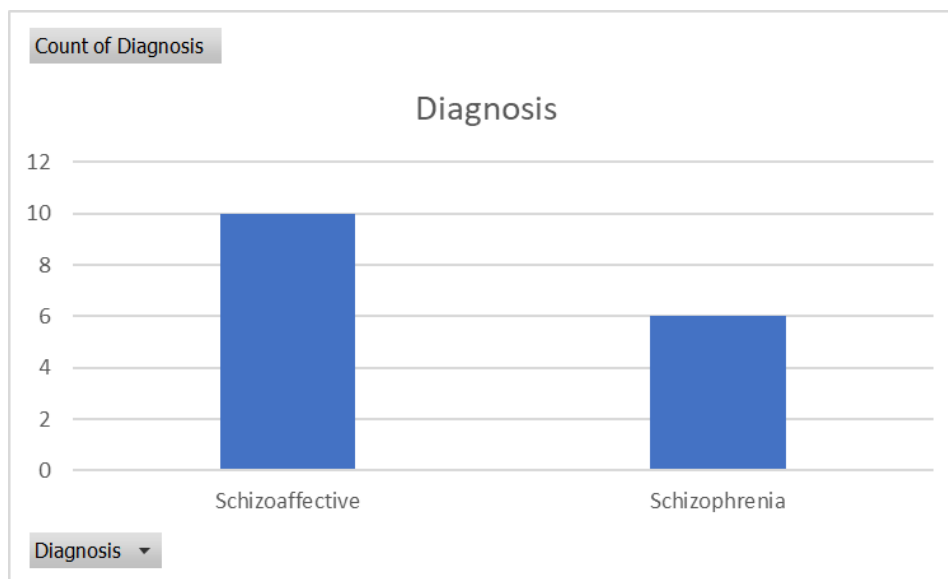


Figure 1. Diagnosis. This figure shows the percentages of participants who had a diagnosis of schizoaffective disorder vs. schizophrenia.

SPSS Inc. software application version 26 released in 2019 was used to conduct Cochran's Q Test to assess the within-groups non-parametric distribution pre-, post-, and post-

intervention regarding the Medication Adherence Rating Scale (MARS) (Table 1). The test was selected to verify whether results during three different periods of time (pre-, post-, and post-post-intervention) were statistically different. Results for each of the 10 MARS questions were not statistically significant at $p > .05$. Cochran's Q test did not indicate any differences among the three different periods of time (Table 1). There was no significant difference related to the question regarding whether participants stopped taking their medications when they felt better pre-, post-, and post-post-intervention. Out of the participants, two reported that they would stop taking medications if they felt better pre- and post- intervention and four reported that they would stop taking medications when feeling better post-post- intervention.

Table 1. MARS Results

Question	Cochran's Q	P- Value	Study Results
Q1	2.25	0.325	The pre-intervention MARS indicated participants' difficulty with remembering to take prescribed medications at due times (pre n = 7). Post-intervention MARS also indicated difficulty with remembering when to take medications (post n = 7).
Q2	5.429	0.066	In contrast, pre-intervention MARS scores indicated carelessness regarding medication-taking (pre n = 5) compared with post-intervention scores (post n = 3). Post-post-intervention MARS scores indicated that there was a decrease in participants forgetting to take medications and being careless about taking medications (post-post n = 4); (post-post n = 0).
Q3	0	1	There was no significant difference related to the question regarding whether participants stopped taking their medications when they felt better pre-, post-, and post-post-intervention. Out of the participants, two reported that they would stop taking medications if they felt better pre- and post- intervention and four reported that they would stop taking medications when feeling better post-post-intervention.
Q4	2	0.368	Although there was no significant difference pre-, post-, and post-intervention, regarding question four of the MARS, there was small improvement in whether the participants would stop medication-taking when they felt worse pre-and post-intervention (pre n = 2; post n = 1). Post-post-intervention remained the same (n = 1).
Q5	0	1	Pre-post-post intervention results improved regarding the question of medication-taking only when the participant felt sick. Regarding the question of medication-taking only when feeling sick, one participant reported "yes" to the question pre- and post-intervention compared to none of the participants post-post intervention, but results were not statistically significant at p = .61
Q6	0.4	0.819	Regarding question six of the MARS indicating that participants felt that it was unnatural for their minds and bodies to be controlled by medication, there was a small improvement pre- and post-intervention (pre n = 3; post n = 2). Post-post-intervention remained the same with only two participants.

Q7	4	0.135	There was a small increase from 14 individuals who reported that their thoughts were feeling clearer on medication to 16 in the two post-intervention evaluations.
Q8	2	0.368	Additionally, there was a small increase from 13 individuals who reported that medications could prevent them from getting sick to 15 in the two post-intervention evaluations. The small number demonstrated clinical improvement but was not statistically significant.
Q9	2	0.368	There was an improvement in MARS question number 9 regarding participants feeling weird or like a “zombie” on medication (pre n = 3; post n = 1; post-post n = 1);
Q10	4	0.135	There was an increase in participants who felt like medications made them feel tired or sluggish (pre n = 5; post n = 7; post-post n = 7) regarding MARS question number 10.

Note. N=16. MARS = medication adherence rating scale. Q1-Q10=questions 1-10. *p>0.05.

In regards to the Mobile Device App Satisfaction Survey (MDASS), the within groups non-normal distribution indicated that the McNemar’s test was appropriate to use pre-and post-intervention for questions 1-4 of the (MDASS) and Cohen’s Kappa was appropriate for question 5 of the survey (Table 2). The McNemar’s test was used to assess the paired nominal data which consisted of the yes/no questions of the survey. It was used to assess subjective satisfaction levels regarding app usage. Cohen’s Kappa was used to assess intra-rater reliability pre- and post-intervention for the ordinal answer choices of question 5. It was used to assess participant ratings of the app from 1-5 (1 being that the app is not useful and 5 being that it is useful).

The MDASS was administered at weeks two and four of the intervention to analyze the effectiveness of the application’s ability to assist participants in taking their medications on time as well as participant satisfaction regarding the app (Table 2). Regarding the McNemar’s and Cohen’s Kappa tests, p -values > .05, indicating that they were not statistically significant. To elaborate, for pre- and post-intervention results regarding questions 1 and 2, $p = .500$ and for

questions 3 and 4, $p = 1.00$. Pre- and post-intervention results for question 5 indicated that there was no statistical difference in overall participant rating of usefulness of the app ($K = .06$, $p = .78$).

Table 2. Mobile Device App Satisfaction Survey Results

McNemar Test 1-4 ^a				
	MDA pre- & MDA post- Q1	MDA pre- & MDA post- Q2	MDA pre- & MDA post- Q3	MDA pre- & MDA post- Q4
N	16	16	16	16
Exact Sig (2-tailed)	.500 ^b	.500 ^b	1.000 ^b	1.000 ^b
Survey Results	There was a small increase in participants who liked the design of the app pre- and post-intervention (pre $n = 14$; post $n = 16$).	There was a decrease in participants who found the application easy to use (pre $n = 16$; post $n = 14$).	“Is the app helping you with your goals? (to take medications on time?)” There was an increase in the participant’s subjective ability to take medications on time. The overall participant’s average regarding question 3 and ability of the app to take medications on time was 93.75% pre-intervention compared to a 100% average post-intervention at week four.	There was an increase in participants who would recommend the application to their friends (pre $n = 15$; post $n = 16$).

a. McNemar Test *b.* Binomial distribution used

Note. $N=16$. MDA = mobile device app satisfaction survey. Q1 -Q4 = questions 1-4. * $p > 0.05$.

Cohen's Kappa- Question 5

	Value	Asymptotic Standard Error ^a	Approximate T ^b	Approximate Significance
Measure of Agreement (Kappa)	.059	.206	.286	.775
N of Valid Cases	16			
Survey Results	For question 5, p -values $> .05$, indicated that they were not statistically significant. Average scores indicated a 4.5/5 score pre- and post-intervention regarding participant-rated usefulness of the app with medication-taking. Pre- and post-intervention results indicated that there was no statistical difference in overall participant rating of usefulness of the app ($K = .06$, $p = .78$).			

a. Not assuming the null hypothesis. b. Using the asymptotic standard error assuming the null hypothesis

*Note. N=16. * $p > 0.05$*

The Wilcoxon Signed Rank test was used pre- and post-intervention regarding the CGI scores (Table 3). The CGI was completed by the NP. The Wilcoxon test was chosen since it is a non-parametric test that compares two score sets from the same participants. Scores indicated that 10 participants had a decrease in illness severity post-intervention compared to pre-intervention and six participants remained at the same level of illness severity. Regarding their overall condition, seven participants showed an improvement in post-intervention compared to pre-intervention of what number, while nine participants remained at the same level in their overall condition pre- and post-intervention. Results were statistically significant at $p < .05$ pre- and post-intervention ($Z = 3.16$, $p = .002$) for CGI question 1 and for CGI question 2 ($Z = 2.65$, $p = .008$).

Table 3. Clinical Global Impressions Scale Results

CGI_Q1 – pre- &	CGI_Q2 – pre &
-----------------	----------------

	CGI_Q1 - post	CGI_Q2- post
Z	-3.162 ^b	-2.646 ^b
Asymp. Sig. (2-tailed)	.002	.008

a. Wilcoxon Signed Ranked Test 1 b. Based on positive ranks

Note. N=16. CGI = clinical global impressions scale. Q1 -Q2 = questions 1 and 2. *p<0.05.

Discussion

Findings

The study results indicated that baseline medication adherence improved regarding the questions associated with carelessness in taking medications and attitudes towards taking medications. In spite of no statistical significance regarding the 10 MARS (patient-rated scale) questions pre-, post-, and post-post-intervention, there was a small clinically significant change as apparent from the mentioned improvement in baseline medication adherence. Although individuals with schizophrenia/schizoaffective disorder may continue to have difficulty remembering to take medications, individual MARS question results indicate that participants are less careless about taking medications, believe that their thoughts are clearer on the medications, and think that medications can prevent them from getting sick. A review of the literature analyzing current research assessing the impact of psychoeducation and/or mobile device applications on medication adherence in the schizophrenia population indicate clinically significant improvement in medication adherence following either of the interventions, resulting in reduced schizophrenia symptoms (hallucinations and delusions) and reduced occurrence and length of psychiatric hospitalizations (Acosta, et al., 2012; Bauml, et al., 2016; Ben-Zeev, et al.,

2013; Cetin and Aylaz, 2018; Chien, et al., 2017; Haddad, et al., 2014; Santo, et al., 2016; Shadare, et al., 2017; Treisman, et al., 2016; Velligan, et al., 2013).

The clinically significant change indicates that psychoeducation regarding illness and the benefits of the mobile device app may be linked with improved medication adherence and can be used in other facilities. MDASS (patient-rated) results pre-and post-intervention were not statistically significant, nevertheless, participants believed the app to be useful in assisting with medication-taking, liked the design, and would recommend it to their friends. Additionally, Santo et al. (2016), reported that Medisafe was considered “engaging, entertaining, very interactive, easy to operate, and carrying high-quality information with visual appeal” via the Mobile Adherence Rating Scale. This suggests that participants are likely to continue to use the app, indicating continued assistance with medication adherence in current and future users. Medisafe Weekly Adherence Report indicated that participants showed an increase in weekly medication adherence via the Medisafe percentage. Participants also verbalized that the app was helpful in assisting them with medication-taking. Safety improves as participants continue to show continued medication adherence, reducing the risks of negative consequences associated with medication non-adherence. Coordination of care may also improve and assist with patient safety via health care information (vital signs, etc.) available via the app.

MDASS results pre- and post-intervention indicate that although participants may have found the application more difficult to use throughout the weeks, other results indicated that they believed it to be useful in assisting with medication-taking, they liked the design, and would recommend it to their friends. MDASS results pre- and post-intervention via the survey were not significant.

Participants showed an increase in weekly medication adherence via the Medisafe percentage reports which are displayed showing the uphill trend in the scatterplot (Figure 2) and verbalized that the application was helpful. Regarding the weekly written medication logs, participants were inconsistent with completing them and reported that they were not helpful in assisting with medication adherence.

