CALIFORNIA STATE UNIVERSITY SAN MARCOS

PROJECT SIGNATURE PAGE

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OF THE REQUIREMENTS FOR THE DEGREE

MASTER OF SCIENCE

IN

NURSING

PROJECT TITLE: Preventative Approach to Weight Gain in Patients with Schizophrenia Who Are Taking Olanzapine

AUTHOR: Dominic D. Lomibao, BSN, RN

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THE PROJECT HAS BEEN ACCEPTED BY THE PROJECT COMMITTEE IN PARTIAL FULLFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF SCIENCE IN NURSING.

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PROJECT COMMITTEE CHAIR	SIGNATURE	DATE
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PROJECT COMMITTEE MEMBER	SIGNATURE	DATE

PREVENTATIVE APPROACH TO WEIGHT GAIN IN PATIENTS WITH SCHIZOPHRENIA WHO ARE TAKING OLANZAPINE

A Research Grant Proposal

Presented to the faculty of the School of Nursing

California State University, San Marcos

Submitted in partial satisfaction of
the requirements for the degree of

MASTER OF SCIENCE

in

Nursing

Family Nurse Practitioner

by

Dominic D. Lomibao, BSN, RN

SPRING
2019

ABSTRACT

of

PREVENTATIVE APPROACH TO WEIGHT GAIN IN PATIENTS WITH SCHIZOPHRENIA WHO ARE TAKING OLANZAPINE

by

Dominic D. Lomibao

Obesity is a health problem that is concerning worldwide because it is associated with many diseases such as hypertension, dyslipidemias, type 2 diabetes, heart diseases, stroke, sleep apnea, metabolic syndrome, cancer, and respiratory problems. People with schizophrenia are at a higher risk for being obese because of their long term use of antipsychotic medications. Olanzapine is commonly used second-generation antipsychotic medication that causes more weight gain than any other antipsychotic medications. Intervention to alleviate this problem is imperative to increase medication compliance, reduce relapse, and improve quality of life of people not only with schizophrenia but with mental illness. The intention of this grant proposal is to examine whether a structured diet, routine exercise regimen, and education are effective interventions in patients with schizophrenia to manage their weight while taking Olanzapine. The findings of this research study will hopefully be an assistance to mental health providers to initiate a plan that is effective in managing weight when prescribing antipsychotic medications.

DEDICATION

I dedicate this work to my mother who has always encouraged and supported me throughout my journey in nursing, and who has always believed in me. I also dedicate this work to Mel, my partner in life, who has always been patient and supportive in following my dreams.

ACKNOWLEDGEMENTS

The past three years has been the most challenging time of my life. I would not have done it alone. I am extremely grateful to have such wonderful friends and family. Thank you to my mother, partner, brothers, sister- in-law, my niece, and my friends for being so encouraging and supportive in achieving my goals. To my classmates, especially Phoebe, I would have not done it without their support and encouragement. Thank you for making this journey an enjoyable experience. To Dr. Nancy Romig, no words can describe how much I appreciate your patience, time, and guidance. Thank you so much.

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Chapter One: Introduction

Obesity is recognized as a public health problem worldwide (Landau et al., 2015). According to Centers Disease Control and Prevention (CDC) (2017), obesity is associated with many diseases such as hypertension, dyslipidemias, type 2 diabetes, heart diseases, stroke, sleep apnea, metabolic syndrome, respiratory problems, gallbladder disease, osteoarthritis, and certain types of cancer (CDC, 2017). Unfortunately, patients who are suffering from mental illness have greater risk of being obese since one of the most common side effect of antipsychotic medications is weight gain (Arthur, 2001).

Background and Significance

Excessive weight gain is seen in patients who are taking antipsychotic medications, which include aripiprazole, clozaril, olanzapine and ziprasidone (Ma et al., 2014). Patients who are diagnosed with schizophrenia and bipolar disorder are at a higher risk for obesity because of the prolonged use of antipsychotic medications (Ma et al., 2014). According to Parsons et al. (2009), the risk of obesity gets higher in patients who are mentally ill when the use antipsychotic medications is longer. Since the prevalence of obesity continues to rise in patients with mental illness, interventions to prevent weight gain in patients who are taking antipsychotics are imperative to alleviate problems associated with obesity.

The Problem

Schizophrenia is a mental disorder that affects more than 25 million people worldwide (WHO, 2005). While the causes of schizophrenia are assumed to be genetic, biochemical, stress, and neuroanatomical abnormalities, the exact causes are yet unknown (Dunphy, Winland-Brown, Brian, & Thomas, 2015). Symptoms of schizophrenia may include hallucinations, delusions, and thought disorder that can lead to social and occupational difficulties which can negatively impact

their lives (Dunphy, Winland-Brown, Brian, & Thomas, 2015). Although there is no cure for schizophrenia, the most common and recommended treatment for symptoms of schizophrenia are second-generation antipsychotics (SGAs) such as olanzapine (Lambert, 2009). However, SGAs cause more weight gain than first-generation antipsychotics (FGAs), and based on different studies, olanzapine evidently causes more weight gain than the other SGAs (Maayan & Correll, 2010). A study of newly diagnosed patients with schizophrenia who are taking olanzapine showed a weight gain of an average of 13.9 kg in one year (Maayan & Correll, 2010). Furthermore, a 12-week study from the Second-Generation Antipsychotic Treatment Indications, Effectiveness and Tolerability (SATIETY) revealed increased in glucose and triglyceride while taking olanzapine (Maayan & Correll, 2010).

Obesity is a public health problem that has been correlated with mortality and increased comorbidity of other physical disorders (Sharpe & Hills, 2003). Since being obese also causes psychological problems as well as medical problems, such as depression and low self-esteem, patients who are taking antipsychotic medications may stop taking medications due to weight gain (Sharpe & Hills, 2003). Thus, this interventional study will focus on weight management in patients with schizophrenia who are taking Olanzapine.

The Purpose of Research

The purpose of this project is to implement interventions to prevent obesity and assist patients who are challenged with schizophrenia manage their weight while taking olanzapine. Many researchers have identified that there is a problem of weight gain among patients who are taking olanzapine, but few recent literatures have been found regarding intervention to manage their weight gain. An investigation of a weight management program and implementing these interventions to patients who are taking olanzapine to manage their symptoms of schizophrenia

may alleviate this problem. Understanding weight management from different studies will assist in this project to implement effective ways to manage weight gain in patients with schizophrenia who are taking olanzapine.

Implications for Nursing Practice/Policy/Research

Since there are many diseases associated with obesity and patients who are mentally ill are at a higher risk than the general population, reducing weight gain can help healthcare providers alleviate diseases associated with obesity. According to Littrell, Hilligoss, Kirshner, Petty, and Johnson (2003), diet, exercise, and educational intervention to manage weight gain with mentally ill patients have resulted in positive outcomes. This will also increase medication compliance and having to avoid relapse from their mental illness. Furthermore, managing weight gain will improve quality of life among patients who are challenged with mental illness.

Hypothesis

The applicable null hypothesis for this research is, "Education, diet and exercise will not be effective in managing weight gain in patients with schizophrenia who are taking olanzapine." The alternative hypothesis is, "Education, diet and exercise will be effective in managing weight in patients with schizophrenia who are taking olanzapine."

Providing education, diet program, and exercise program to the chosen population is hypothesized to be effective to manage weight in a four-month period.

Research Question

"Does a program of education, diet and exercise change weight among patients diagnosed with schizophrenia who are taking Olanzapine?"

Research Variables

The dependent variable for this project is weight. Participants' weight will be obtained in the start of the study and will be checked monthly to monitor the effectiveness of the interventions. The independent variables are education, diet, and exercise. Research show that the efficacy of these interventions have made positive impact in managing weight. The desired outcome is no weight gain at the end of the 4-month program. Research in the area of effectiveness in managing weight gain will be reviewed.

Chapter Two: Review of the Literature

Literature Search

While performing the literature search on weight management associated with olanzapine and weight gain prevention program, keywords and phrases used were: “weight gain”, “weight management”, “weight changes”, “antipsychotic medications”, “weight gain prevention”, “weight prevention program”, “olanzapine”, and “obesity”. The databases utilized to acquire pertinent research articles for the research were CNAHL Plus, PubMed, Cochrane Database, and Google Scholar CSUSM, and dated between 2001- 2017. This literature review focused on interventions implemented which effectively manage weight in patients with schizophrenia.

Major Variables

The major variables identified in this project are: the dependent variable is weight, and the independent variables are education, diet, and exercise.

