Mitigating Weight Gain with Atypical Antipsychotic Medication: Caregiver Education

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Abstract

Recommended first-line treatment with atypical antipsychotic medication for management of schizophrenia and other psychotic disorders is contributory to weight gain and associated comorbidities. Beyond comorbid conditions – weight gain can lead to poor self-image, poor compliance and treatment outcomes in an already stigmatized population.

Caregivers were selected as participants as they are a primary support in this population. In alignment with the Health Belief Model the purpose of this evidence-based intervention was to increase risk awareness, increase knowledge of strategies to offset risk, increase confidence and self-efficacy and empower health related behaviors among caregivers. Participants were identified by providers in an outpatient mental health clinic as caregivers of patients prescribed atypical anti-psychotic medications adults aged 18 and above, able to read and understand English, and agree to provide consent. They were asked to (1) complete a demographic and knowledge pre-test, gauge perceived knowledge/confidence, (2) view an educational PowerPoint focused on atypical anti-psychotic medications, benefits, risks and strategies to mitigate weight-gain, and (3) complete a knowledge post-test and gauge perceived knowledge/confidence.

Descriptive statistics were used to examine distribution of variables, due to small sample size, Wilcoxon Signed Ranks test was used to compare outcomes. Qualitative data was also gathered to further develop interventions and inform practice. Comparison between pre- and post-test analysis demonstrated improvement in all areas of knowledge, perceived knowledge, and perceived confidence. Statistical analysis demonstrated statistical significance and high practical significance. One-hundred percent of participants recommended the intervention and provided qualitative feedback, and suggestions that may be used to inform practice.

Keywords: schizophrenia, weight, diet, exercise, antipsychotic, intervention, caregiver
Mitigating Weight Gain with Atypical Antipsychotics

Individuals with mental illness, specifically schizophrenia, are at an increased risk for mortality and morbidity due to the nature of their disease, their lifestyle choices, and side effect profile of first line medications (Van Gaal, 2006). Atypical anti-psychotics, also called second generation antipsychotics are often prescribed as the preferred treatment for schizophrenia since they have a reduced risk for development of extra pyramidal symptoms (EPS) in comparison with first-generation antipsychotics. However, the side effect profile of atypical antipsychotic medication is such that there is an increased risk for metabolic comorbidities generally following the development of weight gain. The overall risk potentiates the development of cardiovascular disease, diabetes, decreased energy, and increased stress on the musculoskeletal system (Xiao, Baker, & Oyewumi, 2012). The addition of side effects, especially weight gain, further jeopardizes well-being already compromised by mental illness or may lead to non-compliance which is a detriment to any progress that has been made toward improvement in psychiatric symptoms. Strategies that are designed to mitigate weight gain could offset the physiological risk profile and potentially improve compliance and effective management of psychiatric symptoms.

Problem Statement

Undesirable side effects of atypical antipsychotics such as weight gain, in an already compromised population could effectively reduce treatment compliance and thereby efficacy. Providers efforts to mitigate risk factors contributing to weight gain could improve treatment outcomes by eliminating or significantly reducing undesirable side effects. A meta-analysis evaluating numerous approaches to mitigating metabolic side effects revealed that non-pharmacological interventions including nutrition and exercise programs were effective at
reducing weight gain and other risk factors in patients taking antipsychotic medication (Caemmerer, Correll, & Maayan, 2012). Approaches that are supplemental to medication could yield a better quality of life by addressing mental and physical well-being.

Furthermore, patients who are hospitalized or otherwise encounter a provider to address symptoms of psychiatric illness have the advantage of a provider and healthcare team present to aide in treatment success and recognition of risks and how to mitigate them. These same patients are essentially expected to follow treatment guidelines upon discharge or cessation of encounter or hospitalization. However, patients with illness such as schizophrenia requiring treatment with atypical antipsychotic medication may already be at a disadvantage when unsupervised due to cognitive deficits or otherwise functional impairments. In order to offset that disadvantage and also optimize treatment efforts while mitigating risks it is necessary to capitalize on the use of primary supports in the home or residential setting. This role is generally designated to family or other caregivers that have assumed a role of responsibility in caring for the patient but is generally not another healthcare provider.

Purpose and Rationale

The purpose of this paper is review evidence regarding the contributory factors of weight gain in patients taking atypical antipsychotics, and how to incorporate caregiver responsibility in efforts to mitigate the development of weight gain by empowering action toward health related behaviors. Current research and literature will be examined to identify strategies that have demonstrated efficacy at reducing the incidence and progression of weight gain associated with atypical antipsychotics as well as caregiver perception of risk and likelihood of efforts toward mitigation. The rationale for inquiry is to develop a plan for mitigating the undesirable side effect of atypical antipsychotic medications that incorporates caregiver support. Interventions
aimed at lifestyle modifications including increasing activity and maximizing nutritional intake can potentially mitigate risks to overall physical and mental health and well-being. Increasing caregiver knowledge of risk and benefit of intervention may increase caregiver support, longevity and ongoing success.

**Background and Significance**

**External Evidence**

The risk for obesity is 1.5-2 times higher for patients with schizophrenia than in the general population, putting them at a greater risk for development of metabolic syndrome which is the leading cause for mortality and morbidity among patients with schizophrenia (Bonfioli, Berti, Goss, Muraro, & Burti, 2012; Riordan, Antonini, & Murphy, 2011; Xiao et al., 2012). Weight gain is the most noticeable sign of metabolic syndrome, is often the most distressing to the patient, and is a precursor for additional metabolic side effects such as increased blood pressure, triglycerides, and blood glucose (Koch & Scott, 2012). Additionally, evidence has shown a history or diagnosis of schizophrenia can negatively impact treatment determinations and referral to supplemental treatment such as weight management (Sullivan et al., 2015). The study indicates that the prejudice is based on the expectation that the patient will be unable to effectively adhere to treatment, comprehend education material, manage treatment or make appropriate treatment decisions. Additionally, in the absence of a healthcare provider after discharge or cessation of high frequency encounters with a healthcare team, evidence suggests that family and caregiver involvement is associated with decreased incidence of relapse, maximizing treatment benefits while minimizing risk and improving overall treatment outcomes (Britto, 2014; Chovil & Panagiotopoulos, 2010; Eteamah, 2016). The combined evidence
suggest that caregiver education is desirable and beneficial to both patients as well as caregivers and other key stakeholders in the healthcare community and general population.

