Anti-psychotics, Weight Gain, and Children's Health: Making Informed Choices

Edith Kanyongo, MSN, RN, PMHNP-BC

The University of Texas Arlington College of Nursing

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Faculty Project Advisor: Donna Hamby DNP, RN, APRN, ACNP-BC

Statistician: Richard E. Gilder, RN-BC, MS

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Abstract

Background: Second generation antipsychotics (SGA) can cause weight gain. Increased weight gain increases the risk of metabolic complications such as, type 11 diabetes mellitus, myocarditis, prolonged QTC interval, extrapyramidal side effects and hyperlipidemia. SGAs are often prescribed to children with mental illness putting them at higher risk of obesity and other related complications. Unhealthy weight gain due to SGA therapy in children is a significant public health problem considering the association of obesity and the risk of cardiovascular disease. *Purpose:* The purpose of this quality improvement project was to educate and encourage participants to act in preventing SGA related weight gain. *Methods:* A convenient sample of pediatric patients aged 8-18 (N=26) who met the inclusion criteria were enrolled. The same group was used as pre and posttest groups. The pre-test was used as the control group. All participants and their parents/guardians watched an educational video then picked a 5210-healthy action they wanted to improve over a 3 months period. The pre and post-test results were compared. All participants were weighed before starting and on completion of the study. Pre and post weight results were compared. Re*sults:* A Mann-Whitney-u statistical test was used to analyze the data. The weight pretest mean was 26.13 and the posttest mean was 26.87. The fruits and vegetables group had a mean of 8.29 in the pretest and 20.71 in the post-test. The physical activity group had a mean of 5.44 in the pretest group and 11.56 in the post test group. The zero sugary drinks pre and posttest screen time mean was 3.25 and 1.75 respectively. The screen time

pre and posttest mean was the same at 2.50. *Conclusion:* The results show that it is beneficial to educate and encourage patients to act on preventing SGA related weight gain. It was also noted that at least two of the 5210 health habits are effective in preventing weight gain.

Keywords: Weight gain, second generation antipsychotic, serious mental illness,

Antipsychotics, Weight Gain, and Children's Health: Making Informed Choices

Section I: Background and Significance

SGA related weight gain is a major concern in children with serious mental illness (SMI). In the United States (US), one out of five children suffer a mental illness in a given year with an estimated cost of $247 billion annually on childhood mental disorders (CDC, 2018; Ogden et al., 2010). The most common occurring childhood mental illnesses are, attention deficit hyperactivity disorder, bipolar-spectrum disorders, major depressive disorder, externalizing mood/Impulse control, irritability associated with pervasive developmental disorders, and disruptive behavior (Reeves et al., 2013). These disorders cause lower academic achievement, criminal involvement, aggressive behavior/violent behavior, and poor social interactions. SGA therapy is often used to improve the quality of life of these children (McIntyre, & Jerrell, 2008). While SGA therapy helps relieve symptoms, it is also associated with multiple serious adverse effects including weight gain, type 11 diabetes mellitus, myocarditis, prolonged QTC interval, extrapyramidal side effects and hyperlipidemia (Üçok & Gaebel, 2008).

Unfortunately, SGA prescribing has been increasing in the USA and has doubled in the last 10 years, increasing weight gain prevalence (Vitiello et al., 2009). Therefore, unhealthy weight gain due to SGA therapy in children is a significant public health problem considering the association of obesity and the risk of cardiovascular disease (Reeves et al., 2013).

Statement of Problem

Unfortunately, with SGA use therapeutic success comes with major weight gain or obesity. Without proper education on risks vs benefits, patients will stop taking the medication once they start gaining weight, thereby increasing treatment non-adherence in this population. Children and adolescents tend to have greater risk for SGA weight gain compared to adults (NPS, 2014). Patients' lack of knowledge is one of the problems that lead to weight gain and treatment non-adherence. Even though providers educate patients about medication risks and benefits at the time of prescribing, patients do not retain all the information on the first visit. Multiple studies have concluded that patients recall and comprehend as little as 50% of what is discussed during the typical medical visit (Schillinger, 2003). According to Kessels (2003), patients tend to focus on information related to their diagnosis and fail to retain instructions on treatment or risks and benefits of treatment. That means appetite and/or weight changes may come as a surprise. Some parents understand the side effects but do not understand the magnitude of the weight gain. In any case an extra educational piece apart from the psychiatric evaluation visit would help patients and families to understand and be proactive in preventing the weight gain.

Some other risks of weight gain include dietary patterns, physical inactivity, medication use, and other exposures (CDC, 2018). Childhood body weight is also believed to be strongly influenced by genes. A study by Llewellyn, Trzaskowski, Plomin, and Wardle (2013), shows evidence that adiposity in childhood has genetic influence from multiple common single-nucleotide polymorphisms (SNP). In mentally ill patients with some of these preexisting risks, adding an SGA makes the situation worse. Regardless of the cause of weight gain the

complications, risks, costs, and financial burdens are the same. It is therefore very important for health care providers to implement interventions that will help alleviate this problem.

Intended Improvement

The intended improvement is to promote action towards preventing SGA related weight gain to prevent weight related complications in the future.

Review of Literature

Evidence from multiple research studies show that pharmacological therapy with second generation antipsychotics (SGA) causes weight gain. Several research studies were analyzed, and all agree that there is a strong relationship between weight gain/metabolic effects and SGA use in children (Correll, et al., 2009; McIntyre & Jerrell, 2008; Reekie et al, 2015; Stigler, Potenza, Posey, & McDougle, 2004). The researchers also recommend weight management programs and proper monitoring of side effects.

Association of SGA and Weight Gain

McIntyre, and Jerrell (2008) conducted a retrospective cohort study. A sample of 4140 children and adolescents were treated with one of five SGAs or two conventional antipsychotics, and 4500 randomly selected children not on antipsychotic pharmacological therapy. The purpose of their study was "to identify factors associated with incident cardiovascular events and metabolic disturbance in children and adolescents treated with antipsychotics". The results showed that the experimental group had a higher prevalence of obesity. Those exposed to more than one antipsychotic had much higher risk for obesity or weight gain, type 2 diabetes mellitus, and dyslipidemia. The researchers concluded that antipsychotics are indeed associated with some metabolic and cardiac-related adverse events in children and adolescents, especially when multiple antipsychotics or mood stabilizers are involved (McIntyre & Jerrell, 2008).

A non-randomized cohort study was conducted by Correll, et al. (2009) to study the relationship of SGA pharmacological therapy with metabolic effects, weight gain and lipid profile changes in patients without prior antipsychotic medication exposure. A total of 272 children of ages 4-19 years of age were studied over 12 weeks. The SGA medications included in the study were olanzapine, aripiprazole, risperidone, and quetiapine (Correll, et al., 2009). It was concluded that antipsychotic medication use is significantly related to significant weight gain. There were also metabolic variations among the medications. Participants gained an average of 19 lbs. over the 12-week period. At 10.8 weeks of therapy, weight increased by 8.5 kg with olanzapine, 6.1 kg with quetiapine, by 5.3 kg with risperidone, by 4.4 kg with aripiprazole compared with 0.2 kg weight gain in the comparison group (Correll, et al., 2009). Again, this study supports the idea that SGA use is associated with significant weight gain and recommend weight management education.

Ineffective Patient Education

As stated earlier patients do not retain all information given on first visit particularly information on treatment and treatment adverse effects. Educating patients represents one of the 3 main functions of a medical encounter (Crane 1997; Engel et al., 2009; Roter, 2000). Evidence shows that effective patient education must be multifactorial, individualized, and delivered in a variety of methods and settings outside of the examining room for patients to retain information better. There is evidence that ineffective communication of information about adverse effects by physicians or prescribers is contributing to medication non-adherence. In a study by Brown and Bussell (2011), patients reported lack of understanding of their disease, medication, lack of involvement with decision making or being involved in their treatment. Physicians tend to prescribe complicated drug regimens, failing to effectively educate patients on the benefits and

adverse effects that can be caused by the medications. It is therefore important to get patients involved in their own care. To do so they need to be educated effectively. Education will make patients feel empowered and they will more likely be motivated to manage their disease and adhere to treatment.