Structured diet program to manage antipsychotic-induced weight in patients with schizophrenia. This study reviewed was focused on the effectiveness of structured diet program to manage antipsychotic-induced weight in patients with schizophrenia who are taking different antipsychotics. Direk and Ucok (2008) conducted a prospective study to evaluate 32 participants with schizophrenia in a 3-month diet program to manage weight gain while taking antipsychotics. At the beginning of the study, participants filled out a form regarding their current eating habits. In addition, lipid panel and fasting blood glucose, as well as weight and body mass index were obtained. The researchers collaborated with a registered dietician to produce an effective diet plan. The dietician was involved during interviews to be more familiar with the population and reviewed weekly goals to make sure that their goals were achieved each week. Weights were measured on a weekly basis. Motivational interview was done each visit to

encourage healthy eating habits. Participants were also encouraged to walk at least 45 minutes daily. Findings showed that the diet program was effective in managing weight gain in patients with schizophrenia who are taking antipsychotic medications. At the end of the program, participants who participated in the program for three months lost an average of 6.19 kg and the participants who stayed longer in the program lost more weight than those who did not stay. However, patients in the control group gained an average of 1.6 kg. This study showed that a structured diet is effective in managing weight in patients taking antipsychotic medications. Therefore, a structured diet program with assistance of registered dietician should be considered in this project to create an intervention that is successful in managing weight in schizophrenic patients who are taking olanzapine.

Effects of education for weight management. Litrell, et al. (2003) conducted a quasi-experimental study to examine the effectiveness of educational intervention to manage weight gain in patients with schizophrenia who are taking antipsychotic medications. All participants were diagnosed with schizophrenia according to DSM IV and just began taking olanzapine. The 70 participants were divided in to two groups and were randomly assigned to an interventional group or a standard care group for six months. The interventional group must attend weekly classes which included 1-hour psychoeducational class for 16 weeks using the "Solutions for Wellness" modules that was developed specifically for people with schizophrenia. Participants weight and BMI were obtained at baseline, four months and six months. Although participants who were assigned to the interventional group had very little change in weight at the end of the six-month program, participants in the standard care group gained an average of 9.57 pounds. Litrell, et al. concluded that educational interventions have positive outcome in managing weight with schizophrenic patients who are taking antipsychotic medications. Litrell, et. al. suggested

that when developing an educational intervention, sex and race should be considered in order to develop an effective intervention to the target population.

Effects of exercise in mentally ill patients. Weber (2010) conducted a systematic review to study the effects of exercise in patients who are mentally ill. She also studied the consequences of obesity and researched interventions to prevent weight gain. Weber reviewed articles published between 1998 and 2010 to examine interventions that was effective in managing weight in the nursing practice. In her review of findings, one of the study was conducted by Beebe et al. (2005) to examine the effects of exercise in patients with schizophrenia. It was a pilot study of 16 weeks examined the effects of walking in patients with schizophrenia. It was the first nursing research to study the effects of exercise in mentally ill patients and it revealed that walking is an effective way to reduce body fat and it also demonstrated that those who participated had less psychiatric symptoms. In addition, studies from other researchers revealed that exercise also improves symptoms of depression due to increased levels of brain-derived neurotrophic factors. Not only does exercise improve mood over time, it also has a positive effect on physical symptoms such as feeling of less fatigued. Weber reported that although exercise combined with diet resulted in positive outcomes to manage weight, there are not many research conducted on weight management in patients with mental illness and further research is needed. As recommended by Haskell et al. (2007), this study will implement the intervention that is recommended by the American College of Sports Medicine and the American Heart Association to manage weight, which is at least 30 minutes of moderate-intensity aerobic activity five days per week or vigorous-intensity aerobic activity at least 20 minutes three times per week, for better outcome in managing weight in patients with mental illness.

Theoretical Framework

The theoretical framework that will guide this study to improve the patients' health is the Pender Health Promotion Model (HPM), which was developed by Nola Pender in 1982. Pender developed this framework to investigate health promoting behaviors, and effective intervention. The HPM's purpose is to guide nurses assist their patients improve their health, functional ability, and improve quality of life (Peterson & Bredow, 2013).

HPM is based on two theories of human behaviors. The expectancy-value theory is the first theory that Pender based the HPM in that people are more likely to achieve goals if the goals are: achievable, have values to them, and have outcomes that are desirable to them (Peterson & Bredow, 2013). The other theory that Pender based the HPM on is the social-cognitive theory, which is a theory of self-efficacy. This theory is based on the person's confidence to achieve a goal (Peterson & Bredow, 2013). Pender believed that a person is more likely to successfully achieve a goal if he or she is competent of certain behaviors (Peterson & Bredow, 2013).

The HPM consists of three major categories. The two categories are predictors, which are individual characteristics and experiences, and behavior-specific cognitions and affect. The third category is the behavioral outcome. In the Health Promotional Model, the first category is the individual characteristics and experiences and it consists of two parts; the prior related behavior and the personal factors. The second category is the behavior-specific cognition and affect, which is the major motivational mechanism. The parts included in this category are: perceived benefits of action, perceived barriers to action, perceived self-efficacy, activity-related affect, interpersonal influences, and situational influences. The third category consists of two concepts; the intermediate competing demands and preferences and commitment to plan of action. This theoretical framework will assist this researcher to develop an effective intervention

to manage weight in patient who is taking olanzapine by changing unhealthy behaviors and improving their lifestyles. To apply HPM in this study, interventions will be tailored to patients who have diagnosis of schizophrenia and are taking olanzapine, set goals that are achievable by individuals with schizophrenia, identify barriers from achieving these goals, and identify support systems. The HPM is employed by many nurses to provide and guide effective ways of managing chronic illnesses; therefore, this model will be utilized in this study to help guide the researcher in creating interventions to assist patients with schizophrenia to manage weight gain who are taking Olanzapine.

Health Promotion Model

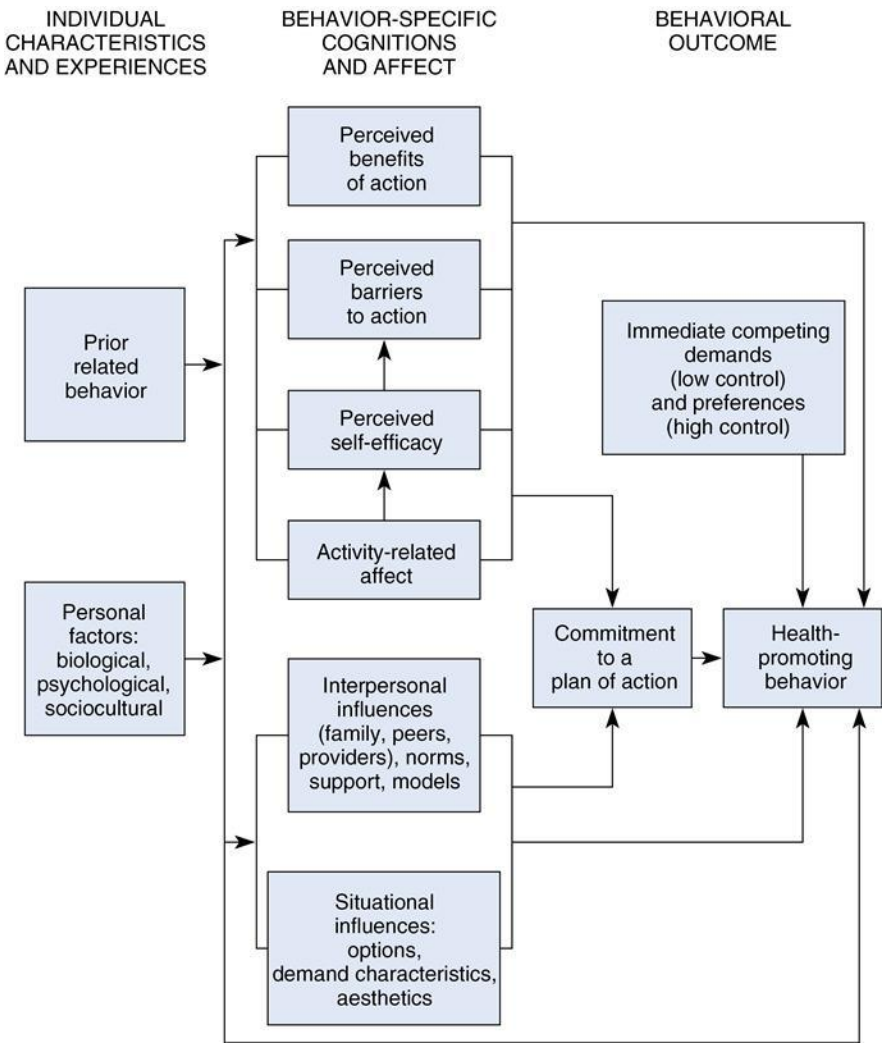

Figure 1. Health promotion model. Reprinted from *Theoretical Basis for Nursing* (4th ed.) (p. 235), by M. McEwen & E.M. Wills, 2014, Philadelphia, PA: Lippincott Williams & Wilkins. Copyright 2014 by Wolters Kluwer Health. Reprinted with permission.

Chapter Three: Methodology

Introduction

Many patients with schizophrenia are challenged with weight problems associated with taking olanzapine that increases their risk of metabolic syndrome, such as diabetes, and increases their mortality rate twice than the general population (Weber, 2010). Research shows that olanzapine increases the risk of obesity in patients who are mentally ill resulting in medication nonadherence and leading to relapse (Weber, 2010). The purpose of this study is to implement an intervention that will assist these patients in managing their weight to increase medication adherence and improve quality of life. This chapter will review the research design, sampling method, and data collection process for the study.