Finally, CGI Scale, completed by the nurse practitioner, focused on whether there was improvement in baseline medication adherence in four weeks. Pre- and post-intervention CGI scores were statistically significant indicating that the nurse practitioner felt that participants improved in their illness severity and global improvement. When providers discover a positive change in patient functioning, they may be interested in utilizing the app to review during routine office visits. They may track patient adherence and further provider education can assist them with viewing laboratory test results, vital signs, and other pertinent information. CGIs, alternatively, indicated a positive significant change ($p < .05$) in the provider's rating of participant illness severity pre-and post- intervention at $p = .002$ for question 1 and $p = .008$ for question 2 (Table 4). Question 1 is: "Considering your total clinical experience with this particular population, how mentally ill is the patient at this time?" Scores range from "1 = Normal, not at all ill" to "7 = Among the most extremely ill patients." Question 2 is: "Rate total improvement whether or not in your judgment it is due entirely to drug treatment. Compared to his/her condition at admission to the project, how much has he/she changed?" Scores range from "1 = Very much improved" to "7 = Very much worse."

Overall, participants found the psychoeducation program and utilization of the Medisafe application useful in assisting them with taking their medications. The statistically significant

provider CGI scale pre- and post-intervention results and the uphill trend via weekly medication adherence percentage reports both indicate an improvement in medication adherence compared to baseline levels.

Objectives Achieved

The following objectives were achieved: 1. Improved baseline medication adherence in four weeks, 2. Implementation of the psychoeducation program in four weekly one-hour sessions, 3. Implementation of Medisafe as a self-report measure for improved baseline adherence, 4. The evaluation of the effectiveness of Medisafe as an appropriate tool prior to conducting the intervention, and 5. Implementation of a weekly medication adherence log per participant.

Regarding Objective 1, baseline medication adherence showed improvement via the CGI, which was a subjective measure completed by the nurse practitioner on-site. In contrast, the MARS results showed no significant differences pre-, post- and post-intervention. Medisafe percentage reports indicated variable differences in percentages and an overall steady increase in adherence throughout the four weeks. MDASS indicated that participants found Medisafe useful in adhering to medications. Despite statistical insignificance regarding the MARS and MDASS, 10 of the participants subjectively reported the usefulness of the application. Although the weekly written medication adherence logs were implemented, participants verbalized that they were not useful in assisting with medication-taking and participants were inconsistent in completing the weekly logs.

Table 4 displays the fulfillment of DNP project objectives 1-3. Objective 2: Implementation of the psychoeducation program in four weekly-one-hour sessions was completed on the dates mentioned prior.

Objective 4: Evaluate the effectiveness of the Medisafe app as a tool to increase medication adherence prior to conducting the intervention was completed prior to the beginning of implementation. As mentioned, Medisafe was ranked number one among advanced phone reminder apps via the Mobile Adherence Rating Score regarding ease of use, entertainment, carrying high-quality information, and visual appeal. (Santo et al., 2016). Objective 5: Implementation of co-investigator's weekly medication log to assess medication adherence/nonadherence was completed during the weekly psychoeducation groups. As mentioned prior, participants were inconsistent with completing the logs and reported that they were not helpful in assisting with medication adherence.

Key Facilitators and Barriers

Facilitating factors that impacted the project include IRB approval, helpful staff at the study site, potential participants' willingness to participate in the groups, the application being easy to access on site, and several participants being savvy with technology including mobile device applications.

Barriers included participant recruitment and the sample size being impacted. All participants were required to agree to participate in approximate one-hour weekly groups for four weeks and also carry a smart-phone. Several potential participants did not carry a smartphone and others carried smartphones that did not have enough data or space to download the Medisafe application. Staff assistance from participants' case managers could have positively impacted the

participants' abilities to more easily use the mobile device app. Case managers could have been educated on how to utilize the mobile device app and then individually assisted the participants with any further questions or problem shooting of the application. Of the original 22 participants, two decided not to participate, despite teaching, stating that they did not want to attend groups. One found the application difficult to use after the first week, and reported that she no longer wished to participate, despite education about the benefits of the application and efforts to provide additional technological support. One participant also had a co-occurring diagnosis of obsessive-compulsive disorder (OCD) and her caseworker reported that she does not leave her house often to attend the day program due to preoccupation with obsessions and compulsions around her home. She was not present in the day program during group times, despite being present during recruitment. Another participant was unable to download the application onto his smartphone due to having an older version of the phone, despite the co-investigator's multiple attempts to download it. Lastly, one participant later reported that he would be busy in college and would not be able to attend the partial care program groups consistently, despite education that the application would be helpful with his busy schedule.

Data analysis of app usage may have been impacted by participants' severity of illness as per CGI scores thus skewing clinical significance. Those with borderline-moderate illness severity had an easier time utilizing the app as opposed to those who were markedly-severely ill. Also, participants who were originally more tech-savvy were able to utilize the app easier and more efficiently than those who were not. Participants who had a CGI illness severity rating of "near normal" and who were able to learn how to use the app quickly had greater success with the app. Of those with greater illness severity and who were not savvy with technology, select participants were able to overcome those barriers with additional teaching regarding the app.

Other participants had difficulty correctly documenting their medication-taking despite the additional teaching.

Unintended Consequences

Positive unintended consequences included that despite that application appearing differently on the individual smartphones, the co-investigator and participants were able to maneuver and utilize the application effectively. Regarding the question of whether or not participants would be able to achieve better medication adherence without the use of a mobile device app, the co-investigator was able to discover that the written medication logs used to document weekly medication adherence was ineffective in comparison to using the Medisafe app.

Negative unintended consequences included that participants who were not savvy with their mobile devices, were greater in age, had a diagnosis of schizophrenia as opposed to schizoaffective disorder, or had greater severity of illness as per the CGI scale, had greater difficulty with documenting their medication-taking onto the application. Difficulty resulted in some weekly adherence reports showing lower percentages despite the participants reporting taking their medications on time when they heard the alarm from the application go off. Four participants had difficulty correctly documenting the medications weekly and needed additional teaching.

Additionally, throughout the four weeks, participants appeared distracted during the groups, speaking and catching up with one another regarding the past weekend since they attended on Monday and Tuesday mornings. Several announcements had to be made throughout the sessions by the co-investigator regarding the current educational material. Also, participants

did not find the meditation exercise beneficial at the end of the groups and several would not participate and would talk during the exercise.

Plan for Process Evaluation

The PDSA was used to assess the project's facilitators/barriers/unintended consequences. Pre-implementation project planning included identifying an evidence-based psychoeducational program and mobile device application that could be used to improve baseline medication adherence in outpatients with schizophrenia/schizoaffective disorder; engaging stakeholders for feedback on running the four-week psychoeducational group; identifying patients who met inclusion criteria with smartphones; and evaluating the efficacy of the MARS tool and weekly adherence percentage reports in regards to improving patients' baseline medication adherence. Planning in the pre-implementation stage was adequately completed.

Pre-implementation "doing" consisted of conducting informative sessions with potential candidates and implementation of the four-week psychoeducation program/utilization of Medisafe application. "Studying" consisted of assessing weekly adherence reports on the mobile device apps, comparing pre- and post-interventions MARS, MDASS, and CGI scores, and "Act" included evaluating the outcomes and determining improvement areas to the psychoeducation program and to the monitoring utilization of the Medisafe app.

Throughout the project, regarding barriers, identification of participants who met inclusion criteria remained an ongoing process and implementation consisted of changes in recruitment. Originally, the co-investigator was to hold a meeting in a scheduled group room during the "Technology Information" group time to explain the study purpose, goals, and objectives of the study; thoroughly discuss and go through the consent form while verifying participant

understanding via asking participants to describe the study topics in their own words; and discuss the benefits and length of the psychoeducation program including the usage of a smartphone application. The recruitment process did not result in an adequate number of participants and so modifications occurred where recruitment included making announcements during weekly client meetings on Tuesday mornings, which resulted in increased participant recruitment. Unintended consequences were addressed, as mentioned prior, and the key facilitators resulted in adequate completion of their portions of the PDSA cycle.

Implications/Recommendations

Clinical Practice

Advanced practice nurses (APNs) at the facility can continue to run psychoeducation groups weekly to ensure that patients are educated on their diagnosis, symptoms, medications, and the Medisafe application. For patients that continue to use the mobile device application (app), weekly/monthly adherence percentage reports can be seen by the provider during routine office visits. The provider, in this way, can have a clearer idea of how adherent the patients are to their psychiatric medications. Because study results indicate that participant severity of illness and degree of being tech-savvy may have impacted medication adherence results via the app, providers may benefit from completing additional teaching with future patients who have these issues.

Advanced utilization of the app includes the ability for patients to input reasons for nonadherence or missing select medication times, further providing the APN with important adherence information. Providers can be educated on how to utilize the app to best suit their needs since along with viewing weekly/monthly medication adherence reports, the application

may also be useful for viewing laboratory test results, vital signs, and other information from patient visits with primary care providers, improving collaboration of care.

To expand the group of patients involved in psychoeducation and Medisafe app utilization, the interventions can be conducted in patients with other disorders, including bipolar disorder, anxiety disorders, and major depressive disorder. As mentioned, prior research has indicated that psychoeducation alone may not be enough to impact adherence behavior in the schizophrenia population and behavior reinforcement strategies such as a mobile device app cell-phone alarm has shown to improve baseline medication adherence which can continue to positively impact clinical practice.

Healthcare Policy Implications

If psychoeducation and use of Medisafe continue to demonstrate improved baseline medication adherence in the schizophrenia/schizoaffective disorder population, medication administration policies at the facility may include utilization of both to ensure continued adherence. Policies for medication-taking can include other individuals with mental health illnesses such as those with major depression, bipolar disorder, and anxiety.

Although the utilization of mobile device apps may be beneficial to both provider and patient, it is apparent that data is more readily available via electronic health records and now the mobile device apps. Because of the increased availability of private patient information, it is important that policy implications regarding new technology reflect HIPAA regulations. It is additionally important that healthcare professionals, developers of technology, and policymakers collaborate to implement safe and efficient patient care regarding the app (Sweeney, 2017).

Federal and state roles regarding healthcare policy may differ regarding technology. Coordination among healthcare officials and governing officials at the state and federal levels is important to avoid conflicting initiatives in healthcare and may lead to violations regarding patient information and care. Furthermore, policy should emphasize outcomes, value, and the benefits of the consumer and community rather than centering around the providers (Newhouse, et al., 2012). By utilizing the interventions of psychoeducation and the mobile device app, coordination of care in outpatient facilities may improve, creating a safer continuum of care among different disciplines.

Implications on Quality/Safety

Regarding psychoeducation, forming a therapeutic alliance between provider and patient may improve a patient's ability to advocate for themselves, which may result in the patient participating in their care and improving their medication adherence (Corey, 2009). When a patient feels that they are educated in their diagnosis, medications, and related factors, they may be better equipped to participate in treatment decisions and better understand that their choices (i.e. being adherent or nonadherent to psychiatric medications) can either improve their prognosis or cause negative consequences.

Utilization of the mobile device app, Medisafe, as a reminder for administration of medications is simple and adoptable. Providers and patients can collaborate to promote app utilization to improve medication adherence. When patients with schizophrenia/schizoaffective disorder are taking their psychiatric medications as prescribed, they may experience less psychiatric symptoms and create an internal environment in which stimuli (symptoms) are controlled or removed (Chong et al., 2016). In turn, patients' functioning and quality of life will

improve since medication nonadherence is related to worsening of psychiatric symptoms and decompensation, which may lead to high risk of re-hospitalization, criminal activity, self-injury, and social isolation (American Psychiatric Association, 2013).

Safety may improve as patients may continue to be more adherent with medications, reducing the risks of negative consequences that occur with medication nonadherence. Coordination of care may also improve patient safety as different providers may easily view patients' weekly/monthly adherence reports, laboratory testing results, etc. on patients' mobile devices.

Implications on Education

Psychoeducation, as mentioned, may assist in forming the therapeutic alliance between the provider and patient, improving the patient's ability to advocate for their needs and make treatment decisions easier. Weekly psychoeducational groups including the utilization of the mobile device app may continue to occur in the facility and other coordinating facilities to assist patients with mental health illnesses in better adhering to their scheduled medications. Educating providers on the topics that patients are most interested and would be most beneficial to them regarding diagnosis and treatment would assist them on developing the education plans for their weekly groups.