The overwhelming evidence of the association of weight gain and atypical antipsychotic use calls for the need to implement weight management interventions to decrease the risk, of diabetes mellitus, heart problems, and other comorbidities. The following research studies were reviewed to determine the best ways to prevent or decrease weight gain in SGA use (Kalavainen, Korppi, & Nuutinen, 2007; Polascek et al., 2014; Savoye et al., 2007; Siegrist et al., 2013).

Weight Management Interventions

Let's go 5210 (Rogers & Motyka, 2009)

Derived from the expert team guidelines, let's Go 5210 is a national obesity prevention program for children ages birth to 18 years old. They are known for their catchy phrase 5210 which stands for:

- 5. Five or more servings of fruits and vegetables per day
- 2. Two hours or less of screen time per day
- 1. One hour or more of physical activity per day
- 0. Zero sugary drinks including juices and sodas

Even two-year old children can catch on and help maintain guideline recommendations to stay healthy. Older children can keep a record of how many fruits and vegetables they consume daily. Two hours or less of recreational screen time is recommended to children 2 years or older.

Screen time should not be given to children less than 2 years old. Also recommended is one hour of physical activity which can be broken into smaller chunks and limiting sugary drinks to none and increasing water and low-fat milk consumption. Fruits and water should not be substituted for fruit juice. Children need eight glasses of water a day (Rogers & Motyka, 2009).

The 5-2-1-0 childhood obesity prevention is a program that involves health care providers that give patients dietary and physical activity prescriptions. The prescriptions promote daily healthy habits. Providers also administer healthy habits questionnaires and monitor patients' weight and or BMI. The program started in Maine (MMC-5210) and has spread to cities and states all over the US. Some of the states that have adopted the program are Florida, Kentucky, New Hampshire, Los Angeles, Virginia, and California. The 5210 is easy to use, clear, concise and lets every member of the family participate by carrying some responsibility on managing a healthy life (Polascek et al., 2014; Rogers & Motyka, 2009).

Polacsek et al., 2014 conducted a quasi-experimental study where seven sites participated using 5210 guidelines. The Maine Youth Overweight Collaborative (MYOC) was done between 2004 and 2009 with two non-MYOC control sites. Data from post-MYOC in 2009 were used as the baseline and comparison group. The main outcome measures of the research study included rates of recording of BMI percentile in chart, weight classification, use of the 5210-behavioral screening tool, parental reports of counseling received on 5210 topics, and clinician reports of changes in knowledge, beliefs, and practices. On the three years follow up, there was evidence of sustainable improvements on family management of risk behaviors primary-care, in managing overweight risk among children. Declines were observed for more-complex behavioral and system outcomes (Polascek et al., 2014).

Studies support the idea of including parents in educating patients on weight management interventions. Kalavainen, Korppi, and Nuutinen (2007) compared "the efficacy of group treatment stressing a health-promoting lifestyle with routine counseling in the treatment of childhood obesity.' They sampled 70 participants ages 7-9 years old who were obese in a randomized control trial. Over a period of six months, children and their parents received 15 group counseling sessions to promote health life styles. The researchers concluded that family-based group treatment focusing on health-promoting lifestyle, given separately for parents and children offers an effective intervention to reduce obesity in school-aged children. This study supports the involvement of parents in educating the pediatric patient.

Another research study by Siegrist, Lammel, Haller, Christle, and Halle (2013) to determine the effects of a school-based prevention program on obesity It involved school-based educational program to promote physical activity and lifestyle awareness. The aim of the study was to enhance health obesity measures. Participants in the intervention group attended 10 health-related classroom sessions at school over one year. Parents attended two and teachers attended three educational lessons. Parents and teachers also received 10 health related newsletters. The results showed no significant difference in weight and obesity between the children in the intervention group (13.5%) and control groups (14.1%). However, there was a decrease in waist circumference for all children with mean change of 1.7 cm. The program involved children, parents, and teachers, and suggested that a generalized approach in increasing physical activity will be favorable in a subgroup of obese children (Siegrist et al., 2013). This study shows efficacy in weight management education and supports the idea of including parents and family members in the health education component.

Savoye et al. (2007) conducted a randomized control trial to examine the effects of a weight management program on adiposity and metabolic complications of overweight children. The researchers analyzed the results of 209 overweight children with a BMI greater than 95th percentile for age and sex compared with control group. Participants were 8 to 16 years old from mixed ethnic groups. Weight management showed improvements compared to control group at six months and the improvements were sustained up to 12 months. It was concluded that the "The Bright Bodies weight management program" showed beneficial results on body composition and insulin resistance in overweight children and adolescents. The effects were sustained up to 12 months (Savoye et al., 2007).

Educational Video

Brock and Smith (2007) conducted a quasi-experimental study to determine the effectiveness of using a digital video on a personal digital assistant (PDA) to educate patients in a clinical setting. The results showed evidence that technology-assisted education with use of a digital video via PDA is a convenient and effective way to deliver health education materials. The results were true for subjects of varying ages and educational levels in a variety of locations within clinical environments. The study subjects were HIV/AIDS patients initiating treatment. First visit showed a statistically significant knowledge increase in disease process, medications, and adherence behaviors measured after participants watched the PDA-based video. At the second visit (four to six weeks later), statistically significant improvements in self-reported adherence to the medication were reported. Participants reported that they liked the PDA-based video. The video was viewed in both private and semi-private areas. They also reported it was an appropriate learning method regardless baseline literacy (Brock, & Smith, 2007).

In a systematic review by Abed, Himmel, Vormfelde, and Koschack (2014) 20 studies were reviewed to evaluate the efficacy of video presented patient education to modify behavior. Ten of the studies reported success in behavior modification. They also report that videos showing real people who are doing something are more effective. An earlier literature review suggested that use of video modelling facilitates knowledge acquisition, reduces anxiety, and improves self-care (Krouse, 2001). Another study was done to evaluate participants' attitudes towards the use of a video and leaflet to encouraging patient participations in safety-related behaviors. They concluded that use of video and leaflet could be effective at encouraging patient involvement in some safety-related behaviors (Davis, Sevdalis, Pinto, Darzi, & Vincent, 2013).

Pertinent Non-Research/Guidelines.

The national institute of health (NIH). NIH recommends a low-calorie diet combined with increased exercise for weight loss. The result will be reduction in abdominal fat plus increased cardiorespiratory fitness. Weight loss lowers elevated blood pressure in overweight and obese persons with high blood pressure. NIH (2018) recommendations for overweight and obese persons were put into consideration: NIH recommends physical activity, health life styles, and diet modification to decrease risk of obesity and related diseases. They also state that behaviors of children and adolescents in diet and physical activity are grossly influenced by society, families, communities, schools, healthcare providers, and the government (NIH, 2018).

Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity Recommendations. Practice guidelines Barlows and expert team (2007) formulated by an expert committee, which was comprised of representatives from 15 professional organizations, appointed experienced scientists and clinicians. They used both available evidence and expert opinion to develop the recommendations. Based on current knowledge the recommendations encourage patients and families to adopt and maintain specific eating, physical activity and sedentary behaviors to prevent weight gain. The expert team guidelines recommend giving the families a list of recommended eating and activity habits in the form of a prescription. The recommendations are as follows:

- Limiting high sugar beverages
- Promoting consumption of 9 servings of fruit per day as recommended by the United States Department of Agriculture (USDA) (www.mypyramid.gov)
- Limiting screen time including television, computers, tablets and other electronics. American Academy of Pediatrics recommends no television for

children 2 years or younger and maximum television time of 2 hours per day for children older than 2 years old.