Research Question and Hypothesis

Research Question. "Does a program of education, diet and exercise change weight among patients diagnosed with schizophrenia who are taking Olanzapine?"

Hypothesis. The applicable null hypothesis for this research is, "Education, diet and exercise will not be effective in managing weight gain in patients with schizophrenia who are taking olanzapine." The alternative hypothesis is, "Education, diet and exercise will be effective in managing weight in patients with schizophrenia who are taking olanzapine."

Identification of Setting

The settings for the research will be conducted at the behavioral health outpatient unit in three major medical centers in southern California, Sharp Grossmont, Sharp Mesa Vista, and Scripps Mercy.

Research Design

The research design for this study will be a quasi-experimental study, a one-group pretest-posttest design, to examine the effectiveness of diet, exercise, and education to manage weight in patients with schizophrenia who are taking olanzapine. The Pender's Health Promotion Model will be utilized to guide this study. The aim is to determine whether diet, exercise, and education are effective interventions to manage weight in patients with schizophrenia taking olanzapine.

Population and Sample

Selected participants in this study must be diagnosed with schizophrenia, taking olanzapine routinely, and who participate in an outpatient therapy at least once a week.

For this study, the sample size needed will be 85 participants. The sample size was determined using G* Power version 3.1.9 software, and the type of power analysis was an a priori calculation. The significance level is set at 0.05, power of .80, and effect size of 0.30. Twenty percent was added to the initial sample size, which was 71, due to drop out or mortality.

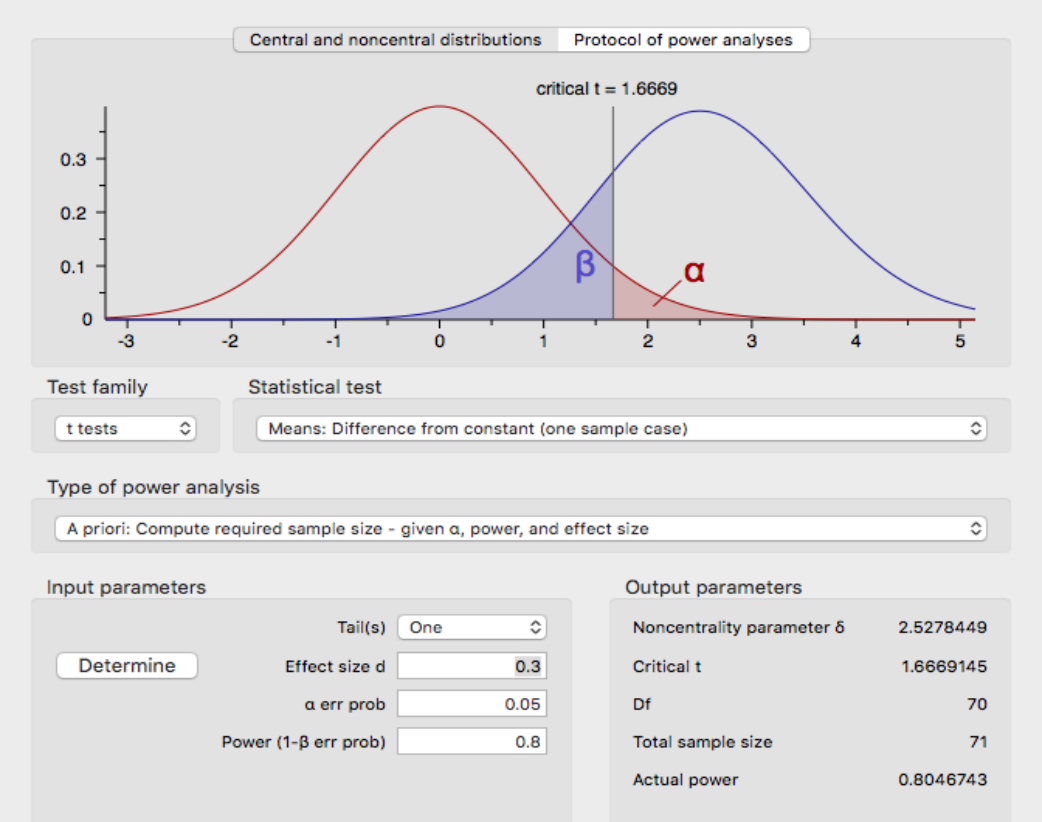

Figure 2. G*Power analysis for sample size

All participants must meet the following criteria to be eligible in the study. To be eligible to participate, the inclusion criteria are: 18 to 45 years old, having a body mass index (BMI) of 25 or higher, being adherent to medications, taking olanzapine for at least one month and symptoms are well controlled and stable with olanzapine, and no medical condition or physical limitation that may affect their ability to participate in the program. He or she must have a proof of physical examination within the last year and must provide a list of medical diagnosis and medications if any. In addition, the participant must consent to participate in the study for four months. The exclusion criteria are being diagnosed eating disorder or medical condition that may affect their participation while in the program, taking medications that affect weight, being pregnant and/or breastfeeding, being absent in more than one session, and being non-adherent to

medications while in the program. The researcher will fill out a form with eligibility criteria to collect the data (Appendix A).

Measurement Methods

Basic demographic information will be collected using basic demographic questionnaire (Appendix B). The questionnaire will include age, gender, ethnicity, race, highest grade completed, psychiatric diagnosis, medical diagnosis, and medications, height, and weight. Weight and height will be collected at the start of the program and participants will be weighed every month until the end of the program. Body mass index (BMI) is calculated using the CDC adult BMI calculator at the start and at the end of the study. Participants are provided activity trackers prior to the study and they are required to wear the activity trackers at all times during the study. The activity trackers will allow the researcher to collect activity data weekly when the participants bring them in class for recharge.

Data Collection Process

After obtaining the IRB approval (Appendix C) from CSUSM and the facility, the study will be announced at the outpatient in the behavioral health unit by means of flyers or staff announcement (Appendix D). The applicants will meet with the researcher and the researcher will explain the program thoroughly. If they agree to participate in the entire program, then they will be screened for the inclusion and exclusion criteria. If the participant meets the criteria for inclusion, a signed consent will be obtained (Appendix E). Demographic information will be collected before starting the program. The participants will take a test to evaluate their knowledge of diet and exercise (Appendix F). The same test will be given at the end of the study for comparison. While in the program, monthly weight is obtained at the same time of the day they were initially weighed. In addition, they will be weighed without jackets, hats, shoes, and

all pockets will need to be emptied. Their activity data will be collected weekly when they bring their activity trackers in class for recharge. In addition, participants are required to sign-in to track their attendance.

Interventions

Diet. A 4-month ketogenic diet will be implemented with the assistance of a registered dietician. Ketogenic diet is a diet that is gluten-free and low carbohydrate diet (Kraft & Westman, 2009). Positive effects of this diet include weight loss and decreased symptoms of schizophrenia (Włodarczyk, Wiglusz, & Cubała, 2018). According to Włodarczyk, Wiglusz, and Cubała (2018), eliminating gluten and decreasing the amount of carbohydrate intake generate ketosis, increase glutamate metabolism, and increase the gamma-aminobutyric acid (GABA) activity, thus resulting in reduction of hallucinations in patients with schizophrenia. The role of a registered dietician is to help create a ketogenic diet that is easily prepared by someone with mental illness. The participants will be given food journals before the study. The registered dietician will meet with the participants to evaluate their diet and educate them on which foods to eliminate from their diet.

Exercise. The American Heart Association recommends 30 minutes of moderate-intensity aerobic activity five days per week, or vigorous-intensity aerobic activity for 20 minutes, three days per week for healthy adults (Weber, 2010). In this 4-month program, the participants are only required to do moderate-intensity aerobic activity, such as walking, for 20 minutes, three days a week to make the goal more achievable for them. An activity tracker will be provided to help them reach their goals every week. The participants are encouraged to do more if possible.

Education. During this 4-month program, the participants will require to attend a weekly educational class. The researcher will use the Solution of Wellness Manual (Appendix G) which is an educational toolkit designed for patients with mental illness (Vreeland et al., 2010). The modules in this manual are easy to understand and addresses important topics, such as how to live a healthy lifestyle by means of diet and exercise, benefits of diet and exercise, different types of exercises, and health risk factors that are contributed to unhealthy lifestyle (Vreeland et. al., 2010). According to Vreeland et al (2010), patients with mental illness who used this manual improved their knowledge of making healthier choices. In addition, a registered dietician will assist in developing a nutritional education.

Coding and Scoring

The IBM SPSS 25 will be utilized to analyze the data. A graph will be created to easily correlate the variables.

