An intervention study to prevent weight gain or reduce weight in people with serious mental illness who take second generation antipsychotics.

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Statement of the Contribution of Others

Work	Contribution
Chapter 1	• Editorial advice - Professor Kim Usher, A/Professor Kim Foster & A/Professor Petra Buettner
Chapter 2	• Editorial advice - Professor Kim Usher, A/Professor Kim Foster & A/Professor Petra Buettner
Chapter 3	• Editorial advice - Professor Kim Usher, A/Professor Kim Foster & A/Professor Petra Buettner
Chapter 4	• Editorial advice - Professor Kim Usher, A/Professor Kim Foster & A/Professor Petra Buettner
Chapter 5	• Editorial advice - Professor Kim Usher, A/Professor Kim Foster & A/Professor Petra Buettner
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Declaration on Ethics

The research presented and reported in this thesis was conducted within the guidelines for research ethics outlined in the *National Statement on Ethics Conduct in Research Involving Human (1999),* the joint *NHMRC/AVCC Statement and Guidelines on Research Practice (1997),* the *James Cook University Policy on Experimentation Ethics, Standard Practices and Guidelines (2001)* and the *James Cook University Statement and Guidelines on Research Practice (2001).*

The proposed research methodology received clearance from the James Cook University Ethics Review Committee, Human Research Ethics Committee:

Approval number: H 3075

3rd August 2011

Signature **Date**

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"To understand God's thoughts we must study statistics, for these are the measure of His purpose"

Florence Nightingale

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Abstract

Introduction: Weight gain and obesity has reached epidemic proportions with the prevalence of Metabolic Syndrome (MetS) reaching 20-25% of the global population. MetS is a cluster of metabolic abnormalities, including weight gain, associated with an increased risk of cardiovascular disease, diabetes and stroke. While individuals in the general population are at risk of physical conditions such as MetS, people with mental illness are at even higher risk. The increased incidence of MetS for people with serious mental illness has been linked in part to the use of second generation antipsychotic (SGAs) medication.

Background: Antipsychotic medication has long been associated with physical side effects, including cardiovascular and metabolic effects such as weight gain. The association between weight gain, diabetes and the SGAs is linked to a number of hypotheses including the blocking of the serotonin receptors (5-HT_2) by the medication which results in a decreased serotinergic transmission thereby causing weight gain and obesity, genetic predisposition, and enviromental factors. Australian studies have reported the prevalence rates of MetS for people with serious mental illness as ranging between 51% and 68%. The pervasiveness of physical health issues, including weight gain, in mental health consumers has prompted calls for nurse-led health prevention and intervention programs and practices.

Study: The study used a randomised control trial (RCT) to test the effect of a nurse-led intervention on weight gain in people with serious mental illness (SMI) prescribed and taking second generation antipsychotic medication. After ethical approval, 104

participants, recruited to the study from the local area, were consented and randomly allocated to the control or intervention group. The intervention group received a 12 week healthy lifestyle booklet, designed specifically by the researcher. The intervention group also received the healthy lifestyle booklet but also participated in a program of weekly group sessions underpinned by the spirit of motivational interviewing. The weekly sessions consisted of nutrition and exercise education, exercise sessions, support through nurse involvement, and motivational interviewing.

Participants in both the control and intervention group were measured at baseline and at completion of the 12 week program. There were seven outcome measures collected in the study including self reported questionnaires, and body measurements. Body measurements included girth (cm), weight (kg), height (cm), and BMI (kg/m^2). Tools administered included the medication compliance questionnaire (MCQ), the Drug Attitude Inventory (DAI-10), the Liverpool University Neuroleptic Side Effect Rating Scale (LUNSERS), and the Medical Outcomes Study Short Form 36 (SF-36v2).

Data analysis: All characteristics were described using percentages for categorical variables. Distribution of numerical variables was assessed for normality and mean and standard deviation was used to describe the characteristic in case of approximate normality. Median and inter-quartile range was used when numerical data was skewed. All characteristics assessed at baseline were compared between intervention and control groups to evaluate the effectiveness of randomisation. Differences in primary outcome measures between baseline and 12 weeks follow-up was compared between intervention and control group using standard bi-variate

statistical tests (for example: Chi-square tests, Fisher's exact tests, Chi-square test for trend, and t tests). Statistical analysis was conducted using SPSS version 18.

Results: The results found that the comparison of baseline characteristics for control group (n=50) and intervention group (n=51) demonstrated that the randomisation process was successful. The majority of study participants (n=101) at baseline self reported a weight problem (n=65, 64.4%), while quite a few more reported previously trying to lose weight (n=81, 80.2%), with participants equally attempting exercise (n=22, 21.1%), diet change (n=23, 22.1%) and exercise and diet combined (n=31, 29.8%), in an attempt to lose weight. The data analysis of the outcome measures for the control group (n=50) and intervention group (n=51), although not statistically significant, demonstrated small positive changes in the predicted direction. There was a mean weight change of - 0.74 kg (SD=3.78 kg, p=0.167) at 12 weeks for the intervention group (n=51), while the control group (n=50) had a mean weight change of - 0.17 kg (SD=3.36, p=0.729) at 12 weeks.

Conclusion: The recruitment and data collection component of this study was conducted over an 18 month time period. The results of the study, while not statistically significant, have shown a positive outcome for participants in the intervention group, with weight measurements indicating small losses. The comparison of baseline characteristics for the control group (n=50) and the intervention group (n=51), demonstrated that the randomisation process was successful. The questionnaire results show that participants of this study were mostly compliant with their psychotropic medication (DAI-10), were able to 'tolerate' their antipsychotic medication and any side effects experienced (LUNSERS), and

were ‘actively participating in their medication intake’ (MCQ). The SF-36v2 results show the participants’ self reported physical and mental health as within the population norm scores collected in Australia in 2004. Researcher observations found a willingness to be engaged in the program and participant motivation to be involved in healthy lifestyle changes.