- Encouraging breakfast daily
- Limiting fast food and eating out in restaurants
- Encouraging family meal times where families eat together at the same time
- Encouraging portion control (Barlows & the expert team, 2007).

Evidence-Based Conclusions

Based on the findings of the reviewed articles there is clear evidence that there is a strong relationship between SGA use and weight gain in children with mental illness. Overweight and obesity significantly increase the risk of health-related issues mainly cardio-metabolic problems (Correll, et al., 2009). Children and adolescents seem to be particularly susceptible to SGA related metabolic side effects and cardiovascular problems of weight gain. The reviewed articles all recommend initiating weight monitoring and weight management programs for children on SGA therapy. Parents/families and children are all key partners in the management and treatment of pediatric psychiatric disorders including managing side effects. The findings from Chovil & Panagiotopoulos (2010) support the value of incorporating the 'family' input in developing educational strategies for medication use and lifestyle modifications to prevent metabolic events. Both guidelines and the reviewed studies support diet and physical activity in programs that involve parents and/or family members to prevent or reduce weight gain.

It is therefore concluded that educating and promoting action using a 4.5-minute video and the "*Let's Go 5210*" (Rogers & Motyka, 2009) will be beneficial to children and adolescents on SGA therapy (Polascek et al., 2014). Including both parties in decision making and setting

goals will give the patient and family a sense of control of the patient's health. Parent education is the key approach to success in childhood obesity management (Vaughn & Waldrop, 2007).

Theoretical Framework - logic Model and Health Belief Model

Logic Model

The simple Logic Model was used as the theory of change to guide the whole quality improvement project. It explains the inputs, activities, production and outcomes of the project; (Weiss, 1972). Appendix D illustrates the logic model related to the project.

Health Belief Model (HBM)

For the education the HBM was used to guide the teaching plan. It is one of the commonly used models for understanding health behaviors. It was developed by social psychologists Hochbaum, Rosenstock and Kegels in the early 1950s. It has been used with excellent success in promoting increased condom use, seat belt use, medical adherence, and health screening use, and more (Hochbaum, Rosenstock & Kegels, 1952). This model will be useful in promoting health habits in physical activity and diet.

The model is built on the premise that a person will make a health-related change if the individual:

1. feels that an adverse health condition can be prevented
2. is positive that by following a recommended action, a negative health condition will be avoided and,
3. is positive that he/she can successfully follow the recommended health habits.

HBM is recommended for motivating individuals at risk to take positive health habits to avoid a negative health outcome. In this quality improvement project participants and their families will be motivated to choose a dietary or physical activity habit to prevent metabolic

complications. HBM is made of six concepts including perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action, and self-efficacy. Appendix E shows how the concepts are used in this project. The relationship of the concepts is shown in Appendix D.

Inquiry Question

In mentally ill children aged 8 to 18 receiving SGA therapy, will an educational video on SGA side effects and use of the *Let's go 5210* (Rogers & Motyka, 2009) recommendations increase awareness and help promote action to prevent weight gain compared to usual care?

Project Objectives

1. Educate parents and children on the metabolic side effects of atypical antipsychotic therapy in children
2. Educate parents and children on the impact of diet and exercise in management of SGA related weight gain
3. Promote action using diet and exercise to prevent SGA related weight gain

Section II Methods and Procedures

Project Design

A quasi experimental one group pre and posttest comparison design was used in the project. Subjects were given a 5210 healthy habits questionnaire Appendix B prior to watching the educational video Appendix C. The same questionnaires were administered at the end of the intervention to compare pre and posttest action levels. Subjects were also weighed prior to education and at the end of the project on their 3rd and final visit. Pretest results served as the comparison group.

Population and Sampling Plan

Population.

Convenience sampling was used to recruit participants from the clinic. A total of 33 participants were recruited from the same clinic. All participants were children or adolescents between the ages of 8 and 18 years. All participants had a psychiatric diagnosis for which they were receiving SGA therapy.

Sampling Criteria.

All patients 8-18 years old who are diagnosed with a DSM-V disorder for which they were on SGA therapy was the target population. Convenience sampling was used to enroll subjects into the study. All clients on SGA therapy who met the inclusion criteria and received services between the 08/31/2017 - 10/31/2017 were asked to participate in the study. Established and new patients included. A total of 33 willing subjects and were recruited and enrolled.

- Inclusion criteria: Ages 8-18 years old on SGA therapy, current or new patients
- Exclusion criteria: Children with eating disorders, children with severe Intellectual disability, or those unable to learn.

Setting

The quality improvement project was done at an outpatient public service mental health community clinic in Dallas Texas. The clinic caters for the all ages and all levels of care. The clinic is one of 8 clinics in the metroplex serving clients including those with moderate to severe levels of functional impairment. The clinic's staff included psychiatrists, psychiatric nurse practitioners, MAs, licensed vocational nurses, case workers, counselors and front desk/intake personnel. The clinic has a total of 4 medical providers two psychiatrists and two psychiatric nurse practitioners.

Measurement Methods

Data collection was ongoing. Pre and posttests were administered by the advanced practice registered nurse (APRN) on the first and last visits, results were recorded electronically. Pre and post-test results were collected using data collection forms as in Appendix F. Weight was checked on the first and last day of the study using the same scale by the same medical assistant (MA). For interrater reliability only one MA weighed and recorded the weight. Both MA and APRN set up the video. The same MA also served as the translator for the Spanish speaking parents and/or guardians. She was trained specifically for the project translation.

At the end of the project, all participants reported how they did with their action of choice to the APRN. They also reported any complications, issues or concerns they encountered during the project. This information will help for future recommendations and study limitations.

Data collection period.

Data was collected over a 12-week period and recorded on a Microsoft Excel spreadsheet see Appendix F.

Privacy and Confidentiality.

Health information was protected as regulated by the Health Insurance Portability and Accountability Act (HIPPAA) (U.S. Department of Health & Human Services, 2018). All participants signed a HIPPAA form to ensure privacy Appendix J. They also signed consent and assent forms before starting the project see Appendix I. All forms including data collection forms were kept locked up at the community clinic. MRN numbers were used for each participant and data was coded at time of starting the project. Appendix H. shows the coded identifier list.

Statistical Analysis

The Mann-Whitney U test was used to determine the difference in 5210 healthy habits

and the difference in weight before and after the education and two months of practicing the chosen healthy habit. Statistical Package for the Social Sciences (SPSS) software was used to compute and analyze data. The level of significance was set at 95%.

Section III: Results

Demographic Characteristics

Gender.