**Internal Evidence**

In observation of individuals seeking psychiatric care in an inpatient setting, there is a phenomenon of weight gain, specifically relative to patients taking atypical antipsychotic medications. Furthermore, undesirable side effects such as weight gain often precede decreased compliance and development of apathy toward continued treatment of schizophrenia, or poor management of weight gain and other metabolic side effects leading to a decline in overall health. This is also observable in the outpatient setting, especially among patients who are newly diagnosed with schizophrenia and have self-reported weight gain despite no reported significant changes in their diet.

Since there is a reasonable expectation of care from the provider, but time with the provider is often limited, the responsibility of care translates to lower levels of care that assume the role of primary support. Furthermore, since the responsibility of care is often passed to family or other caregivers that are not healthcare providers – there is a reasonable expectation of knowledge deficit. However, empirical evidence in both inpatient and outpatient settings demonstrates that caregivers are reaching out, requesting information, and reporting a general lack of resources for ongoing support.

**Review**

Multiple sources were reviewed for information regarding caregiver involvement in treatment of patients with schizophrenia or other disorders and/or taking atypical antipsychotic medication. Evidence indicates that patients with mental illness can be socially isolative which limits their propensity toward physical activity and interaction with others outside of their
primary support group (Cooper, et al., 2016). Social isolation can be limiting to both physiological and psychiatric treatment efficacy which increases the degree to which primary support providers such as caregivers or family should have access to the tools needed to be effective at managing treatment. Additionally, evidence suggest that family members and other caregivers of patients with schizophrenia and/or taking atypical antipsychotic medication who participate in treatment and education programs are interested in learning, report a higher level of skill and knowledge after participation, and are better able to monitor and intervene throughout the treatment course as needed (Britto, 2014; Chovil & Panagiotopoulos, 2010; Eteamah, 2016). If caregivers are seeking information, and able to acquire and accommodate new knowledge – it seems prudent to facilitate the instillation of knowledge.

Since it has been established that there is a health disparity with regard to weight gain related to atypical antipsychotic use and there is evidence to support that caregivers are willing and able to participate actively in facilitating successful treatment, it is necessary to review approaches to management of weight gain and apply key principles and recommendations to a caregiver centered education. To examine effective approaches to management of weight gain, multiple studies were reviewed for efficacy. Deng (2013), suggests that identifying the underlying mechanism for the development of symptoms such as weight gain, intra-abdominal obesity, glucose dysregulation and insulin resistance is an effective approach to treatment of metabolic side effects. In recognition of the effects of antipsychotics on appetite and weight gain, it follows that a program or intervention that addresses these elements can significantly reduce the risk potential. Xiao et al. (2012) introduces several barriers to the management of weight gain and development of metabolic side effects identified by patients, including limited access to resources, lack of structure in their lifestyle, and the rapidity of the weight gain.
Recognizing barriers from the patient perspective is an important consideration in treatment. Vanderhoef (2012) examined the healthcare delivery model and follow-up of a provider group and suggested that an integrative approach to treatment of seriously mentally ill patients was optimal for improving outcomes and successful treatment. An integrative approach in this population would address the psychiatric elements while acknowledging the physiological impact and providing preventative measures. The integrated approach could include the supplementation of pharmacotherapy with nutritional and exercise education. The summary of the review of literature indicates information indicates that an effective approach to both the treatment of schizophrenia and the management of weight gain associated with first-line treatment is multifaceted. An effective approach includes identification of causative factors, consideration of barriers such as access to resources and information, integration of psychiatric and physiological elements and inclusion of primary support or caregivers.

A meta-analysis that reviewed several clinical trials determined that intervention groups with a combination of nutritional counseling and exercise show the most substantial reduction in weight and associated risk factors (Das, Mendez, Jagasia, Labbate, & National Library of Medicine, 2012). Furthermore, lifestyle interventions including dietary and activity modifications may be important long-term strategies that decrease the risk of weight gain and the compounding metabolic effects that follow (Attux et al., 2013).

Multiple studies applied principles from PREMIEIR and DASH comprehensive approaches to weight loss or management in sample populations of patients with schizophrenia and/or taking atypical antipsychotic medications and found that these approaches were more effective at weight management than pharmacological therapy alone (Green et al., 2015; Usher, Park, Foster, & Buettner, 2013; Erikson, Mena, Pierre, Blum, & Martin, 2016; Scheewe, Backx,
The format of each program varied slightly, however generally compared a control group receiving treatment as usual involving pharmacological treatment with antipsychotic medication and informed consent with standard review of indications, risks and benefits. Green et al (2015) and Erikson et al (2016) showed evidence that the intervention of dietary and exercise support in addition to standard treatment was effective at weight reduction in comparison with control groups. Another study utilized a nurse led intervention program included diet and exercise combined with motivational interviewing over a 12-week period. Other studies involving a similar format yielded results that did not demonstrate a statistically significant decrease in weight for the intervention group but did indicate a notable increase in weight for the treatment as usual group (Usher, Park, Foster, & Buettner, 2013; Scheewe, Backx, Takken, Jorg, & Van Strater, 2013). Despite insignificant weight-loss, outcome measurements in other areas of well-being strongly favored the intervention groups (Scheewe et al, 2013).

The review of literature indicates that there is both evidence supporting the implementation of a comprehensive approach to treatment that addresses psychiatric and physiological elements and indications that patient outcomes are generally better with the involvement of caregiver or primary support. Since there is a relevant body of evidence supporting comprehensive intervention and evidence demonstrating both a caregiver knowledge deficit and desire to learn and participate more actively – the provision of an educational intervention for caregivers should empower intervention and facilitate treatment success.