Recommendations: A similar study conducted over a longer period of time may find significant results. As this intervention was only conducted over 12 weeks, it is recommended future studies should implement the intervention over a period of 24 weeks or more. As the study was a randomised control trial formally qualitative data was not collected on the experience of weight gain for people with a serious mental illness prescribed and taking second generation antipsychotic medication. Qualitative research could offer deeper insight into the experience of weight gain, while also identifying individual stages of change. Further, research utilising the Transtheoretical model of change (TTM) and the six stage process – pre-contemplation, contemplation, preparation, action, maintenance and termination- to assess the individual would enable the design of a program that was relevant to the change stage for each participant. Supplementary individual support for participants, such as shopping support or cooking classes, could also increase participants’ ability to choose healthy lifestyle behaviours.

CHAPTER 1: INTRODUCTION

1.1 Introduction

People with serious mental illness die up to twenty years earlier than the general population (Lambert & Newcomer, 2009). Unnatural events, such as suicide and accidents, accounts for only a very small percentage of the difference between life expectancy for people with a serious mental illness and the rest of the population, suggesting other factors, such as poverty, sedentary lifestyle, medications, access to medical services, and social stigma contribute to the poorer physical health experienced by people with serious mental illness. The higher incidence of some serious illnesses, such as diabetes, in people with serious mental illness has been known for some time (Maudsley, 1879; McEvoy et al., 2005; Robson & Gray, 2007). More recently, however, the issues around the physical health of people with a serious mental illness have become more of a concern since the introduction of the second generation antipsychotics (SGAs) which have been linked to serious health problems such as significant and prolonged weight gain, especially around the abdomen, and metabolic symptoms such as hypertension, hyperglycaemia and lipid abnormalities (Holt, Bushe & Citrome, 2005; Lambert & Newcomer, 2009; Newcomer, 2007). The increasing incidence of these physical health problems have been identified in studies such as the Clinical Antipsychotic Trials of Intervention Effectiveness study (CATIE), and have led to the development and implementation of numerous strategies designed to improve the physical health of this group.

However, to date there is limited empirical evidence to support these interventions or to help mental health clinicians choose the best intervention for a person with serious mental illness. The aim of this study was to determine whether a nurse-led healthy

lifestyle intervention could have an impact on weight maintenance/reduction, or ameliorate weight gain, for people with serious mental illness (SMI) already prescribed and taking second generation antipsychotics (SGAs).

1.2 Background to study

Mental health can be defined as “a state of wellbeing in which the individual realises his or her own abilities, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to his or her community” (WHO, 2005, p.5). The World Health Organisation also acknowledges that health is “physical, mental and social well-being and not merely the absence of disease or infirmity” (WHO, 2005, p.4). The importance of including mental and physical health in the same definition cannot be underestimated. These definitions will help to raise awareness of the close relationship between physical and mental health.

The World Health Organisation (WHO) predicts that globally, as many as 450 million people experience a mental or behavioural disorder and 25 million people experience schizophrenia (WHO, 2005). In Australia, it is reported that one in five people will have a mental illness in their lifetime (SANE, 2010). Effectively this means that that for every one hundred people in Australia, twenty will experience a mental illness in their lifetime and about one in every one hundred will develop schizophrenia (SANE, 2010). Further, the incidence of mental illness is described as “very common” in the latest Health of Queenslanders Report, which claims that 47.4% of Queenslanders between the ages of 16-85 years will experience a mental illness at some time during their lifetime (Queensland Government, 2011). Table 1.1 outlines some of the current Australian statistics for mental illness.

Table 1.1 Mental Illness in Australia (SANE, 2010)

% of population affected in Australia
1% of adults are affected by schizophrenia
3% of adults are psychiatrically disabled
6% of adults are affected by depression
14% of adults are affected by anxiety disorders
15% of adults who are seriously affected by mental illness die by suicide

Mental illnesses are diagnosed using the criteria of either the International Classification of Diseases (ICD), or the Diagnostic and Statistical Manual of Mental Health Disorders (DSM). These classifications systems provide internationally accepted criteria for all mental illnesses, enabling consistency of treatment and diagnosis. The term serious mental illness is currently used in the literature to collectively group together mental illnesses that have persistent and enduring symptomatology such as schizophrenia. For the purpose of this study, the term serious mental illness has been used to describe the illnesses for which SGAs are usually prescribed. These illnesses include schizophrenia, bipolar disorder, and other psychotic disorders.

Two of the most prominent serious mental illnesses are schizophrenia and bipolar disorder. Schizophrenia occurs in approximately 1% of the world's population, with 200,000 people in Australia currently diagnosed with this often debilitating disorder (Bardwell & Taylor, 2009). While the exact cause of schizophrenia is not known there are a number of theories including genetic, biochemical, stress, and neuro-anatomical abnormalities (Bardwell & Taylor, 2009). Characteristics of schizophrenia are described as positive and negative. Positive symptoms include hallucinations,

delusions, and thought disorder, while negative symptoms include motivational difficulties that can lead to social and occupational dysfunction. The most widely used and currently recommended treatment for schizophrenia is the prescription of SGAs (Lambert, 2009; Picchioni & Murray, 2007).