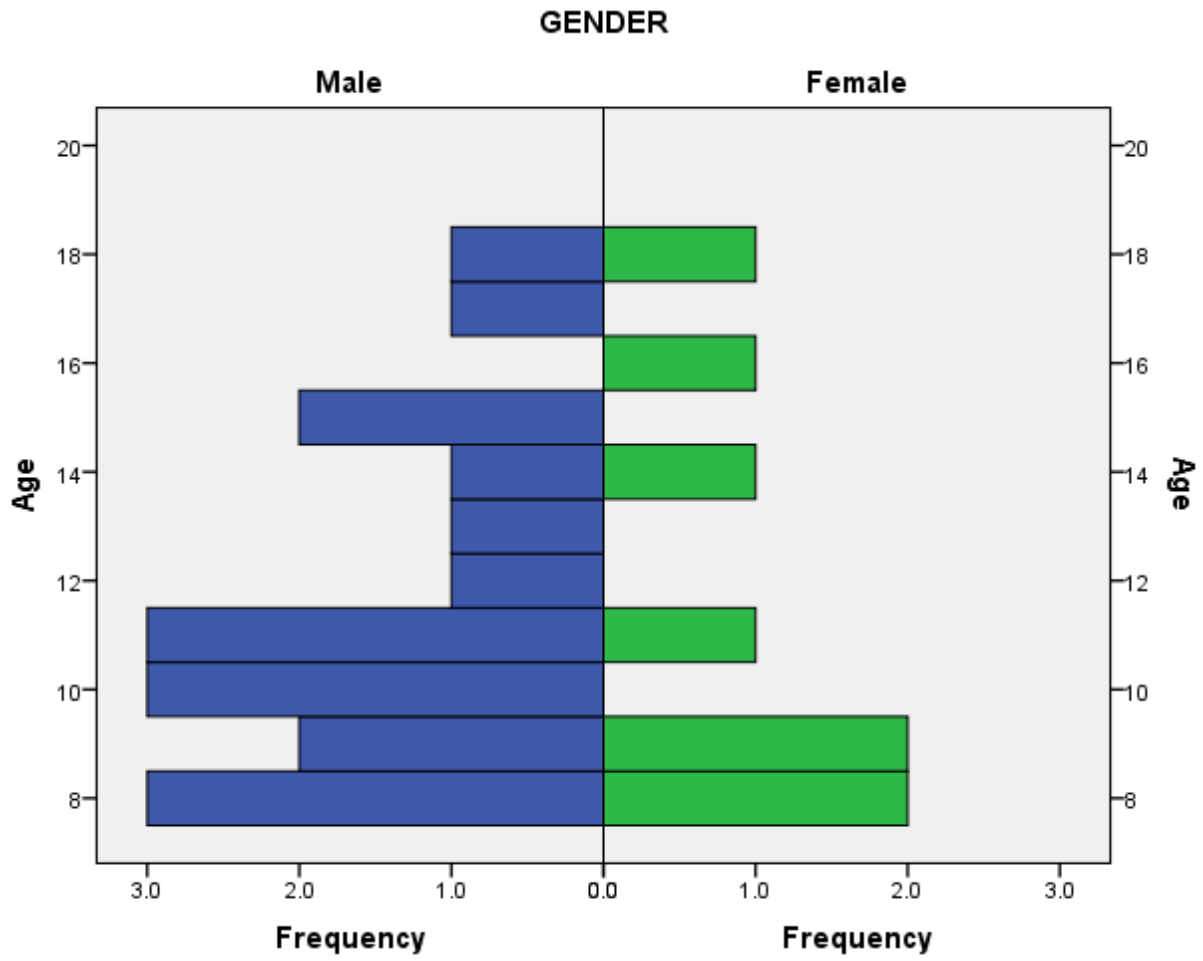
As displayed in Table.1 a total of (N=26) subjects completed the project. There were more boys than girls male (N=18) and female (N=8), however there was no significant difference in gender distribution. Figure 1 shows that there were about 69.2% of the participants were boys and 30.8% were girls.

Table 1. Gender Variation

Age

		GENDER	
		Male	Female
N	Valid	18	8
	Missing	0	0
Mean		11.61	11.63
Median		11.00	10.00
Std. Deviation		3.090	3.889
Variance		9.546	15.125
Range		10	10
Minimum		8	8
Maximum		18	18
Percentiles	25	9.00	8.25
	50	11.00	10.00
	75	14.25	15.50

Figure 1. Gender distribution.



Race/Ethnicity.

Three ethnic groups participated. Table 2 shows that most of the participants were equally distributed between the African American and Hispanic groups with 38.5% each. The White/Caucasian group was 23.1%.

Table 2. Race-ethnicity distribution.

Race

		Frequency	Percent
Valid	AA	10	38.5
	Hispanc	10	38.5
	White	6	23.1
	Total	26	100.0

Age.

There were no significant differences in the age distribution between the ages 8 and 18 years old. There were more boys than girls. The median age for both boys and girls was 11.5. The mean age for the boys was 11.61 (SD=3.090) and girls was 11.63 (SD=3.993). Table 3 illustrates the age distribution.

Table 3. Age distribution.

Age

GENDER			Frequency	Percent	Valid Percent	Cumulative Percent
Male	Valid	8	3	16.7	16.7	16.7
		9	2	11.1	11.1	27.8
		10	3	16.7	16.7	44.4
		11	3	16.7	16.7	61.1
		12	1	5.6	5.6	66.7
		13	1	5.6	5.6	72.2
		14	1	5.6	5.6	77.8
		15	2	11.1	11.1	88.9
		17	1	5.6	5.6	94.4
		18	1	5.6	5.6	100.0
		Total	18	100.0	100.0	
Female	Valid	8	2	25.0	25.0	25.0
		9	2	25.0	25.0	50.0
		11	1	12.5	12.5	62.5
		14	1	12.5	12.5	75.0
		16	1	12.5	12.5	87.5
		18	1	12.5	12.5	100.0
		Total	8	100.0	100.0	

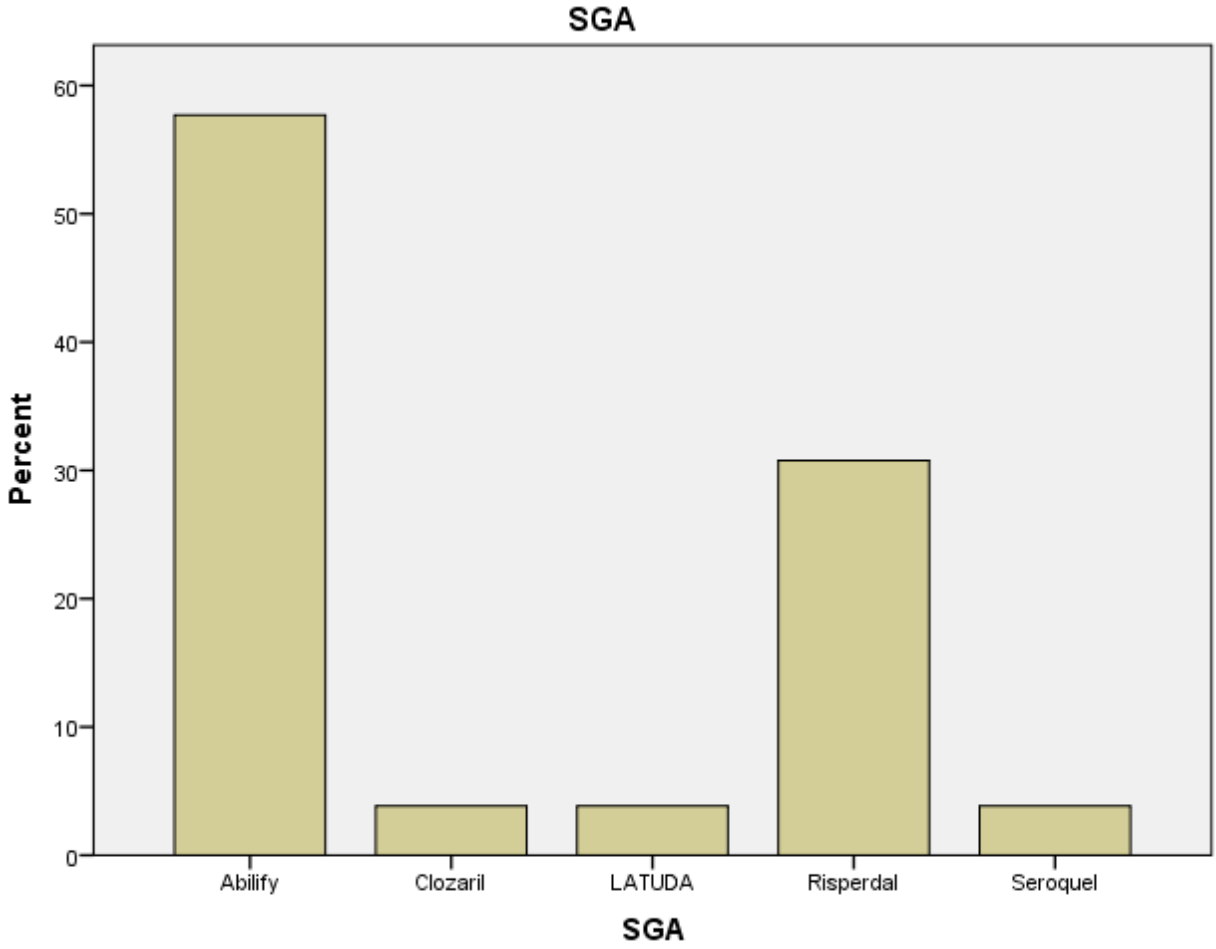
Diagnoses.