This inquiry has led to the clinically relevant PICOT question: In adult caregivers of patient prescribed atypical antipsychotic medication (P), how does an educational intervention (I)
compared to no education (C) affect their knowledge, perceived knowledge and self-efficacy relative to the content presented to them (T) immediately following presentation delivery?

**Search Process**

To gather evidence regarding the clinical question, an exhaustive search of the literature was completed. Three databases – PubMed, CINAHL and PsycINFO- were searched using the keywords (with Boolean connectors) weight (and) antipsychotic (and) intervention (and) exercise (or) nutrition. Restrictions including English language, only human subjects, published between 2012 and 2017. Initial yields were reviewed for relevance to PICOT, and outcomes. Studies that included supplementary pharmacological intervention for weight loss were excluded. Inclusion criteria included primary goal of weight reduction or prevention of weight gain and primary intervention as education or intervention involving nutritional or activity modifications (exercise). Additionally, searching of reference lists within articles yielded additional studies that were reviewed for applicability to PICO. Further searches were conducted to include articles and research specifically addressing caregiver involvement in treatment of patients with schizophrenia and/or taking atypical antipsychotic medication.

The PubMed database was assessed using keywords and inclusion criteria and yielded 17 articles, of which 7 were selected for review (Appendix A). CINAHL database was assessed using keywords and inclusion criteria and yielded 7 articles (Appendix B). After excluding duplicate studies, only 1 additional article was selected for further review. PsychINFO database was reviewed using the same keywords and search criteria and yielded 21 articles (Appendix C). After review for relevance and removal of duplicate items, 2 articles were selected for further evaluation. Each study was reviewed independently and for relevance to PICO and pertinent date to complete evaluation tables.
Critical Appraisal and Synthesis of Evidence

There were ten articles reviewed regarding the use of interventions to mitigate weight gain in patients prescribed atypical antipsychotic medications. The studies included data from USA, Brazil, Australia, and the Netherlands with the highest concentration in the USA (Appendix F). All the articles were recently published within the last five years (Appendix D). Majority sample selection included males and females age 18 and above, recently started in atypical antipsychotic medication for the management of schizophrenia or other related thought disorder. Most of the interventions were in outpatient and community setting, and most involved a combination approach to intervention that was compared to standard treatment. Length of intervention period were ranged from 6 weeks to 1 year and had a frequency of one or more times per week. Level of evidence was strong with design as follows RCT (5), MA (3), PCS (1), and RCR (1) (Appendix D). The meta-analysis (MA) subgroup showed heterogeneity of results respective to weight and other factors, especially when intervention categories were variable.

Conclusions & Discussion

Non-pharmacological interventions involving lifestyle modifications to diet and exercise generate universally better outcomes than control groups offering treatment as usual, generally including pharmacological intervention with standard informed consent. There is some evidence that psychotherapeutic interventions such as motivational interviewing or 1:1 counseling may increase efficacy of treatment and facilitate more positive outcomes. Additional article review for connection with caregiver involvement in treatment efforts demonstrated that caregivers not only had a deficit of knowledge, and wanted to be involved, but that their involvement supported overall treatment success and improved treatment outcomes. The evidence supports implementation of an intervention that is delivered to caregivers which is aimed at weight loss
that includes information regarding dietary modification and increased activity combined with ongoing education and follow-up. Furthermore, outcomes indicate a propensity toward successful outcomes and supports a practice change which includes an educational program directed toward caregivers as well as patients that targets lifestyle modifications such as diet and exercise to offset risks associated with atypical antipsychotic medication.

**Theoretical Framework**

The health belief model is appropriate for an intervention that promotes healthy behavior based on education and promotion of awareness of risk potential (Butts & Rich, 2015). By increasing the awareness of indications and risks of atypical antipsychotic medications, the identification of both strategies for mitigating the risk of weight gain as well as the benefits therein – the increased knowledge and self-efficacy should empower health related behaviors. For the purposes of this intervention the empowerment of caregivers to engage in the health behavior of aiding those in their care to offset the risks associated with their risk profile of their medications. The awareness of risk potential relative to the side effect profile and the long-term effects of continued treatment without intervention could be motivating factor.

**Evidence Based Practice Model**

The model for evidence-based practice change, a revised version of the model by Rosswurm and Larrabee is appropriate for implementation of an intervention to mitigate weight gain in patients taking atypical antipsychotics (Melnyk & Fineout-Overholt, 2015). As indicated in the model (Appendix E), there is an identified need for a change in practice based on internal evidence and compiled high-level external evidence respective of the nature of the problem and common intervention strategies that have proven successful. In moving forward development of an intervention involving caregiver education regarding atypical antipsychotic medication –
indications, risks (i.e. weight gain), strategies to mitigate risk and benefits of intervention. Implementation and evaluation of change with positive immediate outcome – increased knowledge and self-efficacy - should facilitate empowerment to engage in health related behaviors and perpetuate the practice change. This is an appropriate model for this intervention as it translates synthesis of evidence and critical thought into a change in practice that is patient centered while still benefiting key stakeholders. The initial steps have been completed within the synthesis of current evidence supporting the significance of the problem and effective intervention strategies. IRB approval was obtained following submission of proposal and project has been successfully implemented within the target population. Further study and analysis could be generated from successful application of learned information into the patient population and perpetuated.

**Proposed EBP**

**Project Outline**

Proposed intervention is aimed at increasing the knowledge and self-efficacy of caregivers by providing an evidence based educational intervention introducing information about treatment with atypical antipsychotic medication. Specific education is provided relative to indications for atypical antipsychotic medication use, risks associated with use with specific attention to weight gain and associated comorbidities, followed by evidence-based strategies for mitigating weight gain with specific focus on monitoring, dietary modifications, and increasing activity. This intervention is aligned with external evidence that supports the use of education regarding disease management and prevention (Attux et al., 2013; Caemmerer et al., 2012; Das et al., 2012; Erikson, Mena, Pierre, Blum, & Martin, 2016; Green et al., 2015; Scheewe et al.,
2013; Usher et al., 2013; Vanderhoef, 2012). Intervention had a total duration of approximately 1-2 hours allowing for introduction, pre-test, educational powerpoint, questions and post-test.