Table 1. Coding and Scoring

Variables	Description	Type	Coding
Age	Ages in years	Scale	
Gender	Male, Female, Other	Nominal	Male = 1 Female = 2 Other = 3
Ethnicity/Race	White/Caucasian Hispanic/Latino Black/African American Native American/American Indian Asian / Pacific Islander Other	Nominal	White/Caucasian = 1 Hispanic/Latino = 2 Black/African American = 3 Native American = 4 Asian/Pacific Islander = 5 Other = 6

Variables	Description	Type	Coding
Education	Some High School Education High School Graduate Some college/no degree attained Bachelor's degree Master's degree Doctoral degree	Ordinal	Some High School Education = 1 High School Graduate = 2 Some college/no degree attained = 3 Bachelor's degree 4 Master's degree = 5 Doctoral degree = 6
Height	Height in inches	Scale	
Weight	Weight in pounds	Scale	

Data Analysis

There are multiple variables that will be used to accept or reject the null and alternative hypothesis. The dependent variable is weight and the independent variables are education, diet, and exercise. A scatter plot will be conducted to easily analyze the correlations between the dependent variable and the independent variables. The analytic technique is the T-test. The level of significance is set at alpha level of .05 and the confidence interval is set at 80 percent. The test statistic is the T-test.

Bias and Limitations

Potential biases that may impact the study are inconsistent data collection, participants' understanding of the study due to their mental illness, lack of research evidence with the intervention, and if the implementation of intervention is not well designed. The threats to validity include changes in diet, changes in medications, changes in treatments, and changes in patient's willingness to comply with the procedure. This study will only be conducted in three facilities, the number of participants, and using only one group are some of the limitations identified. Since the study will only last for four months, long-term effect will not be identified. Furthermore, the researcher will only rely on self-report since food intake cannot be observed outside the facility.

Ethical Considerations

Prior to starting this research, an institutional review board approval will be obtained from CSUSM and the facilities. No personal identifiers will be collected. All data collected will be confidential. The researcher will thoroughly explain the purpose of the study to the participant and must ensure understanding prior to obtaining consent from the participant.

Summary

The purpose of this study is to implement an effective intervention to manage weight while taking olanzapine to patients who are diagnosed with schizophrenia. Interventions identified to be effective in managing weight according to literature review are: structured diet, exercise, and routine education. This researcher will conduct a study in an outpatient setting in behavioral health units in three major medical facilities. To protect the participants during this research, ethical considerations must be valued by the researcher.

Chapter 4: Grant Elements

Topics that will be discussed in this chapter of this proposal will include three potential grants, justification of the budget, timeline, and plan for dissemination of the findings.

Potential Grants

There are three potential grants that are considered for this study. The first one is the American Psychiatric Nurses Association (APNA). APNA is the largest organization specializing in psychiatric-mental health nursing who is committed in promoting health in the psychiatric population. The APNA is funding research that enhance knowledge and improve practice in mental health nursing. Those projects that are chosen will be awarded between $1,000 to $10,000 to new researchers who have not previously had major intra- or extramural funding. This year, they are accepting proposals to generate new knowledge to advanced psychiatric mental health nursing or to improve evidence-based practice.

This next potential grant is funded by the Sidney R. Baer Foundation. The Sidney R. Baer Foundation is offering grants to researchers whose studies are dedicated to improve quality of life for people who are challenged with schizophrenia and bipolar disorder. This foundation was dedicated to Sidney R. Baer who strongly believed that his life could have been different if he was diagnosed and treated appropriately as a schizophrenic person. He was a successful and wealthy business man who suffered from schizophrenia. In 1999, Baer's legacy to help people with schizophrenia and bipolar disorder started when he and his lawyer established the Sidney R. Baer Foundation. This foundation grants organizations and institutions with research studies that will have positive impact on the schizophrenic population and does not expend more than 7% of the funds to administrative expenses.

Lastly, the selected grant for this study is the NIH Small Grant Program (R03) funded by the National Institutes of Health (NIH) because this study meets the requirements for this grant. NIH funds more than $32 billion each year to support biomedical research and their contribution makes them the largest supporter of biomedical research in the world (NIH, 2019). Their contribution to research has greatly impacted the healthcare by finding new treatments to diseases, enhancing quality of life, and helping people live healthier lives (NIH, 2019). NIH has a program that supports small research projects with limited resources. This program is known as the NIH Small Grant Program (R03). The R03 grants studies that is no longer than two years and costs less than $50,000 per year.

Budget

Program Director/Principal Investigator (Lomibao, Dominic D.):

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY							FROM June 01, 2019	THROUGH October, 2020
NAME	ROLE ON PROJECT	Cal. Months	Acad. Months	Summer Months	INST. BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Lead Researcher: Dominic D. Lomibao	PI	18				$6,500		$6,500
Research Consultant: Dr. Nancy Coffin-Romig	Chair Advisor	18			$100/hr	$6,500		$6,500
Dietician	Dietician	4			$100/hr	$4800		$4,800
Research Assistant	Physical Education Teacher	4			$25/hr	$2500		$3,000
					SUBTOTALS			$20,800

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY	FROM June 01, 2019	THROUGH October, 2020
CONSULTANT COSTS Statistician		$2,000
EQUIPMENT *(Itemize)* Computer x 1 ($400); Printer x 1 ($200); Ink x 1 ($107); Paper ($80) LETSCOM Fitness Tracker watch x 85 ($2,550) Lockbox x 1 ($50)		$3,387
SUPPLIES *(Itemize by category)* IBM SPSS 12-month Grad Pack Base v24 ($53) Pencils ($13) Food Journal x 85 ($680)		$746
TRAVEL 43rd Annual California Association for Nurse Practitioners Conference Conference fee for students ($350) Gasoline ($40) Parking ($100) Lodging ($100)		$890
INPATIENT CARE COSTS		0
OUTPATIENT CARE COSTS		0
ALTERATIONS AND RENOVATIONS *(Itemize by category)*		0
OTHER EXPENSES *(Itemize by category)* Award ($200) x 85 participants		$17,000
CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	0
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)*		
CONSORTIUM/CONTRACTUAL COSTS	FACILITIES AND ADMINISTRATIVE COSTS	0
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD		

BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD
DIRECT COSTS ONLY

BUDGET CATEGORY TOTALS	INITIAL BUDGET PERIOD *(from Form Page 4)*	2nd ADDITIONAL YEAR OF SUPPORT REQUESTED	3rd ADDITIONAL YEAR OF SUPPORT REQUESTED	4th ADDITIONAL YEAR OF SUPPORT REQUESTED	5th ADDITIONAL YEAR OF SUPPORT REQUESTED
PERSONNEL: *Salary and fringe benefits. Applicant organization only.*	$20,800				
CONSULTANT COSTS	$2,000				
EQUIPMENT	$3,387				
SUPPLIES	$746				
TRAVEL	$890				

BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD DIRECT COSTS ONLY					
BUDGET CATEGORY TOTALS	INITIAL BUDGET PERIOD *(from Form Page 4)*	2nd ADDITIONAL YEAR OF SUPPORT REQUESTED	3rd ADDITIONAL YEAR OF SUPPORT REQUESTED	4th ADDITIONAL YEAR OF SUPPORT REQUESTED	5th ADDITIONAL YEAR OF SUPPORT REQUESTED
INPATIENT CARE COSTS	0	0	0	0	0
OUTPATIENT CARE COSTS	0	0	0	0	0
ALTERATIONS AND RENOVATIONS	0	0	0	0	0
OTHER EXPENSES	$17,000				
DIRECT CONSORTIUM/ CONTRACTUAL COSTS	0	0	0	0	0
SUBTOTAL DIRECT COSTS *(Sum = Item 8a, Face Page)*					
F&A CONSORTIUM/ CONTRACTUAL COSTS	0	0	0	0	0
TOTAL DIRECT COSTS	**$44,823**				
TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD					**$44,823**

Budget Justification

Dominic Lomibao, BSN, RN will serve as the primary researcher on this study. He has been working as a psychiatric registered nurse for over five years. Dominic is a graduate student and he is currently enrolled in the Family Nurse Practitioner Program at California State University San Marcos where he has researched and developed the proposed study. He will be responsible for data collection, data analysis, and coordinator of the study. He is also responsible in conducting 5 classes each week to accommodate 85 participants. Dominic will be working closely with his research chair advisor, Dr. Nancy Romig, a registered dietician, and a statistician to complete this research study. His fee for the entire 6 months will be totalling $6,500.

Research Consultant: Dr. Nancy Coffin-Romig, DNSc, PMHCNS-BC, is an associate professor, and coordinates the Psychiatric Mental Health Nurse Practitioner specialty program. Her clinical background is in the area of trauma, perinatal nursing and psychiatric nursing. She maintains a private therapy practice, and teaches at the undergraduate and graduate level of nursing. She has conducted and published qualitative research focused on the area of domestic violence. Her expertise in qualitative methods is grounded theory, content/thematic analysis and phenomenology. Dr. Romig has successfully obtained intramural and extramural grants in research, program development and educational stipends. Her role as the chair advisor will include assisting the primary researcher coordinate the study, assisting with the management of the timelines, and assisting in the review the research findings. Dr. Romig will be paid a requested salary of $6,500 for the 6 months' period.