About 60% of the sample had a diagnosis of disruptive mood dysregulation disorder (DMDD). About 10 % had schizophrenia, the rest was equally distributed among the rest of disorders including, bipolar disorder, adjustment disorder, and autism spectrum disorders as shown in table 4.

Table 4. DSM Diagnoses

Psych_DX

		Frequency	Percent
Valid	Adjustment disorder	1	3.8
	Autism	1	3.8
	Bipolar	1	3.8
	dmdd	1	3.8
	DMDD	16	61.5
	DMDD/ADHD	1	3.8
	DMDD/autism	1	3.8
	DMDD/IDD	1	3.8
	schizo	2	7.7
	schizo/idd	1	3.8
	Total	26	100.0



SGA

		Frequency	Percent
Valid	Abilify	15	57.7
	Clozaril	1	3.8
	LATUDA	1	3.8
	Risperdal	8	30.8
	Seroquel	1	3.8
	Total	26	100.0

5210 Actions Results

Fruits and Vegetables. About 54% of the participants chose to increase fruits and vegetables in their daily diet. There was a significant difference in the intake of fruits and vegetables between the before and after groups with a mean of 8.29 in the pre-test and a mean of 20.71 in the post-test results. Vegetables were increased by 1-3 servings a day. See table 5.

Table 5. Fruits and Vegetables

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of FRUIT_VEGETABLE_COUNT is the same across categories of TEST_GROUP.	Independent-Samples Mann-Whitney U Test	.000[1]	Reject the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

[1]Exact significance is displayed for this test.

Screen Time. Only 8% of participants chose to decrease daily screen time. Table 6 shows that there was no significant difference in screen time before and after the project with a p value of 1.000, significance level was set at 0.05.

Table 6. Fruits and Vegetables

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of SCREEN_TIME_HOURS is the same across categories of TEST_GROUP.	Independent-Samples Mann-Whitney U Test	1.000[1]	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

[1]Exact significance is displayed for this test.

Physical Activity. 31% of participants chose to increase daily physical activity to at least one hour a day. Figure 4 illustrates there was a significant difference in the pre and posttest groups. The pretest group had a mean of 5.44 and the posttest group had a mean of 11.56. Table 7 shows that there was significant difference in amount of physical activity before and after the project with a p value of 0.007 with significance level set at 0.05.

Table 7. Fruits and Vegetables

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of ACTIVITY_HOURS is the same across categories of TEST_GROUP.	Independent-Samples Mann-Whitney U Test	.007[1]	Reject the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

[1] Exact significance is displayed for this test.

Zero Sugary drinks. Only 8% of participants chose to decrease sugary drinks in their daily diet. Table 8 shows that there was no significant difference in sugary drink consumption per day before and after the project. Results show P value of .333 with significance level set at 0.05. Table 8 also shows that there was equal distribution in the test groups with a mean of 2.50 in the pretest group and 2.50 in the post test group.

Table 8. No Sugary Drinks.

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of NOSUGARY_COUNT is the same across categories of TEST_GROUP.	Independent-Samples Mann-Whitney U Test	.333[1]	Retain the null hypothesis.

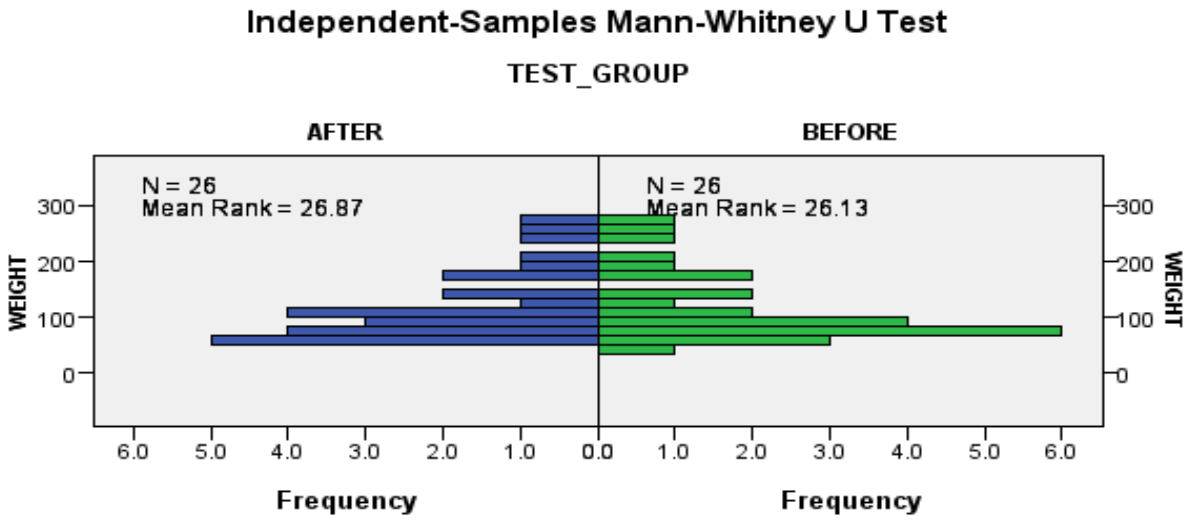
Asymptotic significances are displayed. The significance level is .05.

[1] Exact significance is displayed for this test.

Weight

Figure 4 illustrates the weight results for both pre and posttest groups. The expected results where to prevent weight gain in the after group. The distribution of weight was the same across the categories in the pre and post-tests. There was no significant difference of weight before and after**.** Figure 6 illustrates there was equal distribution in the test groups with a mean of 26.13 in the pretest group and 26.87 in the post test group. Results show P value of .798 with significance level set at .05.

Figure 4. Weight Before and After



Total N	52
Mann-Whitney U	347.500
Wilcoxon W	698.500
Test Statistic	347.500
Standard Error	54.638
Standardized Test Statistic	.174
Asymptotic Sig. (2-sided test)	.862

Data Analysis

Data was analyzed by comparing the pre and post-test questionnaire results of the *Let's go 5210* (Rogers & Motyka, 2009) healthy action choices and the participants weight before and after. Table 8 shows that 67% of the recruited participants completed the project. Table 9 illustrates that of the 26 participants 53.8% chose fruits and vegetables, 30.8 % chose physical activities, 7.7% were screen time and 7.7% no sugary drinks. Comparing the pre and post-test

results the fruits/ vegetables and physical activity groups significantly improved had more participants. However, the screen time and no sugary drinks were both very small sample groups and they did not show improvement in 5210 actions. There was no significant difference in weight pre and posttests results.

Statistical Analysis using Independent Samples Mann-Whitney U test

The Mann-Whitney U test was used to evaluate the effectiveness of using the 5210 healthy actions to prevent SGA related weight gain.

Section IV: Discussion

Program Evaluation

The quality improvement project was implemented at a public service community setting that caters for children and adults with severe mental illness (SMI), most of them on pharmacological therapy. The results showed that giving an extra piece of education on the side effects of medications particularly SGA related weight gain is beneficial to the clients. Results also showed that the clients need knowledge and encouragement to act to prevent the weight gain. Participants were asked and encouraged to pick a healthy habit that they are interested in doing from the 5210 healthy habits and practice that habit for a period of two months. Most of the clients chose to increase fruits and vegetables in their diet and increasing physical activity. These participants significantly increased their fruits, vegetables and physical activity. Very few participants chose to decrease their screen time and sugary drinks, for those who chose to decrease screen time there was no improvement. Some participants did not follow up on the second and third visit and they were dropped out of the project. Some attended the first and last but not the second visit, these were included in the project if they followed up on time for the third visit.