Fortunately, there were not many obstacles to overcome. There was an initial delay in recruitment due to IRB approval, however once approved recruitment was smooth and efficient. Other potential complication with the use of survey and educational material is literacy and understanding of content – fortunately the very few misunderstandings were clarified and did not have an impact on time or results.

Methods

Design

The study design was quasi-experimental, one group, pre-test and post-test and based on the Model for Evidence Based Practice change by Rosswurm and Larrabee and the Health Belief Model (Melnyk & Fineout-Overholt, 2015; Butts & Rich, 2015).

Sample and Sampling

A convenience sample of 15 participants were recruited from a small outpatient psychiatric clinic in Goodyear, Arizona. The inclusion criteria were adults age 18 and above who (1) identify themselves as primary caregivers of patients taking atypical antipsychotic medication for psychotic disorders and receive treatment from Agape Family clinic; (2) are able to read, write and understand English; (3) agree to provide consent. Individuals who do not meet all inclusion criteria or decline participation would be excluded.

Procedure

Caregivers were identified in collaboration with psychiatric providers. Caregivers who were interested in participation contacted the author via information provided on flyer. The author also contacted potential participants identified and referred by psychiatric providers.
During initial interaction the author introduced herself, the purpose of the project, procedure and potential risks and benefits of participating in the project. Caregivers who consented to participate were enrolled.

Eligible caregivers who consented were invited to a one-hour educational presentation held in the clinic. They completed a short pretest survey including demographic information, followed by a PowerPoint presentation delivered by the author, then completed the post-test survey. The PowerPoint presentation included content regarding indications, potential side-effects, risks and benefits of atypical antipsychotic medications, and strategies to reduce side effects especially weight gain associated with these medications. Participants were given the opportunity to ask questions during the presentation. The pretest and posttest surveys were brief (5-10 minutes each to complete), anonymous and linked by a nickname created by participants.

**Measures**

Sociodemographic information, knowledge assessment, perceived knowledge, perceived self-efficacy, and project evaluation.

1. **Sociodemographic information** – questions asked each patient's age, biological sex, highest educational level, relationship to patient, duration of providing care, observation of weight gain, and names of medications taken by patient. These questions were asked in pretest only.

2. **Knowledge assessment** - included 6 questions assessing participant knowledge of relative information based on content of PowerPoint presentation. The questions were multiple choice with only one correct answer for each question. The same 6 knowledge assessment questions were asked on pre- and post-tests for comparison.
3. Perceived knowledge self-assessment – included one question assessing perceived knowledge with a scaled format ranging from little to no knowledge, somewhat knowledgeable, more knowledgeable than most people I know and expert knowledge. The same question was asked on pre- and post-test for comparison.

4. Perceived self-efficacy – included one question assessing perceived knowledge with a scale format ranging from not confident at all, a little bit confident, confident and very confident. The same question was asked on pre- and post-tests for comparison.

5. Project evaluation – included 3 questions assessing perceived benefits, recommendation of presentation and additional suggestions. The questions were open ended for feedback.

Data Analysis

Descriptive statistics were used to describe sample characteristics and examine distribution of variables. Non-parametric methods were used due to small sample size in which normal distribution of data is not assumed (Kellar & Kelvin, 2013). Wilcoxon Signed Ranks test was used to compare data collected at pretest and posttest. Cohen’s D coefficient was used to calculate effect size where small effect size is 0.2, moderate effect size is 0.5, and large effect size is 0.8 (Kellar & Kelvin, 2013).

Results

Sample Characteristics

A total of 15 adult participants (66% female, 33% age 18-29, 33% age 40-49, 40% completed high-school) completed the education and pre- and post-test. About 67% of them identified themselves as a parent or other caregiver. The mean duration for a patient taking atypical antipsychotic medication is 6 years. About 33.3% of patients were reportedly taking
Risperdal, 26.7% taking Seroquel, 26.7% taking Zyprexa, 6.7% taking Abilify, and 6.7% taking more than one atypical antipsychotic medication. All participants reported weight gain in patients after starting the identified medications.

Measures

The mean pre-intervention knowledge score was 3.33 (SD = 1.88, range = 0-6). The mean post-intervention knowledge score was 5.86 (SD = 0.52, range = 0-6). Findings from the Wilcoxon Signed Ranks test indicated the change (Z=−3.077, p=0.002) was statistically significant. Findings from Cohen’s effect size value (d= 1.3) suggest large effect size and high practical significance.

Perceived Level of Knowledge

The mean pre-intervention score for perceived knowledge was 1.6 (1=little to no knowledge, 2= somewhat knowledgeable, 3= more knowledgeable than most people I know, 4= Very knowledgeable). About 40% of participants indicating 1 (little to no knowledge) and 60% percent indicating 2 (somewhat knowledgeable) relative to their perceived knowledge of the content. The mean post intervention score for knowledge was 2.8, 20% of participants indicating 2 (somewhat knowledgeable) and 80 percent indicating 3 (more knowledgeable that most people I know). Wilcoxon Signed Ranks test indicated the change (Z=−3.448, p=0.001) was statistically significant. Findings from Cohen’s effect size value (d=2.1) suggest large effect size and high practical significance.

Perceived Confidence

The mean pre-intervention score for perceived confidence was 1.93 suggesting between not confident and a little bit confident (1=not confident, 2=a little bit confident, 3=confident, 4=very confident). About 53.3% of participants indicated 2 (a little bit confident), 26.7% of
participants indicated 1 (not confident) and 20% of participants indicated 3 (confident) relative to their perceived confidence in the subject area and applying intervention. The mean post-intervention score for perceived confidence was 3.4 with 46.7 percent of participants indicating 4 (very confident), 46.7% of participants indicating 3 (confident) and 6.7% of participants indicating 2 (somewhat confident). Wilcoxon Signed Ranks test indicated that the change from pre-test to post-test scores ($Z=-3.376$, $p=0.001$) was statistically significant. Findings from Cohen’s effect size value ($d=1.8$) suggest a large effect size and high practical significance.