Bipolar disorder is a group of mood disorders that have differing ranges of mood, from the highs of a manic episode to lows experienced during a depressive episode. The symptoms of bipolar disorders can have a significant impact on the persons functioning and include low mood, suicidal thoughts, anhedonia when feeling depressed, and grandiosity, flight of ideas, pressured speech, delusions, hallucinations, and psychomotor agitation when experiencing mania. Treatment for bipolar disorders is dependent on the symptomatology for the person but increasingly the second generation antipsychotics are being added to the medication treatment regime (Livingston, 2011).

The link between physical and mental illness is attributed by many to being first identified by Maudsley (1879) who described his observations of a link between diabetes and schizophrenia. Maudsley commented that “diabetes is a disease which often shows itself in families in which insanity prevails” (p. 113). Maudsley (1879) expanded on his observations conveying that he could not determine which disease came first, the diabetes or the schizophrenia. He stated “they are certainly found to run side by side…more often than can be accounted for by accidental coincidence” (p.113). Further reports of a link between diabetes and schizophrenia occurred in the 1950s (Hiles, 1956), when the term ‘phenothiazine diabetes’ came to light (Holt, Bushe & Citrome, 2005). More recently, the focus of discussion has moved to the

link between second generation antipsychotic medications (the mainstay of current psychiatric treatment) and diabetes (Holt, Bushe & Citrome, 2005; McEvoy et al., 2005). While much of the debate surrounds the increased incidence of diabetes thought to result from the use of SGAs, more screening program are needed to find the 'true prevalence' of diabetes for people with serious mental illness taking SGAs (Holt, Bushe & Citrome, 2005).

Weight gain and obesity is a worldwide epidemic. The definition of overweight and obesity is determined by a number of factors including Body Mass Index (BMI). BMI is a measurement used to calculate overall body fat, and although widely used to assess obesity, it is important to recognise that age, gender and ethnicity can influence overall weight gain and hence BMI scores (NHMRC, 2003). An individual's BMI is calculated by weight (in kg) divided by the square of one's height (in metres), i.e. kg/m^2. Using the BMI calculation, Nutrition Australia (n.d.) and the National Health and Medical Research Council (NHMRC, 2003) provide the following parameters for defining overweight and obesity:

- Underweight – BMI 18.49 and below
- Normal range - BMI 18.50 – 24.9
- Overweight/Pre-obese - BMI 25.00 –29.9
- Moderate Obesity (Obese I) - BMI 30.00 –34.9
- Severe Obesity (Obese II) - BMI 35.0 – 39.9
- Very Severe Obesity (Obese III) - BMI > 40.00

Interestingly, a recent health report released in Australia stated that if current trends continue, about 3.7 million (65%) Queensland adults will be classified as overweight or obese by 2020 (Queensland Government, 2011, p. vii). This report also suggests

that a “5.5 kg reduction in body weight in Australian women would reduce the incidence of diabetes by 23%” (Queensland Government, 2011, p. vii). While being overweight or obese as defined by BMI scores is a health concern, the International Diabetes Federation (IDF) has found that fat in the abdominal area (central obesity) is a higher risk for heart disease, diabetes, and stroke than other determinants, therefore central obesity is now the key risk factor for Metabolic Syndrome (MetS) (IDF, 2006). MetS is the presentation of a cluster of metabolic abnormalities, associated with an increased risk of cardiovascular disease, diabetes and stroke. The definition of MetS now includes waist circumference, in recognition of the ominous effect of fat deposits in the abdominal area. Waist circumference over 102 cm for men and 88 cm for women is considered a higher risk for developing cardiovascular disease and diabetes (IDF, 2006). An estimated 20-25% of the world’s population has Metabolic Syndrome (IDF, 2006). While the cause of MetS is not yet clear, insulin resistance and central abdominal obesity are considered major factors, along with genetic vulnerability, physical inactivity and hormonal changes (IDF, 2006). The International Diabetes Federation (IDF) provides a definition and clinical parameters for MetS that is currently used worldwide and this definition and parameters can be used by the clinician to identify areas of concern for closer monitoring, and for reducing MetS through change to a healthy lifestyle (Usher, Foster & Park, 2006).The current agreed definition of MetS states that a person must have central obesity plus any two of the following: - raised triglycerides, reduced high-density lipoprotein (HDL) cholesterol, raised blood pressure, and raised fasting plasma glucose (IDF, 2006). See Table 2.3 for the current recommended parameters for MetS from the International Diabetes Federation (2006).

While individuals in the general population are at risk of physical conditions such as MetS, people with mental illness are known to experience particularly high rates of co-morbid physical health problems (Lambert, Velakoulis & Pantelis, 2003). Recently, there has been growing concern about the rates of MetS in people diagnosed with schizophrenia and taking SGAs (Hennekens, Hennekens, Hollar & Casey, 2005; Lambert, 2009; McEvoy et al., 2005). An Australian survey of 350 people with a mental illness conducted during 2007 reported that almost all respondents (90%) had a concurrent chronic health problem such as hypertension, diabetes, heart or respiratory disease (SANE, 2007). Australian studies have assessed the incidence of MetS for people with serious mental illness and reported the prevalence rates as 51%, 61.6% and 68% respectively (Tiruputi & Chua, 2007; Brunero et al., 2009; John et al., 2009). Not surprisingly, given the known metabolic effects of SGAs, these findings are significantly higher than the IDF (2006) report which states that 20-25% of the world's population meet the criteria for MetS.