Limitations

The sample size was too small making it difficult to generalize the results. Children with ADHD had difficulties to maintain focus on the video and to learn in one sitting. Some families voiced difficulties in affordability of fruit and vegetables. Some Hispanic families had trouble understanding the video even with a live interpreter. All children understood the video perfectly. Some participants and their families did not come for the middle appointment but came for the last appointment and they were included to complete the project. Those who missed the middle and last appointment they were eliminated from the project. The project was started in the fall and ended in the winter. Pretest weight was done with lighter clothing and the posttest was done in winter with heavier clothing which could cause a variation in pre and post weight. Due to difficulties in scheduling weight was done on different times of the day some after they eat or drink which could also cause variation in the pre and post weight results. SGAs were not grouped by their names, some may cause more weight gain than others and that was not put into consideration. Some participants were taking an SGA and a stimulant, stimulants can decrease appetite which could have also impacted the rate of weight gain in those participants.

Implications

Most parents and/or guardians were very appreciative of the extra education given outside the visit. They liked the idea of the video focusing specifically on the SGA related weight gain. Children and adolescents really liked the idea of being involved in the decision making and having to pick what they would like to do on the 5210. It will be very useful for providers if they can spare time to teach their patients or offer them to watch a short video to bring awareness and promote action to prevent weight gain. If patients know from the beginning, they will more than likely put more effort into putting action to prevent the weight gain and other

complications. Agencies should encourage providers to put more effort into teaching about weight gain and teach ways to prevent it. 5210 videos can be used for individuals or groups. It can be administered by MAs, Nurses, or Doctors.

Suggestions for future studies

The researcher recommends using a larger sample with equal participants on all variables on the 5120 healthy habits. It would be beneficial to remind parents/guardians of ADHD participants to medicate them prior to educational session that will help them to maintain focus and retain the educational information. It will also be better to do the project over a longer period.

Conclusion

It is evident that healthcare providers need to educate patients and encourage them to act in preventing SGA related weight gain. The *Let's go 5210* (Rogers & Motyka, 2009) health habits promote physical activity and healthy food choices thereby preventing weight gain. Involving children in making the choices promote better outcomes as the children typically pick things that they can do. Giving the children sense of control encourages them to bring positive results.

Appendices

Appendix A. 5210 Educational Video link

https://drive.google.com/file/d/0ByZXUZolUPO6S2EzNHlmbmpPakE/view

Fruits & vegetables - more matters! Eat fruits and vegetables at least 5 times a day. Limit 100% juice.

Cut screen time to 2 hours or less a day (TV, computers & video games). No screen time for kids under 2.

Be physically active at least 1 hour every day.

No soda or sugar sweetened sports or fruit drinks.
Instead

5210 Healthy Habits Questionnaire (Ages 10–18)

We are interested in the health and well-being of all our patients. Please take a moment to answer the following questions.

Patient Name: _____ Age: _____ Today's Date: _____

1. How many servings of fruits or vegetables do you eat a day?
   (One serving is most easily identified by the size of the palm of your hand.)
   _____
2. How many times a week do you eat dinner at the table together with your family?
   _____
3. How many times a week do you eat breakfast?
   _____
4. How many times a week do you eat takeout or fast food?
   _____
5. How many hours a day do you watch TV/movies or sit and play video/computer games?
   _____
6. Do you have a TV in the room where you sleep? Yes ☐ No ☐
7. Do you have a computer in the room where you sleep? Yes ☐ No ☐
8. How much time a day do you spend in active play (faster breathing/heart rate or sweating)?
   _____
9. How many 8-ounce servings of the following do you drink a day?

   _____100% juice _____Fruit or sports drinks _____Soda or punch
   _____Water _____Whole milk _____Nonfat (skim), low-fat (1%), or reduced-fat (2%) milk

10. **Based on your answers, is there <u>ONE</u> thing you would be interested in changing now? Please check one box.**

    ☐ Eat more fruits and vegetables.
    ☐ Take the TV out of the bedroom.
    ☐ Play outside more often.
    ☐ Switch to nonfat (skim) or low-fat (1%) milk.
    ☐ Spend less time watching TV/movies and playing video/computer games.
    ☐ Eat less fast food/takeout.
    ☐ Drink less soda, juice, or punch.
    ☐ Drink more water.

5210 LET'S GO!
www.letsgo.org

Please give the completed form to your clinician. Thank you.

Appendix C. IRB approval

Metrocare | THE ALTSHULER CENTER for Education & Research

Date: September 12, 2017

From: Judith Hunter, MD
Metrocare Services Institutional Review Board Chairperson

To: Edith.Kanyongo@metrocareservices.org

Re: Study Approval

Title: **Antipsychotics, Weight Gain, and Children's Health: Making Informed Choices**

The Metrocare Services Institutional Review Board (IRB) reviewed the above-referenced research study via an expedited review procedure on September 12, 2017 in accordance with 45 CFR 46.110(a)-(b)(1). Having met all applicable requirements, the research study is approved for a period of 12 months. The approval period for this research study begins on September 12, 2017 through September 11, 2018.

The research study cannot continue beyond the approval period without continuing review and approval by the IRB. In order to avoid a lapse in IRB approval, the Principal Investigator must apply for continuing review of the protocol and related documents before the expiration date. A reminder will be sent to you approximately 90 days prior to expiration of research study approval.

If you have any questions related to this approval letter or about IRB policies and procedures, please telephone the IRB Office at 214-948-2446.

General Instructions

To maintain IRB approval in good standing, please observe the following requirements:

1. All subjects must sign the consent form before undergoing any research study procedures, including screening procedures. A photocopy of the signed consent form(s) should be given to each participant. The copy of the consent form(s) bearing original signature(s) should be kept with other records of this research for at least six years past the completion of the research study.

2. A photocopy of the signed HIPAA Authorization should be given to each participant. A copy of the HIPAA Authorization bearing original signatures should be kept with other records of this research for at least six years past the completion of the research study.

3. Obtain prior IRB approval for any modifications including addition of new recruiting materials, changes in research personnel or site location, sponsor amendments or other changes to the protocol or associated documents. Only those changes that are necessary to avoid an immediate apparent hazard to a subject may be implemented without prior IRB approval.

4. Report all adverse events, protocol violations, and study closures promptly to the IRB.

5. Make study records available for inspection. All research-related records and documentation may be inspected by the Metrocare Services IRB for the purpose of ensuring compliance with agency policies and procedures and federal regulations governing the protection of human subjects. The Metrocare Services IRB has authority to suspend or terminate its approval if applicable requirements are not strictly adhered to by all research study personnel.

APPROVED BY METROCARE SERVICES

METROCARE SERVICES SEAL

UNIVERSITY OF TEXAS ARLINGTON | OFFICE OF RESEARCH ADMINISTRATION
REGULATORY SERVICES

February 9, 2017

Edith Kanyongo
Dr. Donna Hamby
College of Nursing and Health Innovation
University of Texas at Arlington

IRB Approval Inquiry

Ms. Kanyongo,

Thank you for contacting the Office of Research Administration, Regulatory Services regarding a study to be conducted on the "5210 program" for healthy habits program in Metrocare Services. Upon reviewing the procedures involved with the study, it appears they would not meet the definition of, "research with human subjects" as defined by the Office for Human Research Protections (OHRP) and would therefore not be subject to review or approval by the Institutional Review Board (IRB) at UT Arlington. OHRP defines research as:

- A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. A human subject in research is defined as, "A living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information."

From the description of procedures provided, it appears that the intent of your project is to improve a practice in a particular clinic, and not to contribute to generalizable knowledge. Since this project would simply ensure this clinic confirms with established norms through the "5210 program," this project would not be expected to fill a gap in scientific knowledge. Your study does not meet the above definition and is not subject to IRB review. However, you are responsible for ensuring that your project is still conducted within any legal and ethical guidelines specific to your department and your field.