**Project Evaluation**

Participants were invited to evaluate the educational presentation and overall intervention. All (100%) of participants responded that they would recommend this presentation to others. When asked to provide rationale for their response to their recommendation they felt it was helpful to discuss indications of the medications, timing and onset of weight gain, cardiovascular risks, and health benefits of changes in diet and exercise. They also found it helpful to learn strategies to help patients manage their weight while taking antipsychotic medications. The participants suggested to offer this presentation to “everyone”, “all new patients”, “including more examples of food choices and food logs”, and “rewording some questions”.

**Discussion**

The potential short-term implications for practice change include the implementation of similar educational interventions for caregivers in similar and other practice settings. Additionally, as recommended by participants – inclusion of patients in similar structured educational intervention would also be useful. The short term-benefit for participants is the actual increase in knowledge and confidence and resultant empowerment to act. The use of
small group intervention alleviates the need for separate additional time to be accommodated into an already busy schedule, and the presence of groups of individuals with similar needs helps build an additional secondary support network while also allowing providers to keep current with the questions and concerns within their target population.

Intermediate or long-term implications that result from the empowerment of participants is the actual implementation within the patient population of learned interventions potentially yielding less incidence of weight gain and the development of metabolic comorbidities which translates to improved treatment outcomes, less medication changes, decreased need for face time, decreased need for coordination of care with specialized providers and overall improvement in well-being. Future dissemination of evidence is planned for other similar outpatient mental health providers and at a local conference.

**Conclusion**

The overall efforts of this evidence-based intervention were inspired by the need to mitigate the weight gain associated with use of atypical antipsychotic medication. Since this is the first line medication choice for schizophrenia and other similar disorders which already carry an increased risk for mortality and morbidity, and an increased risk for weight and metabolic disorders -there is a unique dilemma. Furthermore, many patients are stabilized and treated on an outpatient basis without ongoing high frequency support and direction of a healthcare team leaving an already vulnerable individual essentially more vulnerable with additional risks. The dilemma then is to effectively manage psychiatric condition while mitigating the development of a physiological one without the daily support of a healthcare provider. The intervention utilized for this project was to provide education to caregivers – the effective primary support person for patients with schizophrenia needing additional support. Following the health belief model, the
increase in knowledge and self-efficacy, will empower individuals to engage in health-related behaviors. While it is unknow at this time the frequency of enactment of learned information – data analysis demonstrates statistical significance and high practical significance relative to improvements in knowledge, perceived knowledge and perceived confidence which is certainly promising and yields future implications to gather data and analyze applied principles and patient outcomes. As providers we should hold ourselves accountable to providing our patients with the best opportunity possible to achieve treatment success without being a detriment to other area of functioning. Interventions similar to this one provides additional educational support and empowerment of primary supports in the absence of a provider or healthcare team.
References


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MITIGATING WEIGHT GAIN


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http://dx.doi.org/10.3928/02793695-20121107-02


Appendix B

Database Search Strategy

CINAHL
Appendix C

Database Search Strategy

PsycINFO/ProQuest
### Appendix D

#### Synthesis Table

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Appendix E

EBP Model
Appendix F

Quantitative Studies

Table 1
Evaluation Table

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<th>Design/ Method</th>
<th>Sample/ Setting</th>
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<td>Health Belief Model</td>
<td>Multicentral, RCT</td>
<td>n= 160 patients participated in the study (81 in the IG and 79 in the CG group).</td>
<td>DV1 – Weight</td>
<td>Scale Measuring Tape</td>
<td>Two-sided t-tests and chi-square tests - to analyze the differences between the groups at baseline and during follow-up. ANOVA with repeated measures - to compare the intervention versus standard care groups over time</td>
<td>IG= - 0.48 kg (CI 95% - 0.65 to 1.13) CG = + 0.48 kg (CI 95% 0.13 to 0.83; p=0.055). @6months IG= −1.15 kg, (CI 95% -2.11 to 0.19) CG= +0.5 kg (CI 95% -0.42–1.42, p=0.017).</td>
<td>LOE: II Limitations: Short duration Small Sample size Larger sample sizes and increase intervention and follow up time could increase efficacy and improve results.</td>
</tr>
</tbody>
</table>

1:1 – Support from clinician/nurse; ACT -activity session or education; AP – Antipsychotic medication; BGL -blood glucose level; BMI- Body Mass Index; CG – control group; CI – Confidence Interval; DV-dependent variable; EDUC – education/book/pamphlet; ET – Exercise Therapy; HDLC -High Density Lipoprotein Cholesterol; IG – Intervention group; IV- independent variable; LDLC – Low density Lipoprotein Cholesterol; LWP – Lifestyle Wellness Program; MetS -Metabolic Syndrome; N-number of studies; n- number of participants ; NNT -Number Needed to Treat; NPhI – Non-Pharmacological Interventions; NRCT – Non-randomized controlled trial; NUT – Nutritional education; OT – Occupational Therapy; PBF – Percent body fat; RCT- Randomized Controlled Trial; RR – Risk Ratio; SBP – Systolic Blood Pressure; TAU – Treatment as usual; TC – Total cholesterol; TRI- Triglycerides; WC – Waist circumference; WMD – Weighted Mean Difference
### Mitigating Weight Gain