SGAs are currently the mainstay and first choice treatment for people with serious mental illness, including the psychotic disorders (Livingston, 2011). The history of antipsychotic medications is linked to revolutionary change in mental health care, particularly in the 1950s, when the first generation of antipsychotics were introduced with life changing effects for many people who had been cared for behind the locked doors of the local asylum. The first generation of antipsychotic medication provided respite for many from their often tormenting delusions, hallucinations, and thoughts. Unfortunately, along with this relief came many untoward side effects such as dystonia, parkinson-like effects, and tardive dsykinesia, commonly grouped together and known as extrapyramidal side effects (Usher, Foster & Bullock, 2009). See

Table 1.2 for definitions of common movement side effects of first generation antipsychotics.

Table 1.2 Extrapyramidal side effects of antipsychotic treatment (Usher, Foster & Bullock, 2009, p.44).

Side effect	**Description**
Dystonia	Can involve the face, neck, back and upper limbs. Altered muscle tone leads to torticollis, spasming of the eye muscles, arched back, facial grimacing and limb spacity.
Parkinson like effects	Tremor, cogwheel and limb ridgity, hypokinesia, slowness of thinking and mental 'clouding'.
Tardive dyskinesia	Involuntary movements of the face, tongue and limbs like lip smacking, tongue writhing, chewing movements, tick like movements of the eyes and lips and choreoathetoid movements of limbs.
Akathisia	Marked motor restlessness like rocking motions, walking on the spot, the person may also feel restless.

In the 1980s and 90s the new SGAs were introduced and found to be capable of not only relieving psychotic symptoms for people for whom the earlier medications were ineffective but also appeared to have a less serious side effect profile. Clozapine was an exception as this medication was already known to have a very serious side effect - agranulocytosis - and was not released for widespread use until strict protocols for its use were put into place (Livingston, 2011; Usher, et al., 2009). It was, however, soon discovered that while these newer medications did not tend to cause extrapyramidal side effects such as dystonia or tardive dyskinesia, they did lead to other serious side effects; namely weight gain and metabolic symptoms such as hypertension (Usher, et al., 2009). The common triad of side effects of weight gain, diabetes and hypertension are discussed further in Chapter 2.

In summary, psychiatric care and in particular the use of antipyschotic medication has caused widespread revoluntionary change to many lives in the last 50 years.

While the benefits of these medications are evident, it is important to also recognise the detrimental effects of the widespread use of antipsychotics and their link with the significant decrease in life expectancy for people with serious mental illness. The premature loss of life, mainly due to cardiovascular incidents experienced by people with serious mental illness taking antipsychotic medications is of grave concern. The situation is serious and demands urgent attention. As Gray, Hardy and Anderson (2009) enquire, “If we [mental health nurses] don’t do something about it, who will?” (p. 299).

1.3 Aim of study

The aim of the study was to determine whether a nurse-led intervention could have an impact on weight maintenance or reduction, or ameliorate weight gain for people with serious mental illness (SMI) already prescribed and taking second generation antipsychotics (SGAs).

1.4 Objectives of study

1. To undertake a literature review on weight gain and second generation antipsychotic medication;
2. To collect quantitative data to analyse the effectiveness of a multi-component program on weight for people with SMI taking second generation antipsychotic medication;
3. To evaluate the effectiveness of a multi-component program on weight for people with SMI taking second generation antipsychotic medication.

1.5 Theoretical framework of the study

This study used the scientific paradigm as a theoretical framework, and was underpinned by the principles of health promotion and the Transtheoretical Model of Change. The scientific paradigm provides the researcher with the ability to make

statements regarding laws that are supported by statistical correlations which enables the researcher to make generalisations of observable phenomena. These generalisations provide a fundamental tenet of this paradigm allowing explanations to be developed with validated statistical consistency (Lewis-Beck, Bryman, & Liao, 2004).

The scientific paradigm, also known as positivism, was first formulated by August Comte who regarded all sciences as forming a unified hierarchy of related levels. Positivism was further expanded on in the 1920s in Vienna when the term logical positivism was proposed. Logical positivism is concerned with reduction and the view that propositions of the social sciences can be analysed down to physics. Post World War II the third version of positivism developed with the central tenet that "all sciences are concerned with developing explanations in the form of universal laws" (Lewis-Beck, Bryman, & Liao, 2004, p. 837).

The experimental scientific framework utilised for this study was a randomised control trial, incorporating the essential concepts of control, manipulation and randomisation. The randomisation of participants to the control or intervention group enabled the researcher to randomly allocate variables to both groups, therefore controlling for potential confounding bias. Random allocation of the sample recruited, to either intervention or control group, also ensures the research findings can be attributed to the intervention tested and not influenced by variables. Inclusion criteria was developed and implemented in this study as a measure of control that enabled the sample recruited to reflect the population. Another example of control in this study was the use of study protocols to minimise the threat to validity of the study

from extraneous variables. The intervention tested was a healthy lifestyle program developed for people with serious mental illness taking second generation antipsychotics. The healthy lifestyle program was manipulated by the researcher in order to test the effect of the program, by comparing weight measurements between the control and intervention groups. Intervention studies are commonly used to test health care treatments, with the intention of understanding their acceptability and effectiveness in clinical practice (Davidson, et al., 2008).The participant outcome that the program aimed to effect was participant weight level.

Evidence based practice in health care is simply the combination of the best available treatment that has been tested by research and shown to be best practice, along with the preference of the person receiving health care (Nagy, Mills, Waters & Birks, 2010). Randomised Control Trials are considered to be the “gold standard” of research design and thus provide the clinician with the robust evidence to support the health care practice that has been tested (Schneider, Whitehead, & Elliott, 2007). Hence, RCTs when combined in a systematic review provide the highest level of evidence upon which practice should be based.