I have included the link for decision charts provided from OHRP from which this determination is made for your reference. If the procedures that have been outlined and provided to our office change such that IRB approval might be necessary or you have any questions regarding this determination please do not hesitate to contact me at marycolette.lybrand@uta.edu.

Thank You,

Mary-Colette Lybrand, MS, CCRP
Regulatory Services Manager
Office of Research Administration;
Regulatory Services

OHRP reference: http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

REGULATORY SERVICES
SERVICES

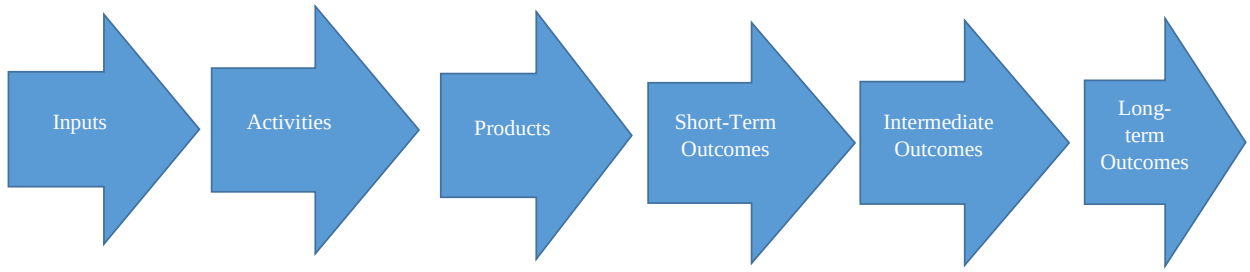
The University of Texas at Arlington, Center for Innovation
202 E. Border Street, Ste. 201, Arlington, Texas 76010, Box#19188
(T) 817-272-3723 (F) 817-272-5808 (E) regulatoryservices@uta.edu (W) www.uta.edu/rs

Appendix D. Health Belief Model

Concept	Definition **SGA adverse effects education**	Application ***Let's go 5210***
1. Perceived Susceptibility	Children/family believe they can get metabolic side effects from SGA therapy.	Children believe by taking SGAs they are at risk of metabolic side effects.
2. Perceived Severity	Children/family believe that risk of SGA adverse effects is significant enough to try to avoid.	Children believe that the consequences of taking SGAs without side effects knowledge or treatment are significant enough to try to avoid.
3. Perceived Benefits	Children/families believe that the recommended healthy habit action protect them from metabolic complications	Children/families believe that the recommended action of choosing a health habit 5210 would help them prevent weight gain and complications caused by SGA.
4. Perceived Barriers	Children will identify their barriers to eating right or excising.	Children/families will identify their personal barriers to eating 5 or more fruits and vegetables, limiting screen time to 2 hours a day, putting in one hour or more of physical activity and no sweetened beverages.
5. Cues to Action	Children will receive a prescription from provider with chosen action from the 5210 health habits recommendation, they pick their own action they are willing to do	Children will receive a prescription from provider with chosen action from the 5210 health habits. The APRN will be remind participants on
6. Self-Efficacy	Children/family will receive training oh 5210 and how they can participate in their own health.	Children will receive training oh 5210 and how they can participate in their own health. They will pick an action they will do and sustain for the entire project time

Appendix E. The Logic Model

Managing Second Generation Antipsychotic Related Weight gain in children -- Logic Model



Inputs	Activities	Products	Short-Term Outcomes	Intermediate Outcomes	Long-term Outcomes
Insurance companies Psychiatrist/Psych NP Patient and family MA Counsilor Front desk Video production	Lets go 5210 Guide lines Educational video Commitment contract Pre and posttest Weight check Training	Studies showing lack of knowledge and evidence of weight gain with SGAs educational video for patients and parents. Barlows recommendations 5210 Guidelines	Understanding of medication side effect Understanding of weight gain complications Choosing of attainable healthy action from 5210 commitment	Action on 5210 and practice of healthy habits consistently Practicing of the 5210 Increased knowledge	Improved Patient emotional stability Weight gain prevention Increased self esteem Medication adherence Prevention of weight related complications

Appendix F. Data Collection Sheet

Coded ID	Age	Sex	Race	Psych DX	SGA	Action	Pretest	post test	Pre weight	Post weigh	1st visit	2nd visit	3rd visit	

APPENDIX H. Coded Identifier List

Name	Medical Record Number	ID Number

CONSENT TO PARTICIPATE IN RESEARCH

Appendix I. Informed Consent

Title of Research: Antipsychotics, Weight Gain, and Children's Health: Making Informed Choices

Funding Agency/Sponsor: University of Texas at Arlington

Names of the investigators and those individuals who will obtain consent.

Study Doctors: Edith Kanyongo: APRN, PMHNP - BC

Research Personnel: Edith Kanyongo

You may call these study doctors or research personnel during regular office hours at (214) 689-5196. At other times, you may call them at (214)-779-1950.

Note: If you are a parent or guardian of a minor and have been asked to read and sign this form, the "you" in this document refers to the minor.

Instructions:
Please read this consent form carefully and take your time making a decision about whether to participate. As the researchers discuss this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. If you decide to participate, you will be given a copy of this form to keep.

Why is this study being done?
This study is being done to educate you and your parent/guardian on health ways of preventing weight gain that can be caused by the medicine you are taking.

Why am I being asked to take part in this research study?
You are being asked to take part in this study because you are taking medication in the second generation antipsychotic class that can potentially cause weight gain.

How many people will take part in this study?
About **40** people will take part in this study at Metrocare Services

What is involved in the study?
If you agree to be in this study, you will be asked to sign this consent form and will have the following tests and procedures. The study will take a total of 2 months from date of first visit. It consists of 3 visits that are one month apart. Each visit will last approximately 30 minutes.

Study intervention

First Visit	Second Visit	Third Visit
1. Weight Check 2. Pre-test questionnaire 3. Watch educational video 4. Meet with APRN (question and answer on video content) 5. Choose one action of choice from 5210 recommendations 6. Sign contract with APRN and receive prescription pad with action of choice from APRN	1. APRN will reemphasize education on physical activity and diet.	1. Weight check 2. Post-test questionnaire

The questionnaire and weight pre and posttests in this study are designed for research, not for medical purposes. They are not useful for finding problems or diseases. Even though the researchers are not looking at your questionnaire and weight results to find or treat a medical problem, you will be told if they notice something unusual. You and

your regular doctor can decide together whether to follow up with more tests or treatment. Because the questionnaire and weight check done in this study are not for medical purposes, the research results will not be sent to you or to your regular doctor.

How long can I expect to be in this study?

The study will take a total of 2 months from date of first visit. It consists of 3 visits that are one month apart. Each visit will last approximately 30 minutes.

You can choose to stop participating for any reason at any time. However, if you decide to stop participating in the study, we encourage you to tell the researchers. You may be asked if you are willing to complete some study termination tests.

What are the risks of the study?

Study Intervention
There are no risk factors or side effects directly associated with this study.

Psychological Stress
Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, take a break or stop your participation in this study at any time.

Loss of Confidentiality
Any time information is collected; there is a potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

What are the possible benefits of this study?
You may benefit by learning and practicing health choice of preventing medication related weight gain which will in turn prevent weight related medical complications.

If you agree to take part in this study, there may be direct benefits to you. The researchers cannot guarantee that you will benefit from participation in this research.

We hope the information learned from this study will benefit others with second generation antipsychotic medications in the future. Information gained from this research could lead to better prevention of medication associated weight gain.

What options are available if I decide not to take part in this research study?

This is not a treatment study. You do not, have to be part of it to get treatment for your condition.

Will I be paid if I take part in this research study?

There is no payment for participating in this study

Will my insurance provider or I be charged for the costs of any part of this research study?
No. Neither you, nor your insurance provider, will be charged for anything done only for this research study (i.e., the Screening Procedures, Experimental Procedures, or Monitoring/Follow-up Procedures described above).