<table>
<thead>
<tr>
<th>Citation</th>
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<th>Decision for practice/ application to practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bonfioli, E (2012)</td>
<td>Health belief model</td>
<td>Systematic review and meta-analysis</td>
<td>N=17 Various settings</td>
<td>DV: Weight loss, prevention of weight gain IV: Variable psychoeducational or cognitive behavioral interventions</td>
<td>Change in BMI</td>
<td>Inverse variance with random effects approach RevMan</td>
<td>IG varying from preventative ad individual lifestyle interventions including diet and physical activity shows a mean BMI reduction of 0.98, corresponding to a weight reduction of 3.12% of initial weight. 3.12% &lt; NIH guidelines, but still sufficient to show improvement. Results indicated an effect toward experimental groups with a greater mean reduction in BMI. 95% CI: -1.31 kg/m² – 0.65 kg/m²</td>
<td>LOE: I</td>
<td>Limitations: In review – poor descriptions of blinding and randomization procedure, no accounting for missing data and compensation for participants in some studies. Implications for further study include increased sample size, more in depth analysis of data with additional controls for bias and heterogeneity</td>
</tr>
</tbody>
</table>

1:1 – Support from clinician/nurse; **ACT** -activity session or education; **AP** – Antipsychotic medication; **BGL** -blood glucose level; **BMI**- Body Mass Index; **CG** – control group; **CI** – Confidence Interval; **DV**-dependent variable; **EDUC** – education/book/pamphlet; **ET** – Exercise Therapy; **HDLC** -High Density Lipoprotein Cholesterol; **IG** – Intervention group; **IV**- independent variable; **LDLC** – Low density Lipoprotein Cholesterol; **LWP** – Lifestyle Wellness Program; **MetS** -Metabolic Syndrome; **N**-number of studies; **n**- number of participants; ; **NNT** -Number Needed to Treat; **NPhI** – Non-Pharmacological Interventions; **NRCT** – Non-randomized controlled trial; **NUT** – Nutritional education; **OT** – Occupational Therapy; **PBF** – Percent body fat; **RCT**- Randomized Controlled Trial; **RR** – Risk Ratio; **SBP** – Systolic Blood Pressure; **TAU** – Treatment as usual; **TC** – Total cholesterol; **TRI**- Triglycerides; **WC** – Waist circumference; **WMD** – Weighted Mean Difference
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<tr>
<td>Caemmerer, J (2012) Acute and maintenance effects of NPhI for AP associated weight gain and metabolic abnormalities: A meta-analytic comparison of RCTs</td>
<td>Health Belief Model</td>
<td>Systematic Literature search and Meta-analysis</td>
<td>N=17 n=810 mean age: 38.8 years 52.7% male 40.8% White 85.6% with schizophrenia-spectrum disorders</td>
<td>DV: weight DV2 – BMI DV3 – HDLC DV4 – LDLC DV5 – SBP DV6 – WC DV7 – PBF DV8 – GLU DV9 – Insulin DV10 – TC DV11 – TRI</td>
<td>Data were analyzed using randomized effects models in Review Manager 5.0</td>
<td>All tests were two-sided and α = 0.05 continuous outcomes (WMD) with 95% (CI) was calculated. dichotomous outcomes: (RR) ± CI was calculated and (NNT) was derived by dividing 1 by the risk difference. Study heterogeneity was measured using I-squared statistic, with I-squared &gt; 50% indicating significant heterogeneity.</td>
<td>NPhI = WT − 3.12 kg; CI: − 4.03, − 2.21, p &lt; 0.0001 BMI= − 0.94 kg/m2; CI: − 1.45, − 0.43, p = 0.0003 WC = − 3.58 cm, CI: − 5.51, − 1.66, p = 0.03 PBF = − 2.82%, CI: − 5.35, − 0.30, p = 0.03 GLU = − 5.79 mg/dL, CI: − 9.73, − 1.86, p = 0.004 Insulin = − 4.93 uIU/mL, CI: − 7.64, − 2.23, p = 0.0004 TC = − 20.98 mg/dL, CI: − 33.78, − 8.19, p = 0.001 LDLC = − 22.06 mg/dL, CI: − 37.80, − 6.32, p = 0.006 TRI = − 61.68 mg/dL, CI: − 92.77, − 30.59, p = 0.0001</td>
<td>LOE: I Limitations: Smaller sample sizes, short duration</td>
</tr>
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1:1 – Support from clinician/nurse; ACT -activity session or education; AP – Antipsychotic medication; BGL -blood glucose level; BMI- Body Mass Index; CG – control group; CI – Confidence Interval; DV -dependent variable; EDUC – education/book/pamphlet; ET – Exercise Therapy; HDLC -High Density Lipoprotein Cholesterol; IG – Intervention group; IV- independent variable; LDLC – Low density Lipoprotein Cholesterol; LWP – Lifestyle Wellness Program; MetS -Metabolic Syndrome; N-number of studies; n- number of participants; ; NNT -Number Needed to Treat; NPhI – Non-Pharmacological Interventions; NRCT – Non-randomized controlled trial; NUT – Nutritional education; OT – Occupational Therapy; PBF – Percent body fat; RCT- Randomized Controlled Trial; RR – Risk Ratio; SBP – Systolic Blood Pressure; TAU – Treatment as usual; TC – Total cholesterol; TRI- Triglycerides; WC – Waist circumference; WMD – Weighted Mean Difference
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<tr>
<td>Curtis, J (2016)</td>
<td>Health Belief Model</td>
<td>Prospective Controlled Study</td>
<td>n= 28 IG-16 TAU - 12</td>
<td>DV1 – Weight DV2 – BMI DV3 – HDLC DV4 – LDLC DV5 – BP DV6 – WC DV7 – DV8 – BGL DV9 – Insulin DV10 – TC DV11 – TRI IV1 - health coaching IV2 - dietetic support IV3 - supervised exercise prescription IV4 – Peer Support IV5 – Medication change</td>