As mentioned prior, providers' additional education for patients with marked-severe illness and who are less used to using technology, may be needed for the patients to properly use the app. In addition, educating the providers on utilizing the app for coordination of care in different disciplines may be the next beneficial step in improving the safety and quality of patient

care. Providers can also further be reminded of the benefits of behavioral activation and the possibility of improved patient adherence.

Educating DNP students on the benefits of psychoeducation and the mobile device app is another way that future providers can begin to have the information to utilize psychoeducation and technology in their practices. Education to both providers and patients can additionally include ways to provide easier and beneficial strategies and directions to utilize the app for those who are less tech savvy, since some participants had difficulty remembering how to use the app, resulting in inconsistent weekly adherence percentage reports. DNP students would, early on, be aware of additional ways to increase medication adherence in their patients, which would assist them in becoming more efficient health care providers.

Implications on Economic/Cost Benefits of Project

Annual U.S. costs for schizophrenia treatment range from \$94 million to \$102 billion and medication nonadherence contributes to the high costs. Indirect financial costs associated with schizophrenia are significantly greater than other chronic and physical health problems. Indirect costs include social service needs, productivity loss, and high risk of criminal activity, (National Institute of Mental Health, 2018).

The QI project may demonstrate improved baseline medication adherence in the schizophrenia/schizoaffective disorder adult outpatient population, resulting in a reduction of symptoms associated with the disorders, thereby reducing the economic burden associated with high treatment costs. Improved medication adherence would also contribute to decreased rates of relapse and re-hospitalizations, which would further reduce the economic burden associated with the disorders. In the U.S., the average readmission costs for those with schizophrenia spectrum

disorders is \$9,285 and \$8,593. In addition, those with schizophrenia have the second highest rate of readmission in hospitals (Wani, Kathe, and Klepser, 2019).

Implications on Identified Facilitators/Barriers and Unintended Consequences

Facilitating factors and positive unintended consequences included the helpfulness of staff, participants' willingness to participate, and ease of access regarding the app. Groups can continue to be run by the APN and, in addition, case managers can assist clients with using their mobile devices. Recommendations for barriers and negative unintended consequences may include continued research utilizing a larger sample size, Medicaid coverage of smartphones (and download of Medisafe) for clients who are not able to afford them, additional time for those with greater illness severity to learn how to utilize the app, and having smaller groups for more focused attention.

Other Implications as Related to the Project

The organization would benefit from the continued psychoeducational groups and use of Medisafe. The facility focuses on care for individuals with mental health, substance abuse, and medical problems. The project interventions may benefit the patients at the facility who have difficulty adhering to their prescribed medications. The partial care program director, nurse practitioners, psychiatrists, and primary care providers at the facility can receive education on the benefits and utilization of the mobile device app and work to facilitate weekly diagnosis and treatment groups, including the utilization of the app, in their respected departments.

Sustainability

The project has great potential for sustainability. The advanced psychiatric nurse practitioner at the site currently conducts weekly health and wellness groups, which may now include a focus on diagnosis, treatment, and the Medisafe mobile device app. Partial care program members with smartphones carry their phones with them mostly everyday, indicating that the medication reminder alarm will be present wherever they are. In addition to the education provided, weekly health education groups may also be opportunistic times for the APN to review medication adherence reports on patients' smartphones to gain insight into how adherent the patients are. The interventions may also be conducted in neighboring facilities where APNs already implement weekly groups, which would suggest great feasibility.

Technology is evolving and the app may expand and be used on devices other than patients' cellphones, helping to further increase medication adherence. Currently, IPADs and tablets have the ability to hold different apps and Medisafe may be utilized on them. This will make it more convenient for patients to be reminded of times to take their medications in case their cellphones are not within reach. In the case that more advanced technology develops in the future, more sophisticated apps may take the place of Medisafe. This will not affect the sustainability of the project due to the common goal of using phone-based technology to boost medication adherence.

Plans for Dissemination and Professional Reporting

Dissemination of the project at Rutgers University will include the final DNP paper, the project poster, and the presentation. Once the manuscript is finished, it will be submitted to Dove Press and disseminated to the Journal of American Psychiatry Nurses Association (JAPNA). Following completion of the project, further research will be conducted regarding using different

aspects of the mobile device app (laboratory values, primary care provider information) to assist in further improving medication adherence in individuals with psychiatric illnesses.

Summary

Medisafe and psychoeducation have shown to be effective in improving baseline medication adherence in the schizophrenia population. The interventions have great implications for clinical practice, healthcare policy, quality and safety, education, etc., yet it is important that additional education is provided for patients with greater illness severity and who are not as familiar with technology. There is great sustainability for the project and room to continue to assist patients with medication adherence using technology and education.

References

- Acosta, F. J., Hernández, J. L., Pereira, J., Herrera, J., & Rodríguez, C. J. (2012). Medication adherence in schizophrenia. *World Journal of Psychiatry*, 2(5), 74-82.
<https://doi.org/10.5498/wjp.v2.i5.74>
- Agency for Healthcare Research and Quality (AHRQ) (2015). Hospital readmissions involving psychiatric disorders. Retrieved from <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb189-Hospital-Readmissions-Psychiatric-Disorders-2012.pdf>
- American Medical Association (2019). Medication adherence. Retrieved from <https://edhub.ama-assn.org/steps-forward/module/2702595>
- American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders* (5th ed.). Washington, DC: Author.
- American Psychological Association (2019). What is cognitive behavioral therapy? Retrieved from <https://www.apa.org/ptsd-guideline/patients-and-families/cognitive-behavioral>
- Bäuml, J., Froböse, T., Kraemer, S., Rentrop, M., & Pitschel-Walz, G. (2006). Psychoeducation: a basic psychotherapeutic intervention for patients with schizophrenia and their families. *Schizophrenia Bulletin*, 32, Suppl 1, S1–S9. <https://doi.org/10.1093/schbul/sbl017>
- Bäuml, J., Pitschel-Walz, G., Volz, A., Lüscher, S., Rentrop, M., Kissling, W., & Jahn, T. (2016). Psychoeducation improves compliance and outcome in schizophrenia without an increase of adverse side effects: A 7-year follow-up of the munich PIP-study. *Schizophrenia Bulletin*, 42(11), 62–70. <https://doi.org/10.1093/schbul/sbw008>

Ben-Zeev, D., Kaiser, S. M., Brenner, C. J., Begale, M., Duffecy, J., & Mohr, D. C. (2013).

Development and usability testing of FOCUS: A smartphone system for self-management of schizophrenia. *Psychiatric Rehabilitation Journal*, 36(4), 289–296.

<https://doi.org.proxy.libraries.rutgers.edu/10.1037/prj0000019>

Centers for Disease Control and Prevention (CDC) (2015). Emergency department visits related to schizophrenia among adults aged 18-64: United states, 2009-2011. Retrieved from

<https://www.cdc.gov/nchs/data/databriefs/db215.htm>

Cetin, N., and Aylaz, R. (2018). The effect of mindfulness-based psychoeducation on insight and medication adherence of schizophrenia patients. *Archives of Psychiatric Nursing*, 32(5), 737-744. <https://doi.org/10.1016/j.apnu.2018.04.01>

Chien, W.T., Mui, J., Cheung, E., & Gray, R. (2015). Effects of motivational interviewing-based adherence therapy for schizophrenia spectrum disorders: a randomized controlled trial. *Trials*, 16(1), 270. <https://doi.org/10.1186/s13063-015-0785-z>

Chien, W.T., Bressington, D., Yip, A., & Karazias, T. (2017). An international multi-site, randomized controlled trial of a mindfulness-based psychoeducation group programme for people with schizophrenia. *Psychological Medicine*, 47(12). 2081-2096.

<https://doi.org/10.1017/S0033291717000526>

Chong, H. Y., Teoh, S. L., Wu, D. B., Kotirum, S., Chiou, C. F., & Chaiyakunapruk, N. (2016).

Global economic burden of schizophrenia: a systematic review. *Neuropsychiatric disease and treatment*, 12, 357-73. <https://doi.org/10.2147/NDT.S96649>

- Cole-Lewis, H., and Kershaw, T. (2010). Text messaging as a tool for behavior change in disease prevention and management. *Epidemiologic Reviews*, 32(1), 56-69. <https://doi-org.proxy.libraries.rutgers.edu/10.1093/epirev/mxq004>
- Corey, G. (2009). Theory and practice of counseling and psychotherapy (8th ed.). Belmont, CA: Brooks/Cole.
- Cascade, E., Kalali, A. H., Mehra, S., & Meyer, J. M. (2010). Real-world data on atypical antipsychotic medication side effects. *Psychiatry (Edgmont)* 7(7), 9–12. Retrieved from <http://search.proquest.com/docview/749016291/>
- Coury, J., Schneider, J. L., Rivelli, J. S., Petrik, A. F., Seibel, E., D’Agostini, B., ... Coronado, G. D. (2017). Applying the Plan-Do-Study-Act (PDSA) approach to a large pragmatic study involving safety net clinics. *BMC Health Services Research*, 17, 1–10. <https://doi-org.proxy.libraries.rutgers.edu/10.1186/s12913-017-2364-3>
- Donnelly, P., & Kirk, P. (2015). Use the PDSA model for effective change management. *Education for Primary Care*, 26(4), 279–281. <https://doi.org/10.1080/14739879.2015.11494356>
- El-Mallakh, P., & Findlay, J. (2015). Strategies to improve medication adherence in patients with schizophrenia: the role of support services. *Neuropsychiatric disease and treatment*, 11, 1077-90. <https://doi.org/10.2147/NDT.S56107>
- Fitch, K., Kosuke Iwasaki, & Villa, K. F. (2014). Resource utilization and cost in a commercially insured population with schizophrenia. *American Health & Drug Benefits*, 7(1), 18–26.
- Foundation for a Mindful Society (2019). A 5-minute breathing meditation to cultivate mindfulness. Retrieved from <https://www.mindful.org/a-five-minute-breathing-meditation/>

- Guy, W. (1976). *ECDEU Assessment for Psychopharmacology, Revised Edition*. NIMH Publication: Rockville, MD.
- Haddad, P. M., Brain, C., & Scott, J. (2014). Nonadherence with antipsychotic medication in schizophrenia: challenges and management strategies. *Patient-related Outcome Measures*, 5, 43-62. <https://doi.org/10.2147/PROM.S42735>
- Hettema, J. (2009). Motivational interviewing. In G. L. Fisher & N. A. Roget (Eds.), *Encyclopedia of substance abuse prevention, treatment, & recovery* (pp. 569-572). Thousand Oaks, CA: SAGE Publications, Inc. <https://doi.org/10.4135/9781412964500.n199>
- Higashi, K., Medic, G., Littlewood, K. J., Diez, T., Granström, O., & De Hert, M. (2013). Medication adherence in schizophrenia: factors influencing adherence and consequences of nonadherence, a systematic literature review. *Therapeutic advances in psychopharmacology*, 3(4), 200-218. <https://doi.org/10.1177/2045125312474019>
- Levin, B., Seifi, A., Cassidy, K., Tatsuoka, K., Sams, K., Akagi, K., & Sajatovic, K. (2014). Comparing medication attitudes and reasons for medication nonadherence among three disparate groups of individuals with serious mental illness. *The Journal of Nervous and Mental Disease*, 202(11), 769–773. <https://doi.org/10.1097/NMD.0000000000000201>
- Matsuda, M., & Kohno, A. (2016). Effects of the nursing psychoeducation program on the acceptance of medication and condition-specific knowledge of patients with schizophrenia. *Archives of Psychiatric Nursing*, 30(5), 581–586. <https://doi.org/10.1016/j.apnu.2016.03.008>
- Mayo Clinic (2019-a). Schizoaffective disorder. Retrieved from <https://www.mayoclinic.org/diseases-conditions/schizoaffective-disorder/symptoms-causes/syc-20354504>