Registered Dietician: Registered dietitian must meet the educational and experiential standards set forth by the Commission on Dietetic Registration of the Academy of Nutrition and Dietetics. He or she will be working closely with the physical education teacher to assist with the diet planning for the participants and will also teach the nutritional portion of the class twice a month for 4 months. He or she is also required to meet with the participants for any nutritional guidance. The projected cost of the registered dietician is $4,800 at $100/hr.

Research Assistant (RA): The RA will be a physical education teacher who holds a Bachelor of Science in Physical Education degree. He or she will be working closely with the registered dietician in conducting the classes. The RA will be teaching six classes per week to accommodate 85 participants at 18 to 20 participants each class for 16 weeks. The RA will be trained in teaching the classes and will be knowledgeable in the content of the Solutions for

Wellness handbook. He will be completing the CITI training prior to the start of the study. The rate for the RA is $25 per hour and will be paid a total of $3,000 for the entire study.

Statistician: The statistician is needed to analyze and interpret the data inputted in the IBM SPSS software. The estimated cost for the statistician is $2,000.

Equipment: The required equipment to conduct the study is estimated to cost $3,387. A refurbished MacBook Air laptop is $400. All pamphlets, flyers, surveys, books and tests will be printed to save money and a printer will cost $200, ink $107, and paper $80. The LETSCOM Fitness Tracker watches are needed to collect activity data and the cost is $30 each and will need 85 for each participant totaling $2550. A lockbox is also needed to keep all documents secured and a lockbox costs $50.

Supplies: Supplies required for the study will cost $66. IBM SPSS 12-month Grad Pack Base v24 costs $53 and is needed to analyze the data collected. Included in the supplies are pencils which cost $13. Will also include Food Journals so participants can keep track of what they eat. Food Journal costs $8 each and will need 85 with the total cost of $680.

Other Expenses: The researcher will award $200 to participant who completes the program. If all 85 participants complete the program, the total cost for the award is $17,000.

Travel Expense: The PI will plan to attend the 43rd Annual California Association for Nurse Practitioners Conference on March 18-22, 2020 located in Riverside, CA to disseminate the findings of the study. The PI will be traveling from San Diego, CA and will using his own vehicle to and from the conference. The cost of the conference is $350 for students. Approximate distance from San Diego to Riverside is 100 miles. The approximate cost of gasoline is $40 at $4/gallon and 20 miles per gallon. Parking is $25/day with total cost of $100

for 4 days. The cost of lodging is $400 at $100 per night. Food will be provided at the conference at no extra cost. Total cost for travel expense is $890.

The sum of all expenses for the study which include the primary researcher fee, research consultant fee, registered dietician fee, RA fee, equipment, supplies, travel expenses, and award is $44,823. Any funds that are not used will be returned to the organization.

Timeline

The timeframe for the study is approximately 16 months which begins on the IRB application and ends on the last conference for dissemination. Once the IRB is approved by the university and the hospitals, the primary researcher will post flyers and recruit participants for the first four weeks. On the fifth week, the researcher will interview qualified participants. The participants will also meet with the registered dietician to discuss diet plan. During this week, the selected participants will be taking a pre-test and will be given a LETSCOM Fitness Tracker watches to be worn at all times and to be brought to class each week for data collection and recharge. The LETSCOM Fitness Tracker has a battery life of 7 days and takes about 1 hour for a full recharge. In addition, they will also receive food journals so they can log their food intake and the dietician can evaluate their diet. The first class will occur on the sixth week and the study is a 16-week program. Every month, the participants will be compensated $50 for their time and effort for a total of $200 for participating in the entire study. The research assistant (RA), who will be trained to teach the class before the study, will have to conduct six classes each week to accommodate 85 participants. Each class is a one-hour class and will have 18 to 20 participants. The RA will teach two classes at Sharp Grossmont Behavioral Health on Mondays, two classes at Sharp Mesa Vista on Tuesdays, and two classes at Scripps Mercy on Wednesdays. The days are subject to change depending on the availability of each site. Every week, the RA

will go over two modules from the Solution of Wellness Manual to cover all the content in the manual, except for week 14 and 15, and weeks that the participants are being weighed which the RA will only go over one module. On the 16th week, the participant will be taking the post-test, weighed for the last time, and will be given $50 and the LETSCOM Fitness Tracker for completing the study. The researcher will then work with a statistician to analyze and interpret the findings. The researcher will have four weeks to analyze the data and finalize the study. The final step will be dissemination of the findings which will be discussed later. Any money that is not used will be returned back to the organization.

Date	**Event**
June 3 – June 28, 2019	IRB Application for CSUSM
July 1 – August 30, 2019	IRB Application for Sharp Healthcare
September 2, 2019 – September 27, 2019	Recruitment of Participants (1st Group), passing out flyers
September 30, 2019 – October 4, 2019	First interview with primary researcher and registered dietician, pre-intervention, pre-test, distribution of LETSCOM Fitness Trackers and Food Journals. First weight
October 7, 2019 – October 11, 2019	First class – Modules 1&2
October 14, 2019 – October 18, 2019	Second class – Modules 3&4
October 21, 2019 – October 25, 2019	Third class – Modules 5&6

Date	**Event**
October 28, 2019 – November 1, 2019	Fourth class – Module 7 Second weight; $50
November 4, 2019 – November 8, 2019	Fifth class – Modules 8&9
November 11, 2019 – November 15, 2019	6th class – Modules 10&11
November 18, 2019 – November 22, 2019	7th class – Modules 12&13
November 25, 2019 – November 29, 2019	8th class – Module 14 Third weight; $50 Thursday – Happy Thanksgiving
December 2, 2019 – December 6, 2019	9th class – Modules 15&16
December 9, 2019 – December 13, 2019	10th class – Modules 17&18
December 16, 2019 – December 20, 2019	11th class – Modules 19&20
December 23, 2019 – December 27, 2019	12th class – Module 21 4th weight; $50 Thursday (Merry Christmas)
December 30, 2019 – January 3, 2019	13th class – Modules 22&23 Wednesday (Happy New Year)
January 6, 2020 – January 10, 2019	14th class – Module 24 Recruitment of Participants (2nd Group), passing out flyers

Date	**Event**
January 13, 2020 – January 17, 2020	15th class – Module 25
January 20, 2020 – January 24, 2020	16th class – Modules 26&27 Last weight; Post-test; $50 Award LETSCOM Fitness Trackers to participants who complete the program. Congratulate participants for completing the program.
January 27, 2020 - February 21, 2020	Data Analysis
March 18, 2020 – March 22, 2020	Plan for dissemination of the findings

**Dates are subject to change*

Plan for Dissemination

To disseminate the findings of this study, this PI will plan to attend the 43rd Annual California Association for Nurse Practitioners Conference and will also submit the findings the Journal of the American Psychiatric Nurses Association (JAPNA).

Conference. The conference chosen to disseminate the findings is the California Association for Nurse Practitioners (CANP) 43rd annual educational conference on March 18-22, 2020 in Riverside. CANP is dedicated in advancing the growth of nurse practitioners in healthcare statewide (CANP, 2019). Their commitment is focused on supporting nurse practitioners, filling the gaps in healthcare, and providing the healthcare needs of the patients (CANP, 2019). Their annual conference is a great opportunity to learn the most recent practice in healthcare. They also support students and provide opportunities to disseminate new research. The conference is also an opportunity to network with other providers.

The International Society of Psychiatric-Mental Health Nurses (ISPN) is an organization that supports advanced-practice psychiatric-mental health nurses in improving care for the mental-health population worldwide (ISPN, 2019). This was a potential conference to disseminate the findings since their conference invite all healthcare providers, including students, interested in psychiatric-mental health. The dates for the 12th Annual ISPN Conference in 2020 is not yet posted in the website but their annual conference occurs between March to April yearly.

The American Psychiatric Nurses Association (APNA) is the largest organization dedicated in advancing the nursing practice specializing in psychiatric-mental health (APNA, 2019). Their annual conferences are focused on wellness promotion, prevention of mental health problems, and treatment of psychiatric disorders (APNA, 2019). This organization supports

students to disseminate their research findings in health promotion for mental health population which makes this conference ideal for this PI to share his findings. The dates for the APNA 34th Annual Conference is yet to be determined but annual conference occurs in the month of October each year.

Journals. The journal chosen to disseminate the findings is the Journal of the American Psychiatric Nurses Association (JAPNA), which is the official journal of APNA. JAPNA is a peer-reviewed journal that publishes research and scholarships to enhance the wellness of the mental health population (APNA, 2019). JAPNA publishes important mental health topics related to the changes in the healthcare systems in regards to treatments, education, research, theory, practice, and policy (APNA, 2019).

The other potential journal to disseminate the findings of this study is the Perspectives in Psychiatric Care, which is the journal for advanced practice psychiatric nurses that publishes peer-reviewed papers. This journal provides current research, clinical application, and knowledge about psychiatric nursing, prescriptive treatment, and education (Wiley, 2019).