<td>Scale Measuring tape Glucometer Serum lab measurements</td>
<td>ANCOVA Pearson chi-square Paired-sample t-tests</td>
<td>IG= WT +1.8 kg (95% CI −0.4 to 2.8) CG= WT + 7.8 kg (4.8–10.7)</td>
<td>LOE: II Limitations: Short term follow up, small sample size</td>
</tr>
<tr>
<td><strong>1:1</strong> – Support from clinician/nurse; <strong>ACT</strong> -activity session or education; <strong>AP</strong> – Antipsychotic medication; <strong>BGL</strong> -blood glucose level; <strong>BMI</strong>- Body Mass Index; <strong>CG</strong> – control group; <strong>CI</strong> – Confidence Interval; <strong>DV</strong>-dependent variable; <strong>EDUC</strong> – education/book/pamphlet; <strong>ET</strong> – Exercise Therapy; <strong>HDLC</strong> -High Density Lipoprotein Cholesterol; <strong>IG</strong> – Intervention group; <strong>IV</strong>- independent variable; <strong>LDLC</strong> – Low density Lipoprotein Cholesterol; <strong>LWP</strong> – Lifestyle Wellness Program; <strong>MetS</strong> -Metabolic Syndrome; <strong>N</strong>-number of studies; <strong>n</strong>- number of participants; <strong>NNT</strong> -Number Needed to Treat; <strong>NPhI</strong> – Non-Pharmacological Interventions; <strong>NRCT</strong> – Non-randomized controlled trial; <strong>NUT</strong> – Nutritional education; <strong>OT</strong> – Occupational Therapy; <strong>PBF</strong> – Percent body fat; <strong>RCT</strong>- Randomized Controlled Trial; <strong>RR</strong> – Risk Ratio; <strong>SBP</strong> – Systolic Blood Pressure; <strong>TAU</strong> – Treatment as usual; <strong>TC</strong> – Total cholesterol; <strong>TRI</strong>- Triglycerides; <strong>WC</strong> – Waist circumference; <strong>WMD</strong> – Weighted Mean Difference</td>
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<tr>
<td>Das, C (2012)</td>
<td>Epidemiology</td>
<td>Critical literature review and meta-analysis</td>
<td>Sample sizes and setting varied based on intervention</td>
<td>Behavioral interventions, exercise and nutrition counseling, and pharmacological treatment implemented alone and together to determine their effect on weight changes associated with AP</td>
<td>PROC MIXED within the statistical analysis software system.</td>
<td>Reported least squares means of each treatment with CI = 95%</td>
<td>Behavioral therapies to treat weight gain associated with AP have had the most consistent beneficial results. Among the behavioral therapies, nutritional counseling combined with exercise showed the most benefit</td>
<td>LOE: I Limitations: Modest values at best, short duration Indicative of the need for increased duration of intervention and follow up</td>
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<tr>
<td>Erickson, Z (2016) Behavioral interventions for AP associated obesity: a randomized, controlled clinical trial Unable to determine Funding source No identifiable bias USA</td>
<td>Health Belief Model</td>
<td>RCT</td>
<td>n= 122 IG = 60 TAU = 62</td>
<td>DV = Weight DV2 = BMI DV3 = psychiatric symptoms DV4 = health knowledge DV5 = HgA1c DV6 = BGL DV7 = lipid levels</td>
<td>Scale Measuring tape Health knowledge quiz Glucometer Serum lab measurements</td>
<td>Intention to treat analysis</td>
<td>Our intention-to-treat analysis found significant differences in predicted trajectory of mean WT change between the groups over 12 months (P &lt; .01), with treatment participants expected to lose an average 4.6 kg, while control participants would gain an average 0.6 kg. BMI and body fat percentage followed the same pattern. Both groups demonstrated statistically significant improvements in health knowledge quiz scores over time (P = .006), without significant difference between groups.</td>
<td>LOE: II Treatment was more effective than usual care control in treating medication-associated obesity, independent of SMI diagnosis, antipsychotic medication, and knowledge gained, suggesting that behavioral interventions are effective in SMI patients</td>
</tr>
</tbody>
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1:1 – Support from clinician/nurse; ACT - activity session or education; AP – Antipsychotic medication; BGL - blood glucose level; BMI - Body Mass Index; CG – control group; CI – Confidence Interval; DV - dependent variable; EDUC – education/book/pamphlet; ET – Exercise Therapy; HDLC - High Density Lipoprotein Cholesterol; IG – Intervention group; IV - independent variable; LDLC – Low density Lipoprotein Cholesterol; LWP – Lifestyle Wellness Program; MetS - Metabolic Syndrome; N - number of studies; n - number of participants; NNT - Number Needed to Treat; NPhI – Non-Pharmacological Interventions; NRCT – Non-randomized controlled trial; NUT – Nutritional education; OT – Occupational Therapy; PBF – Percent body fat; RCT - Randomized Controlled Trial; RR – Risk Ratio; SBP – Systolic Blood Pressure; TAU – Treatment as usual; TC – Total cholesterol; TRI- Triglycerides; WC – Waist circumference; WMD – Weighted Mean Difference
### Conceptual Framework & Definitions