- Mayo Clinic (2019-b). Schizophrenia. Retrieved from <https://www.mayoclinic.org/diseases-conditions/schizophrenia/diagnosis-treatment/drc-20354449>
- McIlroy, M. L. (2018). *Medication adherence among patients with schizophrenia and schizoaffective - bipolar type disorder: A clinical education approach to improve medication compliance*. Available from ProQuest Dissertations & Theses Global. Retrieved from <https://search.proquest.com/docview/2038490575?accountid=13626>
- Medisafe (2019). Platform. Retrieved from <https://medisafe.com/partners/>
- Montes, J., Medina, E., Gomez-Beneyto, M., & Maurino, J. (2012). A short message service (SMS)-based strategy for enhancing adherence to antipsychotic medication in schizophrenia. *Psychiatry Research*, 200(2-3), 89–95. <https://doi.org/10.1016/j.psychres.2012.07.034>
- National Alliance on Mental Illness (2019-a). Schizoaffective disorder. Retrieved from <https://www.nami.org/learn-more/mental-health-conditions/schizoaffective-disorder>
- National Alliance on Mental Illness (NAMI) (2019-b) Retrieved from <https://www.nami.org/Learn-More/Treatment/Mental-Health-Medications/Types-of-Medication>
- National Alliance on Mental Illness (NAMI) (2019-c). Retrieved from <https://www.nami.org/Find-Support/Living-with-a-Mental-Health-Condition/Managing-Stress>
- National Alliance on Mental Illness (NAMI) Austin (2018, October 17). How psychotropic medications work. [Video file]. Retrieved from <https://www.youtube.com/watch?v=hwuiE6-17AA>
- National Alliance on Mental Illness (NAMI) New Jersey (2018). NAMI connection. Retrieved from <http://www.naminj.org/programs/nami-connection/>

National Center for Injury Prevention and Control (2015). Suicide facts at a glance. Retrieved from

<https://www.cdc.gov/violenceprevention/pdf/suicide-datasheet-a.pdf>

National Council Medical Director Institute (2018). Medication matters: Causes and solutions to

medication non-adherence. Retrieved from [https://www.nationalcouncildocs.net/wp-](https://www.nationalcouncildocs.net/wp-content/uploads/2018/09/medication-non-adherence-082918.pdf)

[content/uploads/2018/09/medication-non-adherence-082918.pdf](https://www.nationalcouncildocs.net/wp-content/uploads/2018/09/medication-non-adherence-082918.pdf)

National Institute of Mental Health (n.d.-a). Schizophrenia. Retrieved from

<https://www.nimh.nih.gov/health/statistics/schizophrenia.shtml>

National Institute of Mental Health (n.d.-b). Mental health medications. Retrieved from

<https://www.nimh.nih.gov/health/topics/mental-health-medications/index.shtml>

New Jersey 2016 Mental Health National Outcome Measures (NOMS): SAMHSA Uniform

Reporting System (2016). 2016 SAMHSA uniform reporting system (URS) output tables.

Retrieved from <https://www.samhsa.gov/data/sites/default/files/NewJersey-2016.pdf>

New Jersey State Health Assessment Data (2019). New jersey public health data resources. Retrieved

from [https://www-doh.state.nj.us/doh-](https://www-doh.state.nj.us/doh-shad/query/result/njbrfs/MentHlthTreat/MentHlthTreatCrude11_.html)

[shad/query/result/njbrfs/MentHlthTreat/MentHlthTreatCrude11_.html](https://www-doh.state.nj.us/doh-shad/query/result/njbrfs/MentHlthTreat/MentHlthTreatCrude11_.html)

Olfson, M., Gerhard, T., Huang, C. (2015). Premature mortality among adults with schizophrenia in

the united states. *Journal of the American Medical Association Psychiatry*, 72(12), 1172-

1181. <https://doi.org/10.1001/jamapsychiatry.2015.1737>

Owie, G., Olotu, S.O., and James, B.O. (2018). Reliability and validity of the medication adherence

rating scale in a cohort of patients with schizophrenia from Nigeria. *Trends in Psychiatry*

Psychotherapy, 40(2), 85-92. <https://doi.org/10.1590/2237-6089-2017-0077>

- Palmier-Claus, J.E., Ainsworth, J., Machin, M., Barrowclough, C., Dunn, G., Barkus, E...Lewis, S.W. (2012). The feasibility and validity of ambulatory self-report of psychotic symptoms using a smartphone software application. *BMC Psychiatry*, 12, 172.
<https://doi.org/10.1186/1471-244X-12-172>
- Perreault, M, Katerelos, T.E., Tardif, H, & Pawliuk, N. (2006). Patients' perspectives information received in outpatient psychiatry. *Journal of Psychiatric and Mental Health Nursing*, 13, 110-116. <https://doi.org/10.1111/j.1365-2850.2006.00928.x>
- Pompili, M., Amador, X. F., Girardi, P., Harkavy-Friedman, J., Harrow, M., Kaplan, K...Tatarelli, R. (2007). Suicide risk in schizophrenia: learning from the past to change the future. *Annals of general psychiatry*, 6(10). <https://doi.org/10.1186/1744-859X-6-10>
- Raosoft (2004). Sample size calculator. Retrieved from <http://www.raosoft.com/samplesize.html>
- Schizophrenia Society of Alberta. (2016, January 4). Intro to schizophrenia animation [Video file]. Retrieved from https://www.youtube.com/watch?time_continue=398&v=fGaj2l_mVVk
- Reuter (2016). Kansas city business journal. Retrieved from <https://www.bizjournals.com/kansascity/news/2016/12/15/cerner-chief-competitor-call-truce-for-integrated.html>
- Sadock, B., Sadock, V., & Ruiz, P. (2015). *Kaplan & Sadock's synopsis of psychiatry*. 11th Edition. Philadelphia, PA: Wolters Kluwer.
- Santo, K., Richtering, S. S., Chalmers, J., Thiagalingam, A., Chow, C. K., & Redfern, J. (2016). Mobile phone apps to improve medication adherence: A systematic stepwise process to

identify high-quality apps. *Journal of Medical and Internet Research mHealth and uHealth*, 4(4), 132. <https://doi.org/10.2196/mhealth.6742>

Shadare, E., Williamitis, C., Hanisch, T., & Webb, B. (2017). *Increasing medication adherence and compliance in adults with schizophrenia/schizophrenia spectrum disorder (SSD) by using mobile app alarm reminder for medication administration*. ProQuest Dissertations Publishing. Retrieved from <http://search.proquest.com/docview/1947584036/>

Survicate (2019). 15 mobile app survey questions you can't miss out on. Retrieved from <https://survicate.com/mobile-app-survey/mobile-app-survey-questions/>

Swendsen, J., Ben-Zeev, D., Granholm, E. (2011) Real-time electronic ambulatory monitoring of substance use and symptom expression in schizophrenia. *American Journal of Psychiatry*, 168, 202–209. <https://doi.org/10.1176/appi.ajp.2010.10030463>

Thompson, K., Kulkarni, J., Sergejew, A.A. (2000). Reliability and validity of a new Medication Adherence Rating Scale (MARS) for the psychoses. *Schizophrenia Research*, 42, 241–247. [https://doi.org/10.1016/S0920-9964\(99\)00130-9](https://doi.org/10.1016/S0920-9964(99)00130-9)

Treisman, G. J., Jayaram, G., Margolis, R. L., Pearlson, G. D., Schmidt, C. W., Mihelish, G. L., ... Misiuta, I. E. (2016). Perspectives on the use of eHealth in the management of patients with schizophrenia. *Journal of Nervous & Mental Disease*, 204(8), 620–629. <https://doi-org.proxy.libraries.rutgers.edu/10.1097/NMD.0000000000000471>

United States Computer Readiness Team (2011). Cyber threats to mobile phones. Retrieved from https://www.us-cert.gov/sites/default/files/publications/cyber_threats-to_mobile_phones.pdf

- U.S. Department of Veteran Affairs (n.d.). Facts about antipsychotic medications. Retrieved from https://www.mirecc.va.gov/visn22/Facts_about_Antipsychotic_Medications_Veteran_and_Family_Handout.pdf
- U.S. Food and Drug Administration (2018). Are you taking your medications as prescribed? Retrieved from <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm164616.htm>
- U.S. National Library of Medicine (2019). Schizoaffective disorder. Retrieved from <https://ghr.nlm.nih.gov/condition/schizoaffective-disorder#genes>
- Velligan, D.I., Mintz, J., Maples, N., Xueying, Li, Gajewski, S., Carr, H., Sierra, C. (2013). A randomized controlled trial comparing in person and electronic interventions for improving adherence to oral medications in schizophrenia. *Schizophrenia Bulletin*, 39(5), 999-1007. <https://doi.org/10.1093/schbul/sbs116>
- Wani, R. J., Kathe, N. J., & Klepser, D. G. (2019). Predictors of cost and incidence of 30-day readmissions following hospitalizations for schizophrenia and psychotic disorders: A nationwide analysis. *Quality Management in Health Care*, 28(3), 130–138. <https://doi-org.proxy.libraries.rutgers.edu/10.1097/QMH.0000000000000223>
- White, K.M., Dudley-Brown, S., & Terhaar, M.F. (2016). *Translation of evidence into nursing and health care*. (2nd ed.). New York, NY: Springer Publishing Company.
- World Health Organization (WHO) (2013). Mental health action plan 2013-2020. Retrieved from https://apps.who.int/iris/bitstream/handle/10665/89966/9789241506021_eng.pdf?sequence=1
- World Health Organization (WHO) (2019). Schizophrenia. Retrieved from https://www.who.int/mental_health/management/schizophrenia/en/

Yogeswary, K. (2014). Schizoaffective disorder: An overview. *International Journal of Clinical Psychiatry*, 2(1), 11-15. <https://doi.org/10.5923/j.ijcp.20140201.03>

Appendix A – Site Approval

March 27, 2019

Rutgers University
Institutional Review Board

Re: Meghann Alcala
Quality Improvement Project

To Whom It May Concern,

Ms. Meghann Alcala is currently a Nursing Intern at [REDACTED]. She is scheduled to continue her internship in the Academic Year beginning September 2019. Ms. Alcala has requested permission to conduct a Quality Improvement Project at [REDACTED] as an element of her internship.

[REDACTED] is licensed by the New Jersey Division of Mental Health and Addiction Services, and is accredited by the Joint Commission on Accreditation of Health Care Organizations. Both set standards for the agency's Quality Assurance/Quality Improvement functions. Quality Improvement Projects are an integral element of daily operations focused on implementing strategies for improving the outcomes for clients through the application of the scientific method based on data. It differs from research and, as an integral element of daily operations, does not require that Care Plus obtain IRB approval.

Ms. Alcala has submitted her proposed Quality Improvement Project for [REDACTED] to review. It does not involve any experimental procedures, or procedures that place clients at a risk of harm. It is acceptable as a Quality Improvement Project within the scope of daily operations and not research.

This letter is to confirm that Ms. Alcala is permitted to conduct her Quality Assurance Project during her internship at [REDACTED]. The Project will be under the guidance of her assigned [REDACTED] internship supervisor.