Last potential journal to disseminate the findings of this study is the Archives of Psychiatric Nursing which is the official journal for ISPN. The journal publishes peer-reviewed research and provides new knowledge in the area of psychiatric and mental health (ISPN, 2019).

These three journals are appropriate to disseminate the findings of this study since they focus on alleviating mental health issues thus helping mental health providers improve their care in patients with schizophrenia.

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Appendix A

Eligibility Criteria Form

Initials: _____

Age: _____

Weight: _____lbs

Height: _____ ft _____inches

BMI: _____

Are you between the age of 18 to 45 of age? _____Yes _____No

Are you taking olanzapine at least once a month and stable? _____Yes _____No

Do you take your medications as prescribed to you? _____Yes _____No

Do you have any conditions that can limit your ability to exercise? _____Yes _____No

Do you have an eating disorder? _____Yes _____No

Are you currently pregnant or breastfeeding? _____Yes _____No

Are you willing commit to participate in this study for 4 months? _____Yes _____No

Have you had a physical examination done within the last year? _____Yes _____No

If no, can you provide a proof physical examination prior to the study? _____Yes _____No

Appendix B

Demographic Survey Form

Initials Only: _____

Age: _____

Sex:

☐Female

☐Male

☐Would rather not say

Ethnicity:

☐White ☐Hispanic or Latino ☐Black or African American ☐Native American or American Indian ☐Asian / Pacific Islander ☐Would rather not say

☐Other _____

Race: _____

Highest Grade Completed: _____

Psychiatric Diagnosis:

_____

_____

Medical Diagnosis:

_____

_____

List of Medications: _____

_____

_____

_____

Height:_____

Initial weight _____; 2nd weight_____;

3rd weight _____; Final weight_____

Initial BMI: _____**;** Final BMI: _____

Appendix C

IRB Application

California State University SAN MARCOS

Limited/Expedited or Full Review Application Form

Instructions:
Please fill out this application form using clear language and lay terms. Please answer each section as completely and as concisely as possible. Some questions may not apply to your study. In that case, please add "not applicable" in the text box. Please upload this application form along with additional documents that are supplemental (as applicable) to your submission in IRBNet. For more information, please visit the IRB website. For questions, please contact IRB office at (760) 750-4029 or irb@csusm.edu.

Project Title: Preventative Approach to Weight Gain in Patients with Schizophrenia Who Are Taking Olanzapine!

Proposed Start Date: June 01, 2019

Faculty/Staff Investigator:

Name: Nancy Romig | Department/College: Nursing/California State Universi
Phone Number: (619)729-6089 | E-mail: nromig@csusm.edu
Date CITI Training Completed: 04-21-2017

Student Investigator: *(if the student is the principal investigator)*

Name: Dominic D. Lomibao | Department/College: California State University, San M
Phone Number: (619)888-9279 | E-mail: lomib004@cougars.csusm.edu
Date CITI Training Completed:

Faculty Advisor Name: Nancy Romig | Department/College: Nursing/California State Universi
Phone Number: (619)729-6089 | E-mail: nromig@csusm.edu
Date CITI Training Completed: 4-21-2017

REMINDER: Once the student investigator has completed this application form, he or she must e-mail it to their faculty advisor for review and feedback. Once the faculty advisor gives permission to the student to move forward, then the student will upload this application form along with additional documents to IRBNet. Once the student uploads all the documents, then s/he will share the IRBNet package with the faculty advisor. The faculty advisor must have an IRBNet account to approve the package as the "advisor" by logging into IRBNet. The faculty advisor will receive a notification via e-mail that the package has been shared with them and that they need to sign the package in IRBNet. Please do not "submit" your package in IRBNet until your faculty advisor has signed your package. For more information, please visit the IRB website.

Checklist: Check the additional documents that are uploaded in IRBNet. Check **ALL** that apply:

- [x] CITI Training Certificate for the principal investigator and the faculty advisor, if applicable.
- [x] Letter of support (if you are collecting data off campus, you need to provide a letter of support from the research site. The letter of support must include the letterhead of the organization and list the research activities to provide evidence that the organization is knowledgeable about the study.
- [x] Survey(s), questionnaire(s), and/or interview questions. If you are using an online survey, please upload a PDF copy of the survey.

Checklist (continued…): Check the additional documents that are uploaded in IRBNet. Check ALL that apply.

- [x] Recruitment flier(s), script(s), or advertisement for newspaper, listservs, radio, or TV.
- [x] Consent and child assent form(s) or information sheets. You must provide a separate form for each population group. Please use consent and assent form templates on IRB website. The information provided in this application form must match with the information provided in the consent form or information sheet.
- [ ] **Ed.D. students in the Joint Doctoral Program Only**: Sign, scan, and upload the UCSD-CSUSM JDP IRB Cover Sheet in IRBNet.
- [ ] Verification of translation form (Only for consent and/or assent forms in languages other than English and Spanish)

1. Type of Review (Please select **one**.)

- (●) **Limited/Expedited Review:** Research studies that are minimal risk qualify for limited/expedited review. These studies include but are not limited to benign interventions that involve children (e.g. lab studies) and secondary research that involves collection of identifiable biospecimens where broad consent is required. If limited/expedited review is selected, your submission will be assigned and reviewed by an IRB committee member within three weeks.
- ( ) **Full Review:** Research studies that are more than minimal risk are qualified for full review. If full review is selected, your submission will be reviewed by the IRB committee at a bi-monthly scheduled meeting during the academic year. The IRB committee does not meet during summer.

2. Funding: Is this research study funded?

( ) Yes ( ) No

If yes, please check one below:

( ) Internally funded

( ) Externally funded -> Please provide the funding source:

3. Purpose of Project

Describe the goal(s) of your project. List your research question(s) and discuss why the question is important, and how your study will attempt to answer it. Include how your literature review supports this with at least three citations. [Please do not exceed two paragraphs. Please use lay language.]

Research Question: "Does a program of education, diet and exercise change weight among patients diagnosed with schizophrenia who are taking Olanzapine?" Schizophrenia is a mental disorder that affects more than 25 million people worldwide (WHO, 2005). Excessive weight gain is seen in patients who are taking antipsychotic medications, which include aripiprazole, clozaril, olanzapine and ziprasidone (Ma et al., 2014). Patients who are diagnosed with schizophrenia and bipolar disorder are at a higher risk for obesity because of the prolonged use of antipsychotic medications (Ma et al., 2014). According to Parsons et al. (2009), the risk of obesity gets higher in patients who are mentally ill when the use antipsychotic medications is longer. A study of newly diagnosed patients with schizophrenia who are taking olanzapine showed a weight gain of an average of 13.9 kg in one year (Maayan & Correll, 2010). Since the prevalence of obesity continues to rise in patients with mental illness, interventions to prevent weight gain in patients who are taking antipsychotics are imperative to alleviate problems associated with obesity. !

The purpose of this project is to implement interventions to prevent obesity and assist patients who are challenged with schizophrenia manage their weight while taking olanzapine. To increase medication adherance, decrease comorbidities associated with obesity, and improve quality of life, an investigation of a weight management program and implementing these interventions (structured diet, exercise, and education) to patients who are taking olanzapine to manage their symptoms of schizophrenia is needed.

4. Number of Participants

A) Provide the total number of participants (or number of participant records, specimens, etc.) for whom you are seeking IRB approval. If you have more than one population group, please list the expected number of participants for each population group in your research study.

One group - 85 participants

B) Is this a multi-site study?

○ Yes -> If yes, indicate the total number of participants to be enrolled across all sites

◉ No

5. Participant Population

A) Describe all characteristics of participants including their primary language, age, gender, ethnicity, and vulnerabilities. Explain why you are targeting this specific population.

Selected participants in this study must be diagnosed with schizophrenia, taking olanzapine routinely, and who participate in an outpatient therapy at least once a week. To be eligible to participate, the inclusion criteria are: 18 to 45 years old, having a body mass index (BMI) of 25 or higher, being adherent to medications, taking olanzapine for at least one month and symptoms are well controlled and stable with olanzapine, and no medical condition or physical limitation that may affect their ability to participate in the program. He or she must have a proof of physical examination within the last year and must provide a list of medical diagnosis and medications if any.

B) Indicate whether anyone might be excluded from participating in your research study. If so, please explain why.

The exclusion criteria are being diagnosed eating disorder or medical condition that may affect their participation while in the program, taking medications that affect weight, being pregnant and/or breastfeeding, being absent in more than one session, and being non-adherent to medications while in the program. !

6. Participant Recruitment

A) How will you find, recruit, or identify potential subjects? How will you select the final group of participants from those who expressed interest in participating in your study? REMINDER: Please upload flyers, posters, or other oral or written invitations or recruitment script used to recruit potential participants in IRBNet.

The study will be announced at the outpatient in the behavioral health unit by means of flyers or staff announcement. The applicants will meet with the researcher and the researcher will explain the program thoroughly. If they agree to participate in the entire program, then they will be screened for the inclusion and exclusion criteria. If the participant meets the criteria for inclusion, a signed consent will be obtained.