#### Conceptual Framework

- **Health Belief Model**
  - RCT Multi-site
  - Purpose: to assess whether a lifestyle intervention, tailored for individuals with serious mental illnesses, reduced weight and diabetes risk

#### Definitions

- **DV** = Weight
- **DV2** = BMI
- **DV3** = BGL
- **IV** = The intervention emphasized moderate caloric reduction, the DASH (Dietary Approaches to Stop Hypertension) diet, and physical activity

#### Instrumentation

- Scale
- Measuring Tape
- Glucometer

#### (stats used)

- Wald Test

#### Results

- IG lost 4.4 kg more than CG at 6 months
- IG lost 2.6 kg more than CG at 12 months
- No significant difference during maintenance period

### Citation

Green, C (2015) The STRIDE Weight Loss and Lifestyle Intervention for Individuals Taking Antipsychotic Medications: A Randomized Trial

- Funded by multiple supporters
- No identifiable bias
- USA

### Theory/Design/Method

- **Citation**
- **Theory/ Method**
- **Sample/ Setting**
- **Major Variables**
- **Measurement/ Data Analysis**
- **Findings/ Level/Quality of Evidence:**

### Evidence: Decision for practice/application to practice

- **LOE:** II
- Strengths: increasing the reach and duration of the intervention is an important first step
- Weaknesses: no measure of severity of illness
<table>
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<td></td>
<td>inclusion criteria: age of 18+ diagnosed with schizophrenia, schizoaffective disorder, bipolar disorder, mood disorder not otherwise specified or psychotic disorder not otherwise specified being treated with atypical AP</td>
<td>DV2 - fasting BGL DV3 – triglycerides DV4 - cholesterol</td>
<td>CI – 95% P&lt;0.05</td>
<td>The use of EBP guidelines demonstrated a reduction in risk and incidence of factors associated with metabolic MetS, specifically the four identified DV</td>
<td>Limitations: Lack of consideration for pre-existing conditions and medications</td>
<td></td>
</tr>
</tbody>
</table>
### Framework

<table>
<thead>
<tr>
<th>Scheewe, T. (2013)</th>
<th>Health Belief Model</th>
<th>RCT</th>
<th>Purpose: The objective of this multicenter randomized clinical trial was to examine the effect of exercise versus occupational therapy on mental and physical health in schizophrenia patients.</th>
</tr>
</thead>
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<tr>
<td></td>
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<td>n = 63 ET = 31 OT = 32 Inclusion: IQ &gt; 70 diagnosed with schizophrenia (n = 45), schizoaffective (n = 15), or schizoaffective disorder (n = 3), stable on AP, taking the same dosage for at least 4 weeks prior to inclusion</td>
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<td>Exclusion: Primary diagnosis of substance abuse or alcoholism Evidence of significant cardiovascular, neuromuscular, endocrine or somatic disorder preventing safe participation in the study</td>
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<tr>
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<td>DV1 - CV DV2 - MHSS Schizophrenia DV3 - MHSS Depression DV5 - BMI DV6 - PBF DV - MetS IV1 - ET IV2 - OT cardiovascular fitness levels as assessed with a cardiopulmonary exercise PANS (Positive and Negative Syndrome Scale) MADRS (Montgomery and Asberg Depression Rating Scale) CAN (Camberwell Assessment of Needs) Scale Measuring tape Skin-fold Caliper 2-tailed P&lt;0.05 Multiple analysis of variance for non-categorical variables Chi Square analysis for categorical variables</td>
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<td>Intention-to-treat analyses showed ET had a trend-level effect on depressive symptoms (P = 0.07) and a significant effect on cardiovascular fitness, measured by Wpeak (P &lt; 0.01), compared with OT. Per protocol analyses showed that ET reduced symptoms of schizophrenia (P = 0.001), depression (P = 0.012), need of care (P = 0.050), and increased cardiovascular fitness (P &lt; 0.001) compared with OT. No effect for MetS (factors) was found except a trend reduction in triglycerides (P = 0.08).</td>
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</tbody>
</table>

### Limitations

- Drop rate, poor compliance
- Implications for increasing sample size and duration of treatment and follow up may be warranted.

### Level/Quality of Evidence

| LOE: II |

### Citation

Usher, K (2013) - A randomized controlled trial undertaken to test a nurse-led weight management and exercise intervention designed for people with serious mental illness who take second generation antipsychotics. Funded by Queensland Nursing Council grant and a grant from Eli Lilly. No identified bias. Australia.

<table>
<thead>
<tr>
<th>Framework</th>
<th>Health Belief Model</th>
<th>Experimental RCT</th>
<th>n= 101</th>
<th>DV1 – WT</th>
<th>DV2 – WC</th>
<th>DV3 – BMI</th>
<th>IV1 – EDUC</th>
<th>IV2 – ACT</th>
<th>IV3 – NUT</th>
<th>IV4 – 1:1</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>CG = 51</td>
<td>IV1 – EDUC</td>
<td>IV2 – ACT</td>
<td>IV3 – NUT</td>
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<td></td>
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<td>IG = 50</td>
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<td>Setting was variable</td>
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<td>Inclusion Criteria: a diagnosis of serious mental illness, 18 years of age or older, not currently psychotic, prescribed and taking second generation antipsychotic medication, living in North Queensland, and able to speak and read English.</td>
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<th>Scale</th>
<th>Measuring Tape</th>
<th>Unpaired t-test</th>
<th>Chi-squared test</th>
<th>Mann-Whitney Wilcoxon U-test</th>
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<tr>
<td>IG</td>
<td></td>
<td>(0.74 \text{ kg})</td>
<td>(0.23 \text{ cm})</td>
<td>(0.05 \text{ kg/m}^2)</td>
</tr>
<tr>
<td>CG</td>
<td></td>
<td>(0.17 \text{ kg})</td>
<td>(0.15 \text{ cm})</td>
<td>(0.06 \text{ kg/m}^2)</td>
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Statistical analysis revealed – results not statistically significant.

LOE: II

Strengths: integrated approach

Limitations: short duration, not blinded, location, no gauge for comprehension

1:1 – Support from clinician/nurse; ACT -activity session or education; AP – Antipsychotic medication; BGL -blood glucose level; BMI- Body Mass Index; CG – control group; CI – Confidence Interval; DV -dependent variable; EDUC – education/book/pamphlet; ET – Exercise Therapy; HDLC -High Density Lipoprotein Cholesterol; IG – Intervention group; IV - independent variable; LDLC – Low density Lipoprotein Cholesterol; LWP – Lifestyle Wellness Program; MetS -Metabolic Syndrome; N-number of studies; n- number of participants; NNT -Number Needed to Treat; NPhI – Non-Pharmacological Interventions; NRCT – Non-randomized controlled trial; NUT – Nutritional education; OT – Occupational Therapy; PBF – Percent body fat; RCT- Randomized Controlled Trial; RR – Risk Ratio; SBP – Systolic Blood Pressure; TAU – Treatment as usual; TC – Total cholesterol; TRI- Triglycerides; WC – Waist circumference; WMD – Weighted Mean Difference.