An interesting aspect of evidenced based practice in health care is that the person receiving the health treatment has the choice to participate regardless of the evidence provided. The issue of client choice is identified by Nagy et al., (2010) as a challenge for the nurse. However, Fisher and Happell (2009) argue that mental health nurses must be aware of the “available resources, expertise, and individual patient preference”, all of which need to be considered before putting nursing care into practice (p. 181). While the aim of this study was to determine whether a nurse-

led intervention could have an impact on weight for people with serious mental illness (SMI) living in the community, it was also important to give people choices and the opportunity to develop individual skills. This led to the incorporation of health promotion principles into the study.

Health promotion principles provided the philosophical background to the development of the healthy lifestyle program, 'Passport 4 Life'. The WHO states that the premise of health promotion is that "health is created and lived by people within settings of their everyday life; where they learn, work, play and love" (WHO, 1986, p. 4). The development of personal skills that enable the individual to choose healthy lifestyle changes is a fundamental tenet of health promotion, and is outlined in Principle 4 of the Ottawa Charter: "assisting people to develop personal skills; inform and educate individuals in health to enhance life skills, permitting control to make choices conducive to good health" (WHO, 1986, p. 4).

Health promotion principles, such as strengthening individuals' skills and capabilities are integral to Australian government health planning. The Queensland Plan for Mental Health (2007-2017) includes health promotion and prevention, and community participation as two of their five priority areas for the current Mental Health Plan (Queensland Government, 2008). Thus, the healthy lifestyle intervention tested in this study was developed for use in the community with the underlying intent of further developing individuals' knowledge of healthy lifestyle choices.

The healthy lifestyle program developed in this study is premised on the understanding that any lifestyle change requires changes in behaviour, which is

challenging for most people. Behavioural change is an important aspect of health promotion, and the importance of *enabling people to increase control over their own health* cannot be underestimated (Petrie, 2011, p. 56). Prochaska and DiClemente's (1983) theoretical model of change offers further understanding of an individual's readiness for change. The Transtheoretical Model (TTM) identifies six stages of change – precontemplation, contemplation, preparation, action, maintainence and termination. Each stage of TTM identifies the change phase that the person is experiencing, for example the second stage of contemplation is when the person is intending to change, they are also aware of the pros and cons of making changes (Prochaska & Velicer, 1997). The contemplation stage would be the ideal time in which healthy lifestyle educational information could be introduced, with the intention to increase the person's knowledge. Increased knowledge could then reinforce the individual's reason for considering the adoption of healthy lifestyle choices.

Throughout the stages of TTM, motivational interviewing approaches can be incorporated to assist a person where there is the intention to move to another stage (Prochaska & Velicer, 1997). The consideration of the TTM model in the development of the Passport 4 Life program was designed not only to elicit behaviour change but also to support behaviour change. For example: a person at the contemplation stage of change could increase their knowledge by reading the program, while a person at the action stage would utilise the suggestions in the program, such as increasing exercise by using the pedometer, increasing steps per day by 100 up to the recommended 10 000 steps per day (Australian Government, 1999). In order to operationalise these principles, the spirit of Motivational

Interviewing (MI) has been incorporated into the weekly sessions as MI strategies have been shown to be beneficial at all stages of TTM (Miller & Rollnick, 2002).

Motivational interviewing (MI) is a cognitive behavioural technique that aims to help people identify and change behaviours that may be placing them at risk of developing health problems such as weight gain (Miller & Rollnick, 2002). The spirit of motivational interveiwing was selected for the Passport 4 Life program as MI has been shown to be an effective change management strategy commonly used to help people change risky health behaviours (Miller & Rollnick, 2002). The spirit of MI incorporates three concepts of evocation, autonomy and collaboration; these concepts are described further in Table 1.3.

Table 1.3: The Spirit of Motivational Interviewing
(Adapted from Rollnick, Miller & Butler, 2008, pp: 6-7)

Concept	**Definition for Motivational Interviewing**
Collaboration	Joint decision making between the participant and the clinician will culminate in active collaborative involvement in the behaviour change.
Evocation	Involves understanding and evoking an individual's own values and beliefs that will enable the individual to develop their own reasons to change behaviour.
Autonomy	The clinician is required to "honour autonomy" by accepting that "people can and do make choices about the course of their lives".

The principles of health promotion and MI include valuing the importance of the individual and respecting that the individual has the right to make their health choices. The spirit of MI can be utilised by health professionals to support the health behaviour change that the person has chosen. While the process of therapeutic

relationship building, familiar to mental health nurses, involves similar concepts to MI, such as listening, developing trust and self-awareness (Foster, McAllister & O'Brien, 2006). Further, the concepts used in the spirit of MI are familiar to the mental health nurse who has strong connections to the importance of developing therapeutic relationships.

1.6 Summary

Improving the physical health of people with serious mental illness is a substantial and growing concern for health professionals. Mental health nurses are well placed to play a pivotal role in improving the physical health of people with serious mental illness and improving their life expectancy. The healthy lifestyle program developed and tested for this study can be delivered by nurses. The healthy lifestyle program, 'Passport 4 Life', was constructed specifically for people with serious mental illness and includes the use of easy to understand language, reminders, and suggestions for making healthy changes. It is imperative that nursing and all health professionals are involved in facilitating a change for the better in the physical health of people with serious mental illness already prescribed and taking second generation antipsychotics.