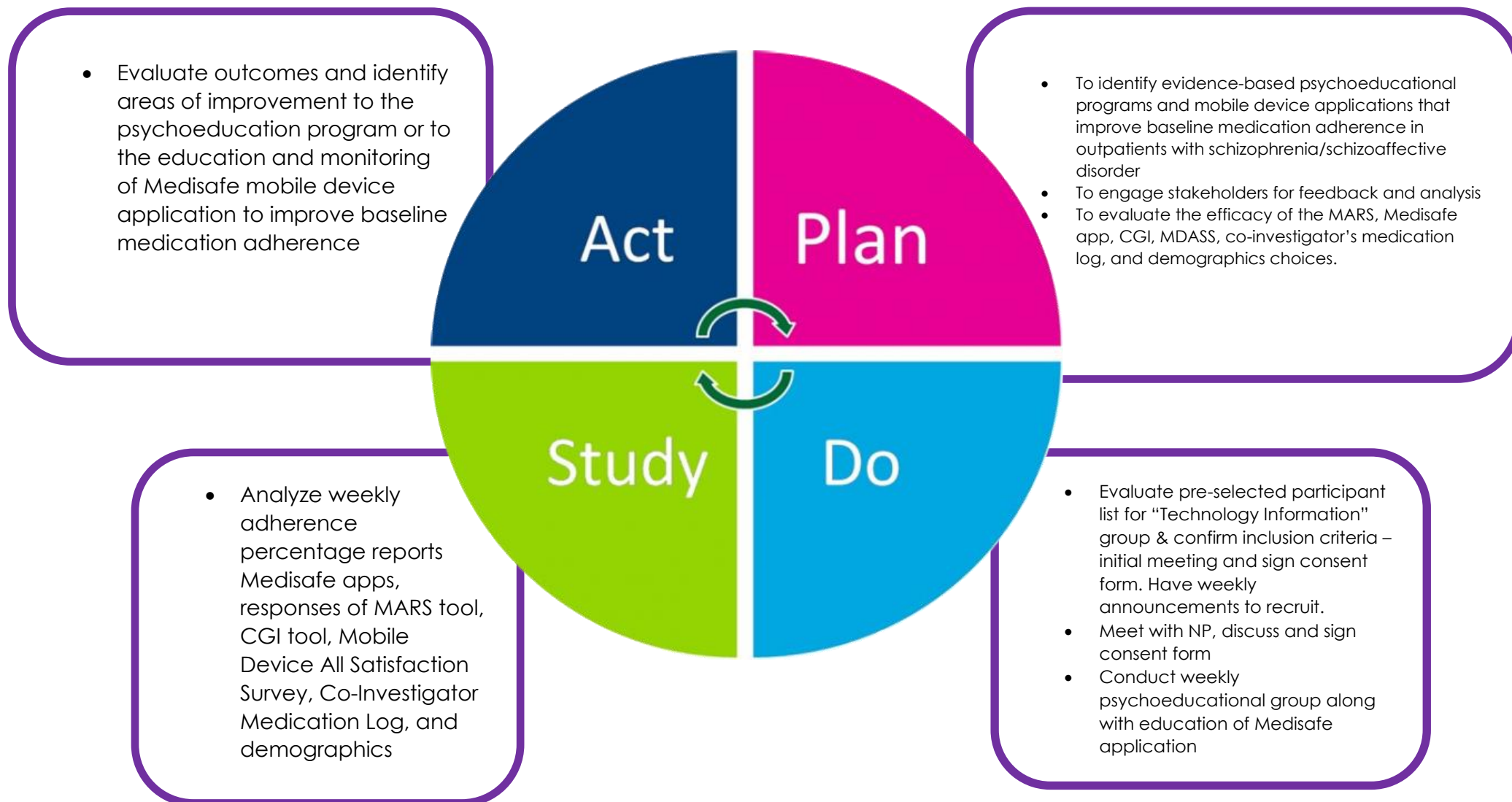
If you have any questions, please contact me at 201-255-8200 ext. 5233.

Yours truly,

[REDACTED]

[REDACTED]

Appendix B – Theoretical Framework



Appendix C – Table of Evidence

Clinical Question: In adult psychiatric outpatients diagnosed with schizophrenia or schizoaffective disorder, will a four-week, approximate one hour per week, psychoeducation program including the education and utilization of a mobile device application result in improved medication adherence compared to baseline medication adherence?

Article #	Author & Date	Evidence Type	Sample, Sample Size, Setting	Study findings that help answer the EBP Question	Limitations	Evidence Level & Quality
1	Bauml, et al., 2016	Research – Randomized Multi-Centre PIP Study	Adult inpatients with schizophrenia/schizoaffective disorder, 41 sample size, 3 psychiatric hospitals in Munich	Psychoeducation during four weekly sessions of 60 minutes each and afterwards four monthly sessions were held for the intervention group (IG). With the exception of the psychoeducational groups, the IG and control group (CG) received the same psychiatric treatment as usual (TAU). At discharge and seven years later, both IG and CG showed good or “very good” compliance. After two years, there was better compliance in IG group. The number of days spent in the hospital up to 7 years significantly showed a better outcome in the IG ($p<.03$) compared to CG: 74.7 days vs 243.4 days	Sample size seven years later post-discharge was small in both groups and selection bias of greater motivated, healthier patients cannot be excluded. Medication type was not documented over 6.5 years – it was only reviewed six months before follow-up. Higher rate of atypical antipsychotics in IG may have influenced a better outcome. Unknown confounders could have influenced both CG and IG.	Level I/B

2	Haddad, Brain, and Scott, 2014	Research – Systematic Review	<p>-Electronic Reminders – RCT in outpatients with schizophrenia</p> <p>- Psychoeducation- 99 studies involving family psychoeducation in those with schizophrenia</p>	<p>-Outpatients with schizophrenia received daily short message service (SMS) text messages over 3 months as medication reminders along with education. Patient-rated adherence with antipsychotic medication compared to the control group, improved.</p> <p>-Improved medication adherence from psychoeducation was shown to be a benefit of family therapy or social skills training.</p>	<p>-Systematic review of electronic reminders using SMS reminders, audiovisual reminders, or paper messages were effective, although short-term— follow-up period <6 months</p> <p>-Apart from one trial, psychoeducation interventions to improve adherence have shown mixed benefits.</p>	Level 1/A
3	Acosta, et al., 2012	Research – Systematic Review	<p>Non-adherence concepts of consequences, prevalence, evaluation methods, methodological restrictions of available studies, intervention strategies, and risk factors were analyzed in patients with schizophrenia.</p>	<p>-Identified and mapped out the risk factors for medication non-adherence as a first step toward designing intervention strategies aimed at reducing nonadherence behavior for schizophrenic patients.</p> <p>-Also highlighting and exploring adherence promoting strategies resulted in better adherence especially through pharmacological related treatment.</p> <p>-Psycho-educative interventions resulted in greater medication adherence.</p>	<p>Currently, short-term treatments based on simple interventions have proven efficient in improving medication adherence, although results are not consistent across different studies.</p>	Level III/C

			The number of studies assessed is not reported.			
4	Cetin and Aylaz, 2018	Research – True Experiment Design with Pre- and Post-test Control Groups	135 outpatients with Schizophrenia (55 from experimental; 80 from control), Community Mental Health Centers located in Balıkesir and Eskişehir,	<p>A psychoeducation program increased cognitive insight level and medication adherence in patients with schizophrenia and can be used by nurses in addition to medication. The program was held for 4 weeks; total of 8 sessions in the experimental group. During this time, clients were taught different meditation techniques such as body scan meditation, sitting meditation, respiration and breath meditation.</p> <p>The mean post-test score of the Beck Cognitive Insight Scale was 4.89 ± 6.05 in the experimental group, 1.68 ± 5.67 in the control group. The difference between the mean scores showed statistical significance at $p < 0.05$. The mean post-test score of the MARS was 1.76 ± 0.42 in the experimental group, 1.50 ± 0.50 in the control group. The difference between the mean scores was statistically significant at $p < 0.05$.</p>	<p>-Findings can only be generalized for the group in the study.</p> <p>-Study was conducted in Community Mental Health Centers (CMHCs) in different provincial centers</p> <p>-Post-test measurement was only made once and there was no follow-up post-study</p>	Level I/B
5	Velligan, et al., 2013	Research – Randomized Control Trial	Individuals diagnosed with schizophrenia or schizoaffective disorder, sample	Participants had baseline assessment of medication adherence in 1 month measured by Med-eMonitor (MM) and pill count & then were placed into 1 of 3 treatment groups (MM, PharmCAT	-Medication adherence assessments involve error.	Level II/A

			<p>size 142 patients (75 male & 67 female), Public mental health clinics in 2 counties in Texas</p>	<p>[electronic monitoring], or treatment as usual [TAU]) for 9 months. Baseline adherence via electronic monitoring were different by treatment group at $p < .01$, PharmCAT > TAU > MM. PharmCAT and the MM improved adherence significantly over TAU and follow-up with all p-values <0.0001. Average adherence rates from the electronic monitoring were around 90% for the active treatments compared to about 72% for TAU. For pill counts, those in PharmCAT had the best adherence followed by MM and then TAU. Active treatments received high satisfaction ratings.</p>	<p>-A great number (197 were consented) of people approached for the trial did not participate and others dropped out during the initial one-month period. There was a high baseline adherence level that could have affected differences in outcomes between treatments. Because there were baseline differences regarding adherence apparent on electronic monitoring, greater adherence levels could have been maintained rather than improved in PharmCAT.</p>	
--	--	--	---	---	--	--

6	Chien, Bressington, Yip, and Karazias, 2017	Research – Single-blind Multi-site, Pragmatic Randomized Control Trial	342 outpatients with schizophrenia spectrum disorders (from 1000), six treatment facilities between three different countries (China, Hong Kong, and Taiwan)	<p>-Participants received 24-week, 12 biweekly 2-hour sessions mindfulness-based psychoeducation groups (MBPEG) (n=114) with 10-12 patients per group, Conventional psychoeducation groups (CPEG) (n=114) had 12 bi-weekly 2-hour sessions (10-12 patients per group using prior psychoeducation manuals. Routine outpatient psychiatric care was provided to the treatment as usual (TAU) group (n=114).</p> <p>-Average rehospitalization lengths were significantly reduced 1-4 in MBPEG groups compared with BPEG and TAU groups. Functioning, insight, and mental state in MBPEG groups were 1-4 times greater, also.</p> <p>-The findings also showed that there were greater rates of remission in the participants in the MBPEG group and those in the CPEG group over the 24-month follow-up. Greater reduction of symptoms and total rates of remission were seen among the MBPEG group when compared with CPEG and TAU groups at both 12- and 24-month follow-up. At the follow-up at 24 months, more than one-third of the participants receiving MBPEG were in complete remission, compared with 26 in the CPEG group and 7% in the TAU group.</p>	<p>There was motivation for the participants to participate; they were not blind to the intervention appropriation, which may result in response bias.</p> <p>-Patients who have had schizophrenia for a shorter duration (a mean of 2.5-2.7 years) may not accurately represent the wider, chronic schizophrenia population or those who have comorbidities including substance abuse and mood disorders. The particular sample may have had high levels of adherence, adequate attendance to intervention sessions, and very low drop-out rate.</p> <p>-The study was conducted by</p>	Level II /A
---	---	--	--	---	--	-------------

					advanced practice nurses who received significant training from the researchers, which may affect its applicability into normal psychiatric care that tends to support brief and simple therapies with uncomplicated training.	
7	Ben-Zeev, et al., 2013	Research – Quasi-experimental	Patients with schizophrenia or schizoaffective disorder, 904 patients, who attend a community-based	Stage 1: Direct service staff surveyed more than half of the patients in order to explore specific mobile health (mHealth) treatment options in community settings. Questions asked included whether they owned a mobile device, their payment methods, and interest in future technological services. 63% of	The first cycle of usability testing showed that several participants had difficulty comprehending abbreviations and longer words such	Level II/A

			rehabilitation agency	<p>participants owned a mobile phone— 91% used it for talking, 31% for texting, and 13% for internet access. 58% used their mobile device daily. Many participants showed interest in receiving mHealth services through their mobile devices including reminders about taking medications or appointments (44%), regular check-ins with practitioners (38%), and psychoeducation including information about treatments and services (31%)</p> <p>Stage 2: Development of mHealth intervention that would not attract unwanted attention, would be easy to use in routines, easy to navigate, and usable regardless of access to a wireless service or data plan with a commercial carrier. A smartphone application was designed that was installed on the device itself, which could be used anytime regardless of poor reception or connection, instead of a web-based application.</p> <p>Stage 3: Usability Testing – 12 patients diagnosed with schizophrenia or schizoaffective disorder participated in 2-hour laboratory-based usability testing of the application. All 12 participants felt confident that they would be able to use the application. The majority viewed it as helpful, indicating that innovative</p>	<p>as “meds” and “transitions” or “environment.” Also, the font was small, and the buttons were close together, resulting in accidentally selecting different options or skipping screens. To prepare for the second usability testing cycle, abbreviations were removed, text amount was reduced, and words were simplified to a fourth-grade reading level, font size was increased, as were the spaces between buttons. There was also a small number of practitioners that participated.</p>	
--	--	--	-----------------------	---	--	--