B) Will participants receive compensation or other incentives?

◉ Yes ○ No

If yes, please explain the type (e.g. course credit, gift cards, cash payment, parking, etc.), the amount and timing of compensation or incentive. Compensation plans should be incremental (not contingent upon study completion) to avoid coercion or undue influence.

After completing the 16 weeks program, the participant will recieve $200 and will get to keep the Letscom fitness tracker.

7. Informed Consent Process

REMINDER: Please upload the consent (and child assent, if applicable) form, information sheet if requesting a waiver of consent or a waiver of documentation of consent, or broad consent form in IRB Net.

A) If participants are 18 years old or older, how and when will you explain the study including the required elements of informed consent to participants? How and when will participants receive the adult consent form?

The researcher will thoroughly explain the purpose of the study to the participants and must ensure understanding prior to obtaining written consent from the participants, and the researcher will provide the consent form prior to the study.!

B) If your study includes participants younger than 18 years old, how and when will you explain the study including the required elements of informed consent to parents and children? How and when will the parent receive the parent consent form? How and when will the child receive a verbal explanation of the study (if age 7 and younger) or the child assent form (for ages 8-17)? [Please note that signed parent consent form must be received before obtaining child assent to participate in the study.]

No participants will be of age under 18 year-old.

C) Will you or a student/research assistant obtain consent from participants?

Yes

D) How much time will participants have to consider participating between the explanation of the study, the receipt of the consent form (and child assent form, if applicable), and the beginning of the study? [Please note that participants should be given sufficient time between when participants receive the consent/assent form and when they are expected to sign and return the form to avoid coercion or undue influence.]

30 minutes

E) Are you requesting a Waiver of Consent or a Waiver of Documentation of Consent for collecting data other than secondary research for which consent is required? [Please note that electronic signatures are accepted as documentation of consent, so you do not need to request a Waiver of Documentation of Consent if you plan to obtain electronic signatures. Additionally, you cannot request a waiver of consent if the research involves more than minimal risk]

○ Yes ◉ No

If yes, please explain:

(1) how the research cannot practically be done without the waiver of consent or a waiver of documentation of consent, AND

(2) how participants will be provided information about the study including the required elements of informed consent with an information sheet or verbally?

Not Applicable.

F) If your study will use incomplete disclosure of the purpose of the study or deception, explain the incomplete disclosure or deception, and provide a rationale explaining why it is necessary for the research.

Not Applicable.

G) If you will ask participants for broad consent for the use of identifiable private information or identifiable biospecimens, list the specific future uses of the information or biospecimens for which participants are giving consent.

Not Applicable.

H) If using secondary research where broad consent has already been obtained for collecting, storing, and maintaining identifiable private information or identifiable biospecimens, explain the informed consent process that was followed to obtain consent from participants.

Not Applicable.

I) If any participants are not fluent or comfortable with English, please explain how you will ensure that participants understand the research activities and required elements of informed consent before giving their consent to participate in your study.

REMINDER: If participants need consent and/or assent forms in a language other than English or Spanish, the researcher must upload Verification of Translation form in IRBNet after the English version of the consent form has been reviewed and approved.

The participants must be literate in writing, reading, and speaking English.

8. Data Collection and Procedures

A) Describe the type of data you plan to collect as part of your research study. Please check ALL that apply.

- ☐ Biospecimens (including blood, urine, saliva, hair, sweat, etc.)
- ☑ Surveys, questionnaires, or interviews
- ☐ Observation of participants
- ☐ Audio, video, image, digital or non-digital records
- ☑ Other: Weight and height

B) Please provide a step-by-step explanation of how you will collect the type of data you checked above in the order it occurs. Additionally, indicate the duration of each data collection method as applicable. For example, if using surveys, questionnaires, or interviews, explain how often participants will be asked to complete them and how long it will take for participants to complete them. If using biospecimens, explain how much and how many times biospecimens will be obtained from the participants.

REMINDER: Please upload a copy of the survey(s), questionnaire(s), interview(s) and/or observation protocol (if applicable) in IRBNet.

Basic demographic information will be collected using basic demographic questionnaire. The questionnaire will include age, gender, psychiatric diagnosis, medical diagnosis, medications, educational level, and ethnicity. Weight and height will be collected at the start of the program and participants will be weighed every month until the end of the program.

C) Provide the projected dates/timeframe in which you plan to conduct your research study starting with the informed consent process. Include when each data collection will take place.

Demographic information will be collected before starting the program. While in the program, monthly weight is obtained at the same time of the day they were initially weighed. In addition, they will be weighed without jackets, hats, shoes, and all pockets will need to be emptied. The participants are required to bring the LETSCOM fitness tracker that were provided for charging and data collection each week. Their attendance with the dietician and weekly classes will also be collected. Each participant will be provided a food journal to log their daily intake which will be reviewed by the registered dietician. !

9. Risks and Inconveniences

A) Explain potential risks and/or inconveniences for each population group and data collection method mentioned above in section 8A. Risks may be physical or psychological (e.g. strong emotional reactions to researcher's questions). Inconveniences may include time required to participate in the research study. [Please be sure the risks listed here match the risks listed in your consent form or information sheet.]

Inconveniences may include time and effort of the participants' participation while in the program. Time required to meet the required physical activity which is 30 minutes a day, 3 times a week for 4 months, and additional 1 hour class per week for four months. They are required to log in their food intake in the food journal provided for them and make changes in their diet suggested by the registered dietician. The participants will be compensated $50 each month for their time and effort for participating in the study. !

B) If applicable, please select which of the following vulnerable population will be involved in your research study:

- ☐ Prisoners
- ☐ Children
- ☑ Other vulnerable populations such as persons with impaired decision-making capacities, economically or educationally disadvantaged persons, etc.

C) Describe any special risks to vulnerable populations.

Clients chosen for this particular project are diagnosed with schizophrenia.

10. Safeguards

Please identify a safeguard for each risk you mentioned in section 9A. Explain how you will minimize each risk. If there is a risk for participants to have a strong emotional response or a physical inquiry, please list referrals and/or resources that may be offered (e.g. clinics or shelters, medical or psychological referrals). [Please be sure the safeguards listed here match the risks listed in your consent form or information sheet.]

To minimize these risks and inconveniences, the following measures will be taken: !
• The participants can talk to the researcher at any time for any concerns that they may have.!
!

11. Data Management and Confidentiality

A) Please explain how the consent and assent forms will be secured. Add the duration of time these forms will be kept and how they will be disposed. [These forms should be stored separate from the rest of the data collected as part of the study. They must be kept in a secure place for three years by the researcher.]

Participants' responses will be anonymous. The results of this study may be used in reports, presentations, or publications but their names will not be used. Results will only be shared in aggregated form and their information will not be identifiable. The researcher will store any data collected in password protected computer and only the researcher will have access to the data. The data collected will be retained up to 3 years and digital files will be erased after the project is completed. !

B) Will personal identifying data (e.g. participants' names, phone number, home and/or e-mail address, student ID, birth date, etc.) be recorded?

○ Yes ◉ No

If yes, explain what information will be recorded, how this information will be stored, and how you will protect the identity of the participants.

Not Applicable.

C) Please explain who will have access to the data collected, where and how data will be stored (e.g. password protected computers, locked filing cabinets, cloud storage, etc.), how long the data will be stored and how it will be disposed.

Results will only be shared in aggregated form and their information will not be identifiable. The researcher will store any data collected in password protected computer and only the researcher will have access to the data. The data collected will be retained up to 3 years and digital files will be erased after the study is completed.

D) If biospecimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens.

Not Applicable.

E) If biospecimens will be banked for future use, describe the procedures for releasing specimens including the process to request a release, approvals required for release, who can obtain specimens, and the data to be provided with specimens.

Not Applicable.

12. Location of Study

Where will the research be conducted? Describe any risks to the participants or confidentiality issues related to using this location. [If your research study involves multiple sites, describe risks and confidentiality issues for each research site.]

REMINDER: If you are collecting data off campus, please upload the Letter of Support from the organization in IRBNet.

The setting for the research will be conducted at a behavioral unit in one of the main medical centers in southern California. !

13. Safety Monitoring (Only for studies that are more than minimal risk and need full review)

Please explain how you will periodically evaluate the data collected regarding harms and benefits to determine whether participants remain safe.

Not Applicable.

14. Data Sharing (Only for studies that include multiple research sites)

Please explain how you will store and share data across multiple research sites and who will have access to it.

Not Applicable.

15. Alternative to Study Participation (If Applicable)

Describe alternative activities non-participants could do during data collection. For example, if conducting a survey in the classroom, explain how those who decided not to participate in the study will spend their time while participants take your survey.

Not Applicable.

16. Participant Debriefing or Feedback (If Applicable)

Describe any feedback or information you will offer participants at the end of the study. [If deception is involved in your research, participants must be debriefed about the nature of the study as soon as possible. Participants must be made aware of the incomplete disclosure of the purpose of the study or deception, including their right to withdraw any record of their participation. You may consider giving the opportunity for participants to request a copy of the results of the study.]