1.7 Overview of the thesis

Following this chapter, Chapter 2 provides a review of the literature, including an overview of the prevalence of MetS for people with serious mental illness, and the importance of acting on the increasing incidence of Mets. The nursing guidelines for assessment and management of Mets are identified and intervention studies from the 1960s to today are discussed in detail, highlighting the importance of healthy

lifestyle interventions for people with serious mental illness taking SGAs. The healthy lifestyle program developed for the study intervention is described in a published manuscript embedded in the chapter.

Chapter 3 of the thesis outlines the study design and methods including study setting, participants, protocols, intervention, and outcome measurements. The study design is a randomised control trial undertaken to test the effect of a healthy lifestyle program on weight management for people with serious mental illness taking second generation antipsychotics. Information on the protocols used in the study, the participant information sheet and consent form, demographic data collection forms, and examples of the survey tools used in the study, are included in the appendices. A manuscript of the healthy lifestyle program (in press) is embedded in this chapter.

Chapter 4 outlines the results of the study. Initially, an overview of participant recruitment is provided followed by descriptions of participant demographic characteristics. Comparison of participant outcomes stratified by intervention and control group is reported.

Chapter 5 presents a discussion of the study results. The chapter begins with a summary of the study including the hypothesis and sample size. The chapter then discusses the statistical results of the study and provides comparisons with other healthy lifestyle intervention studies. The results of this study, while not statistically significant, have shown a positive outcome for participants in the intervention group, with weight measurements indicating small losses. Further, the comparison of baseline characteristics for control group (n=50) and intervention group (n=51)

demonstrated that the randomisation process was successful. A manuscript of the study results (under review) is embedded in this chapter.

Finally Chapter 6 presents the strengths, limitations and implications of the study. Excerpts from a reflective journal kept by the researcher will be presented to enrich the discussion of researcher unexpected experiences encountered by the researcher during the conduct of the RCT. A manuscript discussing these issues (under review) is embedded in the chapter.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

The following chapter discusses the relevant literature on the association between serious mental illness and weight gain. Metabolic syndrome (MetS) is identified as a major concern for people with a SMI and discussed in relation to the link between SMI, MetS and antipsychotic medication. The prevalence, detection and assessment of MetS in the population with a serious mental illness are included, and relevant intervention studies reported. Lastly, the gap in the literature that led to the current study is identified.

As many as 450 million people globally are diagnosed with a mental or behavioural disorder and 25 million people experience schizophrenia (WHO, 2005). While mental illness in Australia is an increasing issue with estimates of 1 in 5 Australians expected to experience a mental illness, and 1 in 100 expected to develop a psychotic mental illness such as schizophrenia, at some time during their lifetime (SANE, 2010). A recent and disturbing trend is the increasing prevalence of concurrent mental and physical illness (WHO, 2005, SANE, 2007). Reports indicate that people with a serious mental illness are more likely to die from a physical illess such as cardiovascular disease, than from mental illness, with the life expectancy of some people with serious mental illness shortened by up to 25 years (Hennekens, Hennekens, Hollar & Casey, 2005; Robson & Gray, 2007; Millar, 2008; Lambert & Newcomer, 2009). More recently, attention has focused on the link between second generation antipsychotic medications (the mainstay of current psychiatric treatment) and metabolic syndrome and its effects; especially weight gain increases in

abdomen girth, and its impact on the development of cardiovascular disease and diabetes (Holt, Bushe & Citrome, 2005; McEvoy et al., 2005). As awareness of this issue has increased, discussion on the topic has escalated with results from the CATIE trial suggesting as many as 54% of people with serious mental illness taking second generation anipsychotics are affected by metabolic syndrome (McEvoy et al., 2005).

The literature review for this study was conducted using the following electronic data bases: CINAHL, Medline, PsychINFO and OVID. Additional literature was sourced from the reference lists of the papers found. Key words used in the search included: schizophrenia, mental illness, serious mental illness, physical illness, metabolic syndrome, intervention studies, motivational interviewing, antipsychotic medication, and weight gain/prevention/loss. The intention of the literature review was to understand the impact of weight gain on people with serious mental illness (SMI) already prescribed and taking second generation antipsychotics (SGAs).

2.2 The relationship between mental illness and physical illness

Awareness of the high rates of physical morbidity and mortality for people with serious mental illnesses (i.e. co-morbidity) such as schizophrenia has increased in recent years. While the coexisting development of related literature identifying the impact of mental illness and its treatment on physical health has led to a plethora of systematic reviews and research studies that have identified numerous physical health concerns for people with serious mental illness (Lambert, Velakoulis & Pantelis, 2003; Hennekens, Hennekens, Hollar & Casey, 2005; Holt, Bushe & Citrome, 2005; Holt, 2006; Millar, 2008; Seeman, 2008; Lambert & Newcomer, 2009;

Seeman, 2010). The most common co-morbidities experienced by people with serious mental illness include coronary heart disease, diabetes, hypertension, dyslipidemias, stroke and emphysema (Beebe, 2008; SANE, 2010).

The physical health of people with a serious mental illness has now become of such concern that there have been claims that people with schizophrenia are more likely to die from cardiovascular disease than from potential complications of their mental illness such as suicide (Beebe, 2008; Hennekens, Hennekens, Hollar & Casey, 2005; Robson & Gray, 2007; Millar, 2008). Reports are increasing on the incidence of cardiovascular disease leading to death for people with SMI (Beebe, 2008; Holt & Peveler, 2010) Given that increased weight, particularly in the abdominal girth area, increases the risk for cardiovascular disease, it is important to note that one of the largest trials to evaluate the effectiveness of antipsychotic medication, the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) study, found 76% of women and 35% of men were obese at the commencement of the study (Meyer et al., 2005). As previously identified, people with schizophrenia are known to have a shorter life expectancy than the rest of the general population, perhaps as much as 9-12 years, with some reports of up to 25 years of life lost prematurely (Lambert & Newcomer, 2009). Interestingly, Connolly and Kelly (2005) link the premature loss of life for the person with serious mental illness to either the mental illness, the treatment for the mental illness, or lifestyle factors. A more recent argument suggests that increased mortalitiy is linked to weight increases and cardiovascular disease as the physical health risks leading to reduced life expectancy for people with serious mental illness(Correll & Nielsen, 2010).