				technology can assist in supporting self-management of illness, including medication adherence.		
8	Santo, Richter, Chalmers, Thiagalingam, Chow, and Redfern, 2016	Research – Systematic Review	Systematic review of medication reminder apps available in the Australian iTunes store and Google Play; 272 medication reminder apps were identified	Mobile App Rating Scale (MARS) found that Medisafe was ranked number one among the advanced app reminders – out of 10 apps regarding engagement, entertainment, interactivity, ease of operation, and ability to carry high-quality medication information with visual appeal.	Search conducted in Australian app store which may limit review results; eligibility criteria may have excluded high-quality reminder apps that may be useful for particular patient groups; researchers unable to assess and download all of the reviewed apps; at the time of the study, there was lack of evidence of app effectiveness in improving medication adherence	Level I/A
9	Shadare, Williamitis, Hanisch, and Webb, 2017	Research – Pre/Post Quasi-Experiment Approach	Adult outpatients ages 18-64 with schizophrenia/schizophrenia spectrum disorders (SSD) in Lanham, Maryland	Baseline information was taken from patients including number of hospitalizations and relapse history. Patients began using the mobile app “My Pillbox” over an eight-week period. After that period, a comparison analysis was completed to evaluate medication adherence using the mobile app reminder. The study result supported the	The study did not mention any other psychiatric disorders that the participants may have had. There was also no clear definition of the type of	Level II/B

				hypothesis of increased baseline medication adherence via mobile app reminder with a corresponding p-value of 0.00001 at a 95% confidence interval.	schizophrenia each participant had. The specific pharmacological medications were not mentioned and the study did not have a control group. Participants on oral antipsychotics were not separated from those on long-acting injectables (LAI) or both. Substance abuse, medical co-morbidities, cognitive functional level, insight into illness, and those experiencing psychotherapy were also not mentioned.	
10	Treisman, et al., 2016	Non-research – Expert Opinion	A group of patient care team members including psychiatrists, medical technology innovator, mental health advocate,	Electronic prescribing systems and drug monitoring databases can assist providers to monitor patient medication adherence. Other adherence strategies are automated voice or short message service text messages, and electronic diaries with reminder sounds.	None reported	Level IV/A

			family caregiver, health policy maker, and third-party-payor had a conference in Baltimore, Maryland to discuss the options and challenges involving eHealth technologies in psychiatry, particularly patients with Schizophrenia			
11	National Council Medical Director Institute: Medication Matters, 2018	Non-research – Expert Opinion	The [REDACTED] including an integrated group of clinicians, administrators, policymakers, innovators, researchers, advocates, educators, payers for a two-day meeting centered on in-depth review and analysis of medication	Reported that the impact of nonadherence to prescribed medications in schizophrenia results in a 75% chance of relapse and 33-70% of readmissions into hospitals. Furthermore, it can lead to homelessness, arrests, violence, and a greater risk for the patients to harm themselves due to psychotic symptoms. Considerations to nonadherence include technology to improve adherence through reminder alarms, pill implants, and compatible devices.	None reported	Level IV/A

			nonadherence, and peer specialists			
--	--	--	--	--	--	--

Appendix D - Recruitment Flyer




RUTGERS
School of Nursing

03/20/19 Version 1

Volunteers Needed for a Study

If you have Schizophrenia or Schizoaffective Disorder,
then this is just for you!
Improving Medication Adherence

- The purpose of the study is to determine whether a 4-week, 1-hour per week psychoeducation program including the use of the mobile device app, Medisafe, conducted by the principal investigator, will improve medication adherence rates compared to baseline medication adherence rates in patients diagnosed with schizophrenia or schizoaffective disorder.
- Join this study that can help you take your medications easier
- Group sessions once a week for 1 hour per week for 4 weeks with education about medications and your diagnosis & details on how to use a fun and easy cell-phone app to take your daily medications easier!
- The first group session will include an introduction and education about symptoms of schizophrenia/schizoaffective disorder. During this time, the cell-phone app will be explained, downloaded onto your phones, and education will be provided on how to use it to record your medications daily.
- We will meet for 1-hour per week for the next 3 weeks following that session, where discussion and educational videos will show information on mental illness and psychiatric medications. During these sessions, I will track your weekly adherence via percentages on your cell-phone app and answer any concerns.
- Learn more about your medications and diagnosis!
- Participate in a new and simple way to take your medications!
- Learn how to use an exciting app on your cell-phone to make taking medication easier



FOR MORE INFORMATION:

Candidates must be English-speaking men or women, at least 18 years of age, who attend the [REDACTED] partial care outpatient program, with the diagnosis of either Schizophrenia or Schizoaffective disorder and have a smartphone. Participants must be willing to attend all sessions of the study. All names and private information gathered will be held in confidence. Those who are interested can call or email the principal investigator, Meghann Alcala, at [REDACTED] or [REDACTED]. Once inclusion criteria are confirmed, candidates will be contacted via phone or email and individual informative sessions will then be scheduled in meeting rooms at [REDACTED] to discuss the purpose, benefits, and length of the program. Copies of the recruitment flyer will be given during the session, as well.

Appendix E – Participant Consent Form



RUTGERS
THE STATE UNIVERSITY
OF NEW JERSEY

School of Nursing

CONSENT TO TAKE PART IN A DNP (DOCTOR OF NURSING PRACTICE) PROJECT

TITLE OF STUDY: Improving Medication Adherence in Psychiatric Outpatients

Principal Investigator: Barbara Caldwell, PhD, APN-C

Co-Investigator: Meghann Alcalá, DNP Student

STUDY SUMMARY: This consent form is part of an informed consent process for a study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not. The purpose of the project is to: see whether a four-week, about one hour per week, psychoeducation (medication and mental health diagnosis education) program, including use of Medisafe (a medication reminder phone app) that is run by the co-investigator will improve medication adherence rates in patients diagnosed with schizophrenia or schizoaffective disorder. If you take part in the study, you will be asked to attend group psychoeducation sessions once a week for about 1 hour each week for 4 weeks, where you will learn symptoms of schizophrenia/schizoaffective disorder, the link between mental illness and stress, the main effects and side effects of antipsychotic medications, and how patients live in the community with their illness. You will also learn how to use a cell-phone application to help you to take medications at due times. Your time in the study will take 5 minutes to complete a survey before the groups begin at the program, about 1 hour per week in the groups for a total of 4 hours in 4 weeks, and then an added 5 minutes to complete a survey after the fourth group ends. We will also have a scheduled group one month later for 5-10 minutes to see if you are still using the app and find it helpful. There will be about 4 hours and 10-20 minutes of total study time.

Possible harms or burdens of taking part in the study may be that there is a small risk that your personal health information collected may be mistakenly shared by participating in this project. Your initials, ethnicity, age, gender, psychiatric medication list, and diagnosis will be collected and assigned a number, allowing the data to be seen without being directly linked to your name. Only the co-investigator and PI will have access to the list of initials and diagnoses. There is also a small risk of the medication list on your cell-phone app being hacked and security risks will be addressed by teaching you how to update your phone system, clean up apps, lock your phone, be wary of public Wi-Fi, stay away from/do not click links in unusual text messages/emails, reset a lost/stolen phone, sign out of the Medisafe account after access, and be wary of giving out your phone number. You may experience

mild discomfort from learning how to use the mobile device app if you are not used to using apps, but all concerns and questions will be addressed. You will be informed of any new findings that may affect your decision to take part in the study and possible benefits of taking part may be understanding your diagnosis better and the importance of taking medications in a timely manner; using an easy cell-phone app to take medications easier and on time; An alternative to taking part in the study. Your alternative to taking part in the study is not to take part in it.

The information in this consent form will provide more details about the DNP project and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After all of your questions have been answered and you wish to take part in the study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this DNP project?

Meghann Alcala, DNP student is the Co-Investigator of this DNP project and will conduct it. A Principal Investigator has the overall responsibility for the conduct of the study. The Principal Investigator is Barbara Caldwell, PhD, APN-C. However, there are often other individuals who are part of the team.

Meghann Alcala, DNP student may be reached at [REDACTED], [REDACTED], [REDACTED]. *Barbara Caldwell PhD, APN-C* may be reached at [REDACTED]
[REDACTED]

The co-investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Why is this study being done?

The purpose of the study is to see if psychoeducation (education about mental health diagnosis and psychiatric medications) and using a cell-phone app with alarms/reminders will help patients with schizophrenia or schizoaffective disorder to take medications easier and on time.

Who may take part in this study and who may not?

You may take part in the study if you have a diagnosis of either schizophrenia or schizoaffective disorder, have a smartphone, attend the partial care outpatient hospitalization program, have a smartphone, speak English, are at least 18 years of age or older, are prescribed psychiatric medications, and are willing to attend all sessions of the study.

Those who are 18 years or older with diagnoses of bipolar disorder, major depressive disorder, or other mental health illnesses will be excluded from the study to focus mainly on schizophrenia and schizoaffective disorder.

Why have I been asked to take part in this study?

You are being asked to take part in the study because you have the diagnosis of schizophrenia/schizoaffective disorder, meet the other requirements described above, and may benefit from learning more about psychiatric diagnosis, psychiatric medications, and a cell-phone app that may help you to take your medications easier.

How long will the study take and how many subjects will take part?

50 participants will take part in the study at the site. attend group psychoeducation sessions once a week for about 1 hour each week for 4 weeks, where they will learn symptoms of schizophrenia/schizoaffective disorder, the link between mental illness and stress, the main effects and side effects of antipsychotic medications, and how clients live in the community with their illness. You will also learn how to use a cell-phone application to help you to take medications at due times. Your time in the study will take 5 minutes to complete a survey before the groups begin at the program, about 1 hour per week in the groups for a total of 4 hours in 4 weeks, and then an added 5 minutes to complete a survey after the fourth group ends. A scheduled 5-10 -minute group one month later will take place to see if the app is considered helpful and is still being used. Approximately 4 hours and 10-20 minutes total for the study will be spent.

What will I be asked to do if I take part in this study?

1st week- 1-hour and 5-minute group psychoeducation with introductions, information about protecting cell-phones, downloading and teaching how to use Medisafe app on phones to track medication taking, and discussion of symptoms of schizophrenia/schizoaffective disorder.

2nd week – 45-minute group psychoeducation with checking weekly medication-taking reports on each patient's Medisafe app, discussion of the link between mental illness and stress. 5-minute mindfulness breathing and relaxation exercise

3rd week – 1-hour group psychoeducation with checking weekly medication-taking reports on each patient's Medisafe app, discussion of the main effects and side effects of antipsychotic medications

4th week – 45-minute group psychoeducation with checking weekly medication-taking reports on each patient's Medisafe app, discussion of how patients can live in the community with mental illness.

5-10 minute scheduled group 1 month later to see if the app has been helpful and if you are still using it.

What are the risks and/or discomforts I might experience if I take part in this study?

There is a minimal risk that your personal health information collected may be mistakenly shared by participating in this project (rare; 1 out of 5). Your initials, ethnicity, gender, age, psychiatric medication list, and diagnosis will be collected and assigned a number, allowing the data to be seen without being directly linked to your name. Only the PI and co-investigator will have access to the list of initials, ethnicity, age, gender, psychiatric medication list, and

diagnosis, which will be kept in a locked drawer. There is also a minimal risk of the medication list on your cell-phone app being hacked (rare; 1 out of 5) and security risks will be addressed by teaching you how to update your phone system, clean up apps, lock your phone, be wary of public Wi-Fi, stay away from/do not click links in unusual text messages/emails, reset a lost/stolen phone, sign out of your Medisafe app after access, and be wary of giving out your phone number. You may experience mild discomfort from learning how to use the mobile device app if you are not used to using apps (rare; 2 out of 5), but all concerns and questions will be addressed. You will be encouraged to speak with your provider if you feel any distress. You will be informed of any new findings that may affect your decision to take part in the study.

There is a less than minimal risk to dignity, rights, welfare, and privacy.

Are there any benefits to me if I choose to take part in this study?

You may not receive any direct benefit from taking part in this study, but results received from your participation may benefit others with similar conditions in the future.

What are my alternatives if I do not want to take part in this study?

There are no alternative treatments available. Your alternative is not to take part in this study.

How will I know if new information is learned that may affect whether I am willing to stay in the study?

During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will I receive the results of the study?

In general, we will not give you any individual results from the study.

Will there be any cost to me to take part in this study?

There will be no costs for you to participate in the study.

Will I be paid to take part in this study?

You will not be paid to take part in this study.