However, the standard medical care for your condition (care you would have received whether or not you were in this study) is your responsibility (or the responsibility of your insurance provider or governmental program). You will be charged, in the standard manner, for any procedures performed for your standard medical care.

What will happen if I am harmed as a result of taking part in this study?
It is important that you report any illness or injury to the research team listed at the top of this form immediately.

Compensation for an injury resulting from your participation in this research is not available from Metrocare Services.

You retain your legal rights during your participation in this research

Can I stop taking part in this research study?
Yes. If you decide to participate and later change your mind, you are free to stop taking part in the research study at any time.

If you decide to stop taking part in this research study, it will not affect your relationship with the Metrocare Services staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

Your nurse practitioner is a research investigator in this study. She is interested in both your medical care and the conduct of this research study. At any time, you may discuss your care with another medical provider who is not part of this research study. You do not have to take part in any research study offered by your nurse practitioner.

Will my information be kept confidential?
In addition to this consent form, you will be asked to sign an "Authorization for Use and Disclosure of Protected Health Information." This authorization will give more details about how your information will be used for this research study, and who may see and/or get copies of your information.

The researchers will not, in any case, disclose information about you or your participation in this study unless it is included in the Authorization for Use and

Disclosure of Protected Health Information for Research Purposes as stated above.

Whom do I call if I have questions or problems?
For questions about the study, contact Edith Kanyongo at (214) 689-5196 during regular business hours and at (214) 779-1950 after hours and on weekends and holidays.

For questions about your rights as a research participant, contact the Metrocare Services Review Board (IRB) Office at 214-948-2446.

SIGNATURES:

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

Your signature below certifies the following:

- You have read (or been read) the information provided above.
- You have received answers to all of your questions and have been told who to call if you have any more questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. The information included in your medical record will be available to your health care providers and other authorized persons including your insurance company.

_____
Name of Participant (Printed)

_____ _____ _____ AM / PM
Signature of Participant Date Time

_____
Legally Authorized Representative's Name (Printed)

_____ _____ _____ AM / PM
Legally Authorized Representative's Signature Date Time

_____
Name of Person Obtaining Consent (Printed)

_____	_____	_____ AM / PM
Signature of Person Obtaining Consent	Date	Time

ASSENT OF A MINOR:

I have discussed this research study with my parent or legal guardian and the researchers, and I agree to participate.

_____	_____	_____ AM / PM
Participant's Signature (age 10 through 17)	Date	Time

Interpreter Statement:

I have interpreted this consent form into a language understandable to the participant and the participant has agreed to participate as indicated by their signature on the associated short form.

_____

Name of Interpreter (Printed)

_____	_____	_____ AM / PM
Signature of Interpreter	Date	Time

Appendix J. HIPPAA

Authorization for Use and Disclosure of Health Information for Research Purposes

NAME OF RESEARCH PARTICIPANT:
_____

What is the purpose of this form?
This authorization describes how information about you and your health will be used and shared by the researcher(s) when you participate in the research study: **Antipsychotics, Weight Gain, and Children's Health: Making Informed Choices:** ("Research Project"). Health information is considered "protected health information" when it may directly identify you as an individual. By signing this form you are agreeing to permit the researchers and other others (described in detail below) to have access to and share this information. If you have questions, please ask a member of the research team.

Who will be able to use or share my health information?
Metrocare Services may use or share your health information with *Edith Kanyongo* and his or her staff at Metrocare Services ("Researchers") for the purpose of this research study.

Will my protected health information be shared with someone other than the Researchers?
Yes, the Researchers may share your health information with others who may be working with the Researchers on the Research Project ("Recipients") for purposes directly related to the conduct of this research study or as required by law. These other people or entities include:

- Metrocare Services Institutional Review Board (IRB). This is a group of people who are responsible for assuring that the rights of participants in research are respected. Members and staff of the IRB at Metrocare Services may review the records of your participation in this research. A representative of the IRB may contact you for information about your experience with this research. If you do not want to answer their questions, you may refuse to do so.

- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

How will my health information be protected?
Whenever possible your health information will be kept confidential as required by law. Federal privacy laws may not apply to other institutions, companies or agencies collaborating with Metrocare Services on this research project. There is a risk that the Recipients could share your information with others without your permission. Metrocare Services cannot guarantee the confidentiality of your health information after it has been shared with the Recipients.

Why is my personal contact being used?
Your personal contact information is important for the Metrocare Services research team to contact you during the study. However, your personal contact information will not be released without your permission.

What health information will be collected, used and shared (disclosed)?
The Researchers will collect List of medications and other treatments, diagnosis, and vital signs.

Will my health information be used in a research report?
Yes, the research team may fill out a research report. (This is sometimes called "a case report".) The research report will not include your name, address, or telephone or social security number. The research report may include your date of birth, initials, dates you received medical care and a tracking code. The research report will also include information the research team collects for the study.

Will my health information be used for other purposes?
Yes, the Researchers and Recipients may use your health information to create research data that does not identify you. Research data that does not identify you may be used and shared by the Researchers and Recipients in a publication about the results of the Research Project or for other research purposes not related to the Research Project.

Do I have to sign this authorization?
No, this authorization is voluntary. Your health care providers will continue to provide you with health care services even if you choose not to sign this authorization. However, if you choose not to sign this authorization, you cannot take part in this Research Project.

How long will my permission last?
This authorization has no expiration date. You may cancel this authorization at any time. If you decide to cancel this authorization, you will no longer be able to take part in the Research Project. The Researchers may still use and share the health information that they have already collected before you canceled the authorization. To cancel this authorization, you must make this request in writing to: Edith Kanyongo: Tel: (214)779-1950.

Will I receive a copy of this authorization?
Yes, a copy of this authorization will be provided to you.

Signatures:

By signing this document, you are permitting Metrocare Services to use and disclose health information about you for research purposes as described above.

_____ _____

Signature of Research Participant Date Time: AM/PM

For Legal Representatives of Research Participants (if applicable):

Printed Name of Legal Representative: _____

Relationship to Research Participant: _____

I certify that I have the legal authority under applicable law to make this Authorization on behalf of the Research Participant identified above. The basis for this legal authority is: _____ _____.

(e.g. parent, legal guardian, person with legal power of attorney, etc.)

_____ _____

Signature of Legal Representative Date Time: AM/PM

Appendix L--- Intervention Steps

First Visit	Second Visit	Third Visit
7. Sign HIPPAA and Consent 8. Pre-tests by APRN 9. Weight check 10. Watch educational video 11. Meet with APRN (question and answer on video content) 12. Choose one action of choice from 5210 recommendations 13. Sign contract with APRN and receive prescription pad with action of choice from APRN	2. APRN will reemphasize education on physical activity and diet.	3. Weight check 4. Post-tests by APRN

Appendix N. Prescription Pad

Pediatric
WELLNESS

American College of Osteopathic Pediatricians (ACOP)

NAME: _____ DATE: _____

BMI: _____ <85% _____ 85-95% _____ >95% _____

(BODY MASS INDEX)

Rx

ACOP PRESCRIPTION FOR HEALTHY LIVING

5-2-1-0 EACH DAY

5: FRUITS OR VEGETABLES

2: LESS THAN 2 HOURS OF TV/COMPUTER/VIDEO GAMES

1: AT LEAST 1 HOUR OF PHYSICAL ACTIVITY

0: CALORIES FROM SWEETENED DRINKS

RETURN IN _____ MONTHS FOR WEIGHT RECHECK

PLEASE RETURN FASTING FOR THE FOLLOWING LABS: ❑GLUCOSE ❑LIPIDS ❑AST/ALT

FOR ADDITIONAL RESOURCES, PLEASE VISIT www.ACOPeds.org

_____

SIGNATURE

(ACOP, 2016)

References

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