Unfortunately, a further complicating factor of physical health issues for people with serious mental illness is that physical disorders often go undetected or unreported in people with serious mental illness, mainly due to service-related barriers including patients' inability to access health assessment services (Robson & Gray, 2007). Concerns around the inadequate screening for physical problems for people with a pyschotic illness was raised recently with the arguement that while there have been some improvements in this regard, there are still vast areas of unrecognised need for this vulnerable group of people (Lambert, 2009). A recent report of a retrospective chart audit, for example, found 32 of 136 people with a mental illness did not have any documented metabolic monitoring (Curtis et al., 2011). This is a sustantial concern given that clinically significant weight gain has been reported in up to as many as 61% of people with first episode psychosis (Alvarez-Jimenez, et al., 2008).

The poorer physical health of people with a mental illness becomes even more problematic where the use of psychotropic medications is concerned. As Muir-Cochrane (2006) argues, the medical co-morbidity for people with schizophrenia is further complicated by the use of antipsychotic medication. Seeman (2008) supports this notion and reports the seriousness of the health burden of antipsychotic medication, especially the potential harm for women. Seeman (2008) identifies a variety of risks for women prescribed and taking antipsychotic medication including amenorrhea, sexual dysfunction, osteoporosis, weight gain, and metabolic syndrome, concluding that there is a disproportionate increase in cardiovascular incidents for women who take antipsychotic medications. In 2010, Seeman's report on the disproportionate side effect toll experienced by women recommended "lower doses for women and where possible avoiding drugs that induce weight gain" (p. 26).

This is supported by Livingston (2011), who cautions that some of the earlier reported claims of decreased side effect profiles for second generation antipsychotic medications may be misleading, due to increasing reports of cardiovascular disease and diabetes, and should now be reassessed.

In summary, the physical health needs of the person with serious mental illness have been neglected in many cases in the past. Unfortunately, while many authors have identified the importance of physical health assessment we continue to discuss and debate why this is not happening without necessarily addressing the issue effectively. The physical health consequences for the person with serious mental illness have been clearly identified, with an expected premature loss of life of up to as many as 25 years. This premature loss of life has been linked to the consequences of serious physical illnesses including cardiovascular disease, diabetes and stroke, and associated with the occurrence of serious mental illness and the use of psychotropic medication. The next section will discuss the mainstay medical treatment of current psychiatric illness, antipsychotic medications and their effects.

2.3 Antipsychotic medications and their effects

Antipsychotic medications are used to manage the symptoms of psychotic mental illnesses such as delusions, hallucinations and thought disorder, which are commonly experienced by the person with a serious mental illness. Antipsychotic medications have been considered the mainstay of psychiatric medical treatment for psychotic symptomatology since their introduction to psychiatric treatment regimes in the 1950s (Usher, Foster & Bullock, 2009). First generation antipsychotics (FGAs)

were, as the the name suggests, the first type of antipsychotic medication used in psychiatric care. Introduced in the 1950s, they resulted in wide spread revoluntionary changes to the treatment of psychotic disorders. These changes consequently led to significant changes in the lives of the people suffering these often debilitating illnesses, and have also had long term influential affects on mental health services, such as the closure of institutional care facilities and the move to community based care (Usher, Foster & Bullock, 2009). FGAs are still in use today, however they tend to be avoided in favour of newer medications because of their often unfavourable side effect profile including the extrapyramidal effects of dystonia, akathisia, pseudoparkinsonism, and the often irreversible side effect tardive dyskinesia (Usher, Foster & Bullock, 2009). However, a recent report has encourgaged clincians to reconsider the use of FGAs when choosing antipsychotic medications because if used at moderate doses the differences in side effect profiles between the first and second generation medications are less prominent (Livingston, 2011).

Second generation antipsychotic (SGAs) medication use was introduced in Australia in the 1990s, even though Clozapine, the first of the SGAs, had been developed and trialed in the 1950s. However, due to the potentially fatal side effect of agranulocytosis, Clozapine was not widely used until 30 years later when protocols were put in place to monitor this side effect in patients prescribed the medication (Usher, et al., 2009). Clozapine remains the only medication to have shown efficacy in treatment resisitant schizophrenia (Livingston, 2011).

A range of SGAs have been developed since the introduction of Clozapine, and while most interact with dopamine,including the FGAs, they are less likely to cause

movement disorders due to their differing mechanism of action (Livingston, 2011; Usher, et al., 2009). Livingston (2011) suggests that the “looser binding” of SGAs to dopamine receptor sites is responsible for the decrease in movement disorder side effects (p. 22). Table 2.2 provides a list of commonly used antipsychotic medication and their side effect profiles. While the general side effect profile for the SGAs is less likely to be linked to extrapyramidal side effects, unlike the FGAs, their side effect profile is likely to include weight gain, hypertension, and diabetes. As mentioned previously, this is thought to be due to their differing mechanisms of action (Usher, et al., 2009). The affintiy of SGAs to serotonin receptor subtypes is thought to have led to the decreased incidence of extrapyramidal side effects (Usher, et al., 2009). In particular, Devlin, Yanovski and Wilson (2000) explain that “medications that block histamine H_1, serotonin 5-HT_{2c}, and dopamine D_2 receptors tend to be associated with weight gain” (p. 858). Although SGAs are more closely linked to metabolic side effects than FGAs, since the 1960s there has been increasing awareness of the potential for a link between antipsychotic medications, weight gain, diabetes, and the consequent increased risk for cardiovascular disease (Usher, et al., 2006).