How will information about me be kept private or confidential?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

Identifying codes and research materials will be kept in a locked file drawer and will only be accessible by the PI and co-investigator. Only information on pre- and post-test surveys and percentages reported from mobile device app will be identifiers and in no way attached to any personal information. Upon completion of the study, all surveys and percentage reports held by the co-investigator will be destroyed according to Rutgers University guidelines.

What will happen to my information or biospecimens collected for this research after the study is over?

The information collected about you for this study will not be used by or distributed to investigators for other studies.

For research on subjects with a disease or medical condition:

Subjects in this study will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which include: Please refer to study summary. In addition, it is possible that during the course of this study, new adverse effects of education and using mobile phone app that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?

It is your choice whether to take part in the study. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.

If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

Study participants can change their minds about participating, refuse to answer any questions asked during psychoeducation groups or any other part of the study, and choose to opt out of the study at any given time without affecting their treatment received at the facility.

In addition, participants can uninstall the Medisafe app from their cell-phones at any time and refrain from using the service without any penalty.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Meghann Alcala DNP student, 65 Bergen Street, Newark, NJ 07103

If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

Who can I call if I have questions?

If you have questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor: Meghann Alcala, DNP student, [REDACTED]

If you have questions about your rights as a study subject, you can call the IRB Director at:

Newark HealthSci (973)-972-3608 or the Rutgers Human Subjects Protection Program at (973) 972-1149.

PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A DNP PROJECT

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What is the purpose of the study and how will my information be used?

You are being invited to take part in this study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research.

What information about me will be used?

- **Surveys or Questionnaires**
- **Ethnicity, Gender, Age, Diagnosis for descriptive information. Psychiatric medications to input into mobile device app. Patients' medication lists will also be evaluated and discussed in the final project (without using any patient identifiers since medication lists will have an assigned number) if any patient is hospitalized during the 1-month study.**
- **Weekly medication-adherence report percentages (numbers) on cell-phone app**

Who may use, share or receive my information?

The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University investigators involved in the study;
- University Hospital or Robert Wood University Hospital personnel to communicate information necessary for health care operations;
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my research record while the research is ongoing?

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the PI or co-investigator, who are in charge of this research study.

Do I have to give my permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say yes now, can I change my mind and take away my permission later?

Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell him or her of your decision: (Meghann Alcala DNP Student, 65 Bergen Street, Newark, NJ, 07103)

How long will my permission last?

Your permission for the use and sharing of your health information will last until the end of the DNP project.

AGREEMENT TO PARTICIPATE

1. Subject consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name: _____

Subject Signature: _____ Date: _____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (printed name): _____

Signature: _____ Date: _____

Appendix F - Budget

<i>Expense</i>	<i>Cost</i>	<i>Total Cost</i>
Recruitment flyers	20 at \$0.00	0.00
Statistician Consultant	\$0.00 x 1 hour	0.00
Dissemination Posters	\$75	75.00
TOTAL BUDGET		75.00

Appendix G – Medication Adherence Rating Scale

Medication Adherence Rating Scale (MARS)

Using the MARS tool, you and your patient can determine willingness and ability to take on medication every day.

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

Results

Appendix H - Educational Materials

Week 1 – A discussion of symptoms of schizophrenia and schizoaffective disorders will be reviewed with information taken from NAMI (2019) <https://www.nami.org/Learn-More/Mental-Health-Conditions/Schizophrenia>.

A YouTube video will be shown regarding symptoms of schizophrenia from the Schizophrenia Society of Alberta (SSA) https://www.youtube.com/watch?time_continue=398&v=fGaj2l_mVVk.

Week 2 - A discussion on the link between mental illness and stress (including ways to reduce stress) will take place with information from the NAMI website. <https://www.nami.org/Find-Support/Living-with-a-Mental-Health-Condition/Managing-Stress>

A 5-minute mindfulness breathing and relaxation exercise will be led by the co-investigator with information from Foundation for a Mindful Society (2019) <https://www.mindful.org/a-five-minute-breathing-meditation/>.

Week 3 - A discussion regarding the main effects and side effects of the top three antipsychotic medications that the participants are using will take place with information provided by NAMI <https://www.nami.org/Learn-More/Treatment/Mental-Health-Medications/Types-of-Medication>

An educational video from NAMI Austin will be provided with information about how psychiatric medications work: <https://www.youtube.com/watch?v=hwuiE6-17AA>.

Week 4 - Information from NAMI will be provided regarding community resources for individuals with mental illness. <https://www.nami.org/Get-Involved/NAMI-FaithNet/Resources>
<http://www.naminj.org/programs/nami-connection/>

Appendix I - How To Use the Medisafe Cell-Phone App

- Click on Medisafe icon on your smartphone
- You will immediately see the day of the week and the medication(s) you are taking that day along with the times that they need to be taken.
- When it is time to take your medication, there will be an alarm and a pop-up (push notification) on your cell-phone screen telling you that it is time to take your medication, along with which medication(s) you will need to take.
- When you click on the pop-up, you will see the medication(s) and 3 buttons (“skip”, “take,” or “reschedule.”)
- Once you take your medication(s), you will click on the “Take” button.
- You will see a green checkmark next to the medication(s) that you took and the time that the medication(s) were taken.

- If you do not click on the pop-up when it is time to take your medication(s), there will be two more pop-ups (reminders) telling you to take your medication(s).
- If you took your medication(s) during the day, but forgot to use the app, you can write a check mark next to which medication(s) you took on the index card where your medications are written.

Appendix J - Weekly Medication Adherence Log

Please write a check mark next to the medications that you took this week after you take them.

	Sun	Mon	Tues	Wed	Thurs	Fri	Sat
8 AM	<ul style="list-style-type: none"> • Med 1 • Med 2 • Med 3 	<ul style="list-style-type: none"> • Med 1 • Med 2 • Med 3 	<ul style="list-style-type: none"> • Med 1 • Med 2 • Med 3 	<ul style="list-style-type: none"> • Med 1 • Med 2 • Med 3 	<ul style="list-style-type: none"> • Med 1 • Med 2 • Med 3 	<ul style="list-style-type: none"> • Med 1 • Med 2 • Med 3 	<ul style="list-style-type: none"> • Med 1 • Med 2 • Med 3
2 PM	<ul style="list-style-type: none"> • Med 1 	<ul style="list-style-type: none"> • Med 1 	<ul style="list-style-type: none"> • Med 1 	<ul style="list-style-type: none"> • Med 1 	<ul style="list-style-type: none"> • Med 1 	<ul style="list-style-type: none"> • Med 1 	<ul style="list-style-type: none"> • Med 1
8 PM	<ul style="list-style-type: none"> • Med 1 • Med 2 • Med 3 	<ul style="list-style-type: none"> • Med 1 • Med 2 • Med 3 	<ul style="list-style-type: none"> • Med 1 • Med 2 • Med 3 	<ul style="list-style-type: none"> • Med1 • Med 2 • Med 3 	<ul style="list-style-type: none"> • Med 1 • Med 2 • Med 3 	<ul style="list-style-type: none"> • Med 1 • Med 2 • Med 3 	<ul style="list-style-type: none"> • Med 1 • Med 2 • Med 3

Appendix K - Mobile Device App Satisfaction

1. Do you like the design of the app?
2. Is the app easy to use?
3. Is the app helping you with your goals? (to take your medications on time?)
4. Would you recommend the app to your friends?
5. How would you rate the app from 1-5 (1 being that it is not useful and 5 being that it is useful)

(Survicate, 2019)

Appendix L - Common Psychotropic Medication Side Effects and Ways to Deal

Side Effects	Ways to Deal with Side Effects
Weight gain (increased risk for high blood sugar and high cholesterol level)	Exercise such as walking, lessening intake of fatty foods, eating healthy snacks
Sleep problems (trouble falling sleeping or sleeping too much)	Controlling noise and lights, relaxation exercises (deep breathing or meditation), sleeping at a reasonable hour to lessen drowsiness during the day
Risk for Infections	Get seasonal vaccines, wash hands frequently, dress warmly during cold weather
Dry mouth, constipation, drowsiness, dizziness, blurred vision	Increase fluid intake, do not drive or operate machinery if feeling drowsy or if having blurred vision, sit up slowly from lying position, stand up slowly from sitting position

(NIMH-b, n.d.)

Please let your provider know about your side effects.

Appendix M - Community Resources in New Jersey – Peer Support Groups**Atlantic County**

2nd Mondays of each month, 7:00 – 8:30 pm

**Bergen County**

2nd Monday of each month, 7:30 pm

**Burlington County**

1st and 3rd Mondays of each month, 7:00 – 8:30 pm

**Camden County**

2nd and 4th Wednesdays of each month, 2:00 – 3:00 pm

**Cumberland County**

3rd Monday of each month, 7:00 – 9:00 pm



Essex County

2nd Monday of each month, 6:00 – 7:30 pm



Gloucester County

Every Wednesday, 6:30 – 8:00 pm



Hudson County

2nd Tuesday of each month, except in August, 7:00 – 8:30 pm



Mercer County

1st & 3rd Wednesdays, 2 – 3:30 pm

2nd & 4th Thursdays, 7 – 8:30 pm



[REDACTED]

[REDACTED]

Middlesex County

1st and 3rd Fridays of each month, 3:45 – 4:45 pm

[REDACTED]

[REDACTED]

[REDACTED]

Monmouth County

2nd and 4th Mondays of each month, 7:15 – 8:45 pm (no meeting 12/25)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

3rd Friday of each month, 1:00 – 2:00 pm

[REDACTED]

[REDACTED]

[REDACTED]

Morris County

3rd Sunday of each month, 4:00 – 5:30 pm

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Ocean County

Speaker meeting, followed by peer and family support circles

2nd Wednesday of each month, 6:30 – 9:00 pm

[REDACTED]

Salem County

1st Wednesday of each month, 7:00 – 9:00 pm

[REDACTED]

Somerset County

1st Thursday of each month, 7:00 – 8:30 pm (Starting November 1, 2018)

[REDACTED]

Sussex County

2nd and 4th Monday of each month, 7:00 – 8:30 pm

[REDACTED]

PTS Connection

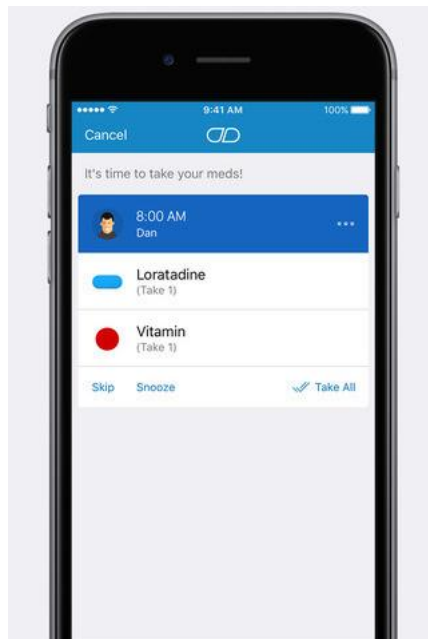
For veterans, police, and first responders recovering from post-traumatic stress (PTS) as a result of their service

4th Tuesday, 7:00 – 8:30 pm

[REDACTED]

Warren County

1st Saturday of every month, Starting September 2, 2017, 11:30 am – 1:00 pm

**Appendix N - Medisafe App**

(Reuter, 2016)

Appendix O - Clinical Global Impressions (CGI) Tool

* Reproduced from Guy, 1976.

Appendix P – Provider Consent Form

RUTGERS
THE STATE UNIVERSITY
OF NEW JERSEY

School of Nursing

CONSENT TO TAKE PART IN A DOCTOR OF NURSING PRACTICE (DNP) PROJECT

TITLE OF STUDY: Improving Medication Adherence in Psychiatric Outpatients

Principal Investigator: Barbara Caldwell, PhD, APN-C

Co-Investigator: Meghann Alcalá, DNP Student

STUDY SUMMARY: This consent form is part of an informed consent process for a study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not. The purpose of the project is to: see whether a four-week, one hour per week, psychoeducation (medication and mental health diagnosis education) program, including use of Medisafe (a medication reminder phone app) that is run by the co-investigator will improve medication adherence rates in patients diagnosed with schizophrenia or schizoaffective disorder. If you take part in the study, you will be asked to complete the Clinical Global Impression (CGI) 3-item scale regarding the 50 study participants before and after the psychoeducation groups take place. Your time in the study will about 2 hours and 14 minutes total; 1 hour and 7 minutes to complete surveys before the psychoeducation program and 1 hour and 7 minutes to complete surveys after the psychoeducation program. Possible harms or burdens of taking part in the study may be study burden and interruption of workflow. There are no immediate, potential, or long-term physical, psychological, social, financial, or reproductive risks with participation in this project. Possible benefits are contributing to assessing whether psychoeducation and use of a mobile device app will improve baseline medication adherence in patients with schizophrenia or schizoaffective disorders. Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After all of your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this DNP project?