Not Applicable.

17. Study Benefits

A) Discuss any potential individual and/or societal benefits. [Please note that often there is no direct benefit for the participants, however, the study contributes to the literature or future research.]

Hopefully, the participants will learn how to manage weight with diet and exercise while taking olanzapine and if the findings are significant, this study will contribute to future research and will benefit patients with mental illness. !

B) Please explain how the benefits from this study exceed the risks to participants?

Yes. The participants will be able to experience less side effects of their medication, increase adherence and prevent relapse.

18. Qualifications of the Researcher(s)

A) Briefly outline the principal investigator's qualifications and experiences related to the research study.

Dominic Lomibao, BSN, RN will serve as the primary researcher on this study. He has been working as a psychiatric registered nurse for over five years. Dominic is a graduate student and he is currently enrolled in the Family Nurse Practitioner Program at California State University San Marcos where he has researched and developed the proposed study.

B) If the principal investigator is a student, include faculty advisor's qualifications.

Dr. Nancy Coffin-Romig, DNSc, PMHCNS-BC, is an associate professor, and coordinates the Psychiatric Mental health Nurse Practitioner specialty program, with clinical background in the trauma, perinatal nursing, and psychiatric nursing area. She also teaches undergraduate and graduate level of nursing at California State University San Marcos. She has also conducted and published qualitative research focus on the area of domestic violence.

C) If using student or research assistants, please explain how you will ensure that these assistants are trained and qualified to assist the project including obtaining consent forms and collecting data. All assistants must complete the CITI training before starting to work on the project. It is the faculty member's responsibility to keep a copy of student assistants' CITI training certificate on their record.

The main researcher for this project is a graduate student specializing in Family Nurse Practitioner and holds a Bachelor's degree in Nursing. He will be completing the CITI training prior to the start of the study. A registered dietician will assist with the diet program and is knowledgeable in initiating the proposed diet safely, and will also be completing the CITI training prior to the study. !
A research assistant will be a physical education teacher with a Bachelor of Science in Physical Education degree who will be trained to teach the weekly classes, and will also go through the CITI training prior to the study.

19. For Student Principal Investigators Only

Please check the box below to verify that you will share your package and obtain your faculty advisor's signature in IRBNet:

☑ I verify that I will share my package with my faculty advisor in IRBNet after I upload this application and other materials, but *before* submitting the package for review.

Appendix D

Flyer

Make a Difference
Earn $200
and
Get a Fitness Tracker

If you are between the ages of 18 to 45 year-old who suffer from schizophrenia and taking Zyprexa, join us for a research study.
For more information, contact Dominic Lomibao, BSN, RN @ 619-888-9279 or lomib004@cougars.csusm.edu

Appendix E

Informed Consent

California State University
SAN MARCOS

Preventative Approach to Weight Gain in Patients with Schizophrenia Who are Taking Olanzapine
Informed Consent

INVITATION TO PARTICIPATE:
My name is Dominic Lomibao and I am a graduate student in the Family Nurse Practitioner program at California State University San Marcos. You are invited to participate in a research study to examine the effectiveness of diet, exercise, and education in managing weight in patients with schizophrenia who are taking olanzapine. You were selected as a possible participant because you volunteered and agreed to participate to the full term of the study and met all the criteria. Please read this form carefully and ask any questions you may have before agreeing to be in the study. You must be 18 or older to participate in the study and no older than 45 years of age.

STUDY PURPOSE:
The purpose of this study is to see if we can help our clients with schizophrenia manage their weight while taking olanzapine with special diet, exercise program, and weekly classes for 4 months.

NUMBER OF PARTICIPANTS:
If you agree to participate, you will be one of the 85 participants who will be participating in this research.

PROCEDURES FOR THE SUTDY:
If you agree to be in the study, you will do the following:

- Take a simple 20 question test before and after the study.
- Take your medication (olanzapine) as prescribed by your psychiatrist and report to the researcher if you are unable to take your medication as prescribed.
- Meet with the registered dietician once a month to discuss your daily diet and follow the diet that is instructed by the dietician.
- Attended a weekly 1-hour class, which will be part of your outpatient treatment program, for 4 months.
- Do a moderate exercise for 30 minutes 3 times a week or more for 4 months.
- Wear a Letscom fitness tracker at all times and bring it to the class every week to collect your activity data and to recharge.
- Report any changes in medications or medical condition while in the program to the researcher.
- Agree to be weighed at the beginning, monthly, and at the end of the study as instructed.

RISKS AND INCONVENIENCES:
There are risks and inconveniences to participating in this study. These include:

- Time and effort of your participation while in the study.
- Time required to meet the required physical activity which is 30 minutes a day, 3 times a week for 4 months.
- Time to log food intake in the food journal provided and make changes in your diet as suggested by the registered dietician to meet the required diet for this study.

SAFEGUARDS:
To minimize these risks and inconveniences, the following measures will be taken:

- You can talk to the researcher at any time for any concerns that you may have.

CONFIDENTIALITY:
Your responses will be anonymous. The results of this study may be used in reports, presentations, or publications but your name will not be used. Results will only be shared in aggregated form and your information will not be identifiable. The researcher will store any data collected in password protected computer and only the researcher will have access to the data. The data collected will be retained upon up to 3 years and digital files will be erased after the project is completed.

VOLUNTARY PARTICIPATION:
Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty. Your decision whether or not to participate in this study will not affect your current or future relations with California State University, San Marcos.

BENEFITS OF TAKING PART IN THE STUDY:
You will learn how to manage weight while taking olanzapine and if the findings are significant, this study will contribute to future research and will benefits patients with schizophrenia. In addition, the participant will be awarded $200 and the Letscom fitness tracker after completing the study.

PAYMENT OR INCENTIVE:
You will be awarded $200 and the Letscom fitness tracker is yours to keep after completing the study.

CONTACT INFORMATION:
If you have questions about the study, please call me at (619) 888-9279 or e-mail me at lomib004@cougars.csusm.edu. You will be given a copy of this form for your records. If you have any questions about your rights as a participant in this research or if you feel you have been placed at risk, you can contact the IRB Office at irb@csusm.edu or (760) 750-4029.

PARTICIPANT'S CONSENT:
By signing below, you are giving consent to participate in the study.

Name of the Participant:_____

Signature of the Participant:_____

Date:_____

Appendix F

Pre- and Post-test

Initials: _____

Age: _____

1. Your weight is the grand total of your:
    a. Bones
    b. Organs
    c. Blood
    d. Fat
    e. Muscles
    f. All of the above
2. What are symptoms of being out of shape?
    a. Feeling out-of-breath after walking up a flight of stairs
    b. Feeling exhausted, weak, or shaky after a few minutes of hard work or exercise
    c. Having poor muscle tone
    d. All of the above
3. To obtain your resting pulse rate, allow yourself to relax for several minutes then count the number of pulse beats in 30 seconds.
    a. True
    b. False
4. If you exercise enough each day to be pleasantly tired but not exhausted, you develop strength, skill, and endurance?
    a. True

b. False

5. Exercise can help you mentally as well as physically.
    a. True
    b. False
6. The benefits of exercise increase for those who make it a lifelong commitment.
    a. True
    b. False
7. Aerobic exercise strengthens the heart and helps it to pump more efficiently.
    a. True
    b. False
8. Exercise improves the body's ability to regulate blood sugar, and can also help manage type II diabetes
    a. True
    b. False
9. Exercise helps control body weight and is essential in any weight loss program.
    a. True
    b. False
10. Exercise can make life more fun.
    a. True
    b. False
11. Ketogenic diet is a low-carb diet.
    a. True
    b. False

12. Ketogenic diet can reduce symptoms of schizophrenia.
    a. True
    b. False
13. Match the type of exercise to which body systems are being most influenced:
    a. Cardiovascular Exercise _____ Stretches the muscles
    b. Flexibility Exercise _____ Stimulates the heart and lungs
    c. Strength-developing Exercise _____ Increases muscle strength
14. Why is walking such a good exercise?
    a. Walking is safe
    b. Walking is easy to do
    c. Requires no special equipment
    d. All of the above
15. Which food is high in protein?
    a. Meat
    b. Vegetables
    c. Rice
16. Which food is high in sugar?
    a. Ice cream
    b. Vegetables
    c. Chicken tenders
17. Which food is high in fat?
    a. Grilled chicken breast
    b. Fried chicken

c. Steamed vegetables

18. What do you avoid if you are doing ketogenic diet?

    a. Steamed vegetables

    b. Grilled chicken breast

    c. Bread

19. It is important to stop and rest and call your doctor if you feel dizziness or lightheadedness when exercising.

    a. True

    b. False

20. It is important to reward yourself for doing a good job.

    a. True

    b. False

Appendix G

Solutions for Wellness Manual

NEUROSCIENCE TREATMENT TEAM PARTNER PROGRAM

Solutions for Wellness Group Program

A program that offers information and tips on healthy living including nutrition, fitness, and exercise.

Lilly