Meghann Alcala, DNP student is the Co-Investigator of this DNP project and will conduct it. A Principal Investigator has the overall responsibility for the conduct of the study. The Principal Investigator is Barbara Caldwell, PhD, APN-C. However, there are often other individuals who are part of the team.

Meghann Alcala, DNP student may be reached at [REDACTED]
[REDACTED]. Barbara Caldwell PhD, APN-C may be reached at [REDACTED]
[REDACTED]

The co-investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Why is this study being done?

The purpose of the study is to see if psychoeducation (education about mental health diagnosis and psychiatric medications) and using a cell-phone app with alarms/reminders will help patients with schizophrenia or schizoaffective disorder to take medications easier and on time.

Who may take part in this study and who may not?

Participants may take part in the study if you have a diagnosis of either schizophrenia or schizoaffective disorder, have a smartphone, attend the partial care outpatient hospitalization program, have a smartphone, speak English, are at least 18 years of age or older, are prescribed psychiatric medications, and are willing to attend all sessions of the study.

Those who are 18 years or older with diagnoses of bipolar disorder, major depressive disorder, or other mental health illnesses will be excluded from the study to focus mainly on schizophrenia and schizoaffective disorder.

Why have I been asked to take part in this study?

You are being asked to take part in the study because you are the clinician for all participants and are able to assess (by using the CGI) whether there is an improvement in clients' symptoms after the psychoeducation program takes place.

How long will the study take and how many subjects will take part?

50 participants will take part in the study at the site. attend group psychoeducation sessions once a week for about 1 hour each week for 4 weeks, where they will learn symptoms of schizophrenia/schizoaffective disorder, the link between mental illness and stress, the main effects and side effects of antipsychotic medications, and how clients live in the community with their illness. They will also learn how to use a cell-phone application to help participants to take medications at due times. The participants will participate 1 hour per week in the groups for a total of 4 hours in 4 weeks, and then an added 5 minutes to complete a survey before the groups and 5 minutes to complete the same survey after the fourth group ends. A scheduled 5-10 -minute group one month later will take place to see if the app is considered helpful and is still being used. Approximately 4 hours and 10-20 minutes total for the study participants will be spent.

What will I be asked to do if I take part in this study?

You will be asked to complete the 3-item CGI tool (for each participant) before the program and then again after the program

What are the risks and/or discomforts I might experience if I take part in this study?

Minimal risks may include study burden and interruption of workflow.

In this study, there are no immediate, potential or long-term physical, psychological, social, financial, or reproductive risks. Your personal information and identifiers will not be collected in this study.

You will be made aware of the allotted time needed to complete the surveys beforehand, giving you a option to opt out.

Are there any benefits to me if I choose to take part in this study?

The benefits of taking part in this study are contributing to assessing whether psychoeducation and use of a cell-phone app will improve baseline medication adherence in patients with schizophrenia or schizoaffective disorders. Your patients' medication adherence and functioning may improve at the end of the study. However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?

There are no alternative treatments available. Your alternative is not to take part in this study.

How will I know if new information is learned that may affect whether I am willing to stay in the study?

During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will I receive the results of the research?

In general, we will not give you any individual results from the study.

Will there be any cost to me to take part in this study?

There will be no cost for you to participate in the study.

Will I be paid to take part in this study?

You will not be paid to take part in this study.

How will information about me be kept private or confidential?

Your information will not be collected.

The surveys that you complete will not have your name and no personal information about you will be collected. The surveys that you complete regarding the participants will be assigned a number so as not to be linked with any participant identifiers. Only the co-investigator and PI will have access to the locked drawer with the information that links the assigned numbers to

participants' names. Upon completion of the study, all surveys held by the co-investigator will be destroyed according to Rutgers University guidelines.

What will happen to my information or biospecimens collected for this research after the study is over?

Your information will not be collected.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?

It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.

If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing Meghann Alcala DNP student, 65 Bergen Street, Newark, NJ 07103

If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

Who can I call if I have questions?

If you have questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor: Meghann Alcala, DNP student, [REDACTED]

If you have questions about your rights as a study subject, you can call the IRB Director at:

Newark HealthSci (973)-972-3608 or the Rutgers Human Subjects Protection Program at (973) 972-1149.

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

AGREEMENT TO PARTICIPATE

1. Subject consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name: _____

Subject Signature: _____ Date: _____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (printed name): _____

Signature: _____ Date: _____

Appendix Q - Schedule for Psychoeducation Group

Week 1 (date) (time)	Week 2 (date) (time)	Week 3 (date) (time)	Week 4 (date) (time)
Approximately 1 hour	Approximately 1 hour	Approximately 1 hour	Approximately 1 hour
Room #	Room #	Room #	Room #

Schedule for 5-10 Minute Group 1 Month Later

Date & Time (5-10 Minutes)
Room #

Appendix R – Participant Demographics, Surveys, and Code Book

ID	Gender	Age	Race/Ethnicity	Education Level	Diagnosis	Employment
1						
2						
3						
4						
5						
6						
7						
8						
9						

DNP Project Excel Code Book

Variable	SPSS Variable name	Coding Instructions
----------	--------------------	---------------------

Identification number	ID	Number assigned to each survey
Gender	Gender	1= Males 2= Females
Race/Ethnicity	Race	1 = Caucasian 2 = Hispanic 3 = African American 4 = Other
Age	Age	Age in years
Education Level	Education	1 = High School 2 = College 3 = Other
Diagnosis	Diagnosis	1= Schizophrenia 2= Schizoaffective Disorder
Employment	Work	1 = Employed 2 = Unemployed
Psychiatric Medication Log – Week 1	ML_1	Medication Names
Psychiatric Medication Log – Week 2	ML_2	Medication Names
Psychiatric Medication Log – Week 3	ML_3	Medication Names
Psychiatric Medication Log – Week 4	ML_4	Medication Names
Medication Reason for Non-adherence	ML_R	1 = Weight Gain 2 = Fatigue/Tiredness 3 = Sexual Side Effects 4 = Extrapyrimalal Side Effects 5 = Other (Comment
Medication Date	Date	Date of medication taken/refused
CGI Scale - Question 1 –Pre-intervention	CGI_Q1	1 = Normal not at all 2 = Borderline mentally ill 3 = Mildly ill 4 = Moderately ill 5 = Markedly ill 6 = Severely ill 7 = Among the most extremely ill patients
CGI Scale – Question 2 – Pre-intervention	CGI_Q2	1 = Very much improved 2 = Much improved 3 = Minimally improved 4 = No change 5 = Minimally worse 6 = Much worse

		7 = Very much worse
CGI Scale – Question 1 – Post-intervention	CGI_Q1-P	1 = Normal not at all 2 = Borderline mentally ill 3 = Mildly ill 4 = Moderately ill 5 = Markedly ill 6 = Severely ill 7 = Among the most extremely ill patients
CGI Scale- Question 2 – Post-intervention	CGI_Q2-P	1 = Very much improved 2 = Much improved 3 = Minimally improved 4 = No change 5 = Minimally worse 6 = Much worse 7 = Very much worse
Weekly Medisafe Report – Week 1	WA_1	Adherence percentage
Weekly Medisafe Report – Week 2	WA_2	Adherence percentage
Weekly Medisafe Report – Week 3	WA_3	Adherence percentage
Weekly Medisafe Report- Week 4	WA_4	Adherence percentage
Medication Adherence Rating Scale – Question 1	MARS_Q1	1 = Yes 2 = No
Medication Adherence Rating Scale – Question 2	MARS-Q2	1= Yes 2 = No
Medication Adherence Rating Scale – Question 3	MARS_Q3	1 = Yes 2 = No
Medication Adherence Rating Scale – Question 4	MARS_Q4	1 = Yes 2 = No
Medication Adherence Rating Scale – Question 5	MARS_Q5	1 = Yes 2 = No
Medication Adherence Rating Scale – Question 6	MARS_Q6	1 = Yes 2 = No
Medication Adherence Rating Scale – Question 7	MARS_Q7	1 = Yes 2 = No
Medication Adherence Rating Scale – Question 8	MARS_Q8	1 = Yes 2 = No
Medication Adherence Rating Scale – Question 9	MARS_Q9	1 = Yes 2 = No
Medication Adherence Rating Scale – Question 10	MARS_ Q10	1= Yes 2 = No

Medication Adherence Rating Scale 2 – Question 1	MARS_2_Q1	1 = Yes 2 = No
Medication Adherence Rating Scale 2– Question 2	MARS_2-Q2	1= Yes 2 = No
Medication Adherence Rating Scale 2 – Question 3	MARS_2_Q3	1 = Yes 2 = No
Medication Adherence Rating Scale 2– Question 4	MARS_2_Q4	1 = Yes 2 = No
Medication Adherence Rating Scale 2 – Question 5	MARS_2_Q5	1 = Yes 2 = No
Medication Adherence Rating Scale 2– Question 6	MARS_2_Q6	1 = Yes 2 = No
Medication Adherence Rating Scale 2– Question 7	MARS_2_Q7	1 = Yes 2 = No
Medication Adherence Rating Scale 2– Question 8	MARS_2_Q8	1 = Yes 2 = No
Medication Adherence Rating Scale 2– Question 9	MARS_2_Q9	1 = Yes 2 = No
Medication Adherence Rating Scale 2– Question 10	MARS_2_Q10	1= Yes 2 = No
Medication Adherence Rating Scale 3 – Question 1	MARS_3_Q1	1 = Yes 2 = No
Medication Adherence Rating Scale 3– Question 2	MARS_3-Q2	1= Yes 2 = No
Medication Adherence Rating Scale 3 – Question 3	MARS_3_Q3	1 = Yes 2 = No
Medication Adherence Rating Scale 3– Question 4	MARS_3_Q4	1 = Yes 2 = No
Medication Adherence Rating Scale 3 – Question 5	MARS_3_Q5	1 = Yes 2 = No
Medication Adherence Rating Scale 3– Question 6	MARS_3_Q6	1 = Yes 2 = No
Medication Adherence Rating Scale 3– Question 7	MARS_3_Q7	1 = Yes 2 = No
Medication Adherence Rating Scale 3– Question 8	MARS_3_Q8	1 = Yes 2 = No
Medication Adherence Rating Scale 3– Question 9	MARS_3_Q9	1 = Yes 2 = No
Medication Adherence Rating Scale 3– Question 10	MARS_3_Q10	1= Yes 2 = No
Mobile Device App Satisfaction – Question 1	MDA_Q1	1 = Yes 2 = No
Mobile Device App Satisfaction – Question 2	MDA_Q2	1 = Yes 2 = No

Mobile Device App Satisfaction – Question 3	MDA_Q2	1 = Yes 2 = No
Mobile Device App Satisfaction – Question 4	MDA_Q4	1 = Yes 2 = No
Mobile Device App Satisfaction – Question 5	MDA_Q5	1 = Not Useful 2 = Somewhat Useful 3 = A Little Useful 4 = Useful 5 = Very Useful
Mobile Device App Satisfaction 2– Question 1	MDA_2_Q1	1 = Yes 2 = No
Mobile Device App Satisfaction 2– Question 2	MDA_2_Q2	1 = Yes 2 = No
Mobile Device App Satisfaction 2– Question 3	MDA_2_Q2	1 = Yes 2 = No
Mobile Device App Satisfaction 2– Question 4	MDA_2_Q4	1 = Yes 2 = No
Mobile Device App Satisfaction 2– Question 5	MDA_2_Q5	1 = Not Useful 2 = Somewhat Useful 3 = A Little Useful 4 = Useful 5 = Very Useful