Table 2.1 Side effect profile of commonly prescribed antipsychotic medication.

Antipsychotic	**Extrapyramidal effects**	**Weight gain**	**Diabetes risk**	**Sedation**
Clozapine	+	+++	+	+++
Olanzapine	++	+++	+	++
Risperidone	++	++	+	++
Amisulpride	++	+	+	+
Quetiapine	+	++	+	+++
Ziprasidone	+	+	+	++
Aripiprazole	+	+	+	++

(Table developed using information from Lambert & Chapman, 2004; Lieberman et al., 2005; Usher, et al., 2009)

While Table 2.1 demonstrates the most commonly prescribed psychotropic medications and some of their associated side effects, it is important to note that metabolic disturbances, especially weight gain, are side effects of all SGAs to differing degrees.

The weight gain associated with the SGAs is, unfortunately, predictable with reports that the most rapid weight gain often occurs at the commencement of treatment with antipsychotic medication (Allison et al., 1999). Table 2.2 shows weight gain per month of treatment for commonly prescribed SGAs; the data included was collected from 1966 – 2010 (Nihalani et al., 2011). While Table 2.2 shows the weight gain that can be expected each month associated with the use of antipsychotic medications, it is important to consider that this weight gain may not lead to obesity for everyone. Of course this depends entirely on the initial weight of the person at the time of commencement of treatment and other associated individual and environmental factors. Unfortunately, many people with serious mental illness tend to be more obese than the general population, which can mean that the baseline weight at the time of commencing SGAs may be higher than expected (Meyer et al., 2005).

Table 2.2 Weight changes expected per month for commonly used SGAs

Antipsychotic	**Weight gain per month**
Clozapine	1.7kg
Olanzapine	2.3kg
Risperidone	1.0kg
Quetiapine	1.8kg
Ziprasidone	0.8kg
Aripiprazole	0.5kg

(Nihalani, et al., 2011)

Weight gain experienced after commencing antipsychotic treatment has been linked to a number of hypotheses. For example,blocking of serotonin 5-hydroxytryptamine 2C (5-HT_{2C}) receptors, slowing of the basal metabolic rate due to interactions with mutliple neurotransmittors which lead to increased appetite and food intake, blocking of histamine-1 receptors (H-1), and blocking of anticholinergic receptors that lead to increased appetite, have all been proposed (Nihalani, et al., 2011).

In summary, the prescription of antipsychotic medication has brought about significant changes to psychiatric treatment and consequently the lives of people with serious mental illness. While the positive effect of antipsychotic medication on delusions, hallucinations and thought disorder is clear, this positive effect should not be measured without considerable concern for their negative side effect profile. The physical health side effects that potentially occur as a result of the prescription and use of antipsychotic medication include a vast array of problems including movement disorders, along with sedative effects and metabolic issues that can often lead to an increased risk for cardiovascular disease and diabetes. While prescription of antipsychotic medication is considered the cornerstone of psychiatric medical treatment it is essential that consideration is given to the assessment and management of these potentially life changing side effects.

2.4 Mental illness, obesity and the metabolic syndrome

It is well known that the prevalence of obesity is increasing in the general population, not only in people with serious mental illness (Nihalani, et al., 2011). The prevalence

of global obesity is reported by WHO (2011) who state that one in ten of the global adult population are obese. While the cause of obesity in the general population is linked to sedentary lifestyles (WHO, 2011), often the increase in prevalence of obestiy for people with serious mental illness is linked to an increase in prescription of antipsychotic medication, but some recent reports indicate that this might not always be the case (Thakore, Mann, Vlahos, Martin & Reznek, 2002; Loh, Meyer & Leckban, 2008). Therefore, regardless of whether the person with a serious mental illness is prescribed and taking antipsychotics or not, they are generally more likely to be more overweight and/or obese than the general poplulation.

Thakore et al., (2002), reported a cross sectional study of 30 mental health consumers in which they found that medication-free people with schizophrenia had higher BMIs (26.7±1.1kg/m^2) than a control group (2.8 ±0.5 kg/m^2). They authors (2002) also reported that increased fat in the abdominal area was more prevalent in participants with schizophrenia compared to a matched control group of medication-free people of the same sex, age, exercise level and diet who did not have schizophrenia (Thakore et al., 2002). A more recent study by Loh et al., (2008) compared 50 people with schizophrenia and 50 demographically matched control participants, and found a 46% rate of obesity for people with schizophrenia versus an 18% rate of obesity for the control group. These two study findings lend support to the hypothesis first identified by Maudsley in 1897, when he observed that diabetes was commonly seen in families where serious mental illness was present (Maudsley, 1897).

The increasing incidence of Type 2 diabetes mellitus in the general population is linked with a number of factors including genetic predisposition and enviromental

factors that lead to an increased body weight which may subsequently lead to an increased risk of diabetes (IDF, 2006. For people with serious mental illness, an added factor is thought to be antipsychotic medication. The direct effects of the antipsychotic agents on glucose transportation, elevation of serum leptin, and antagonism of serotonin 5-HT receptors decreases pancreatic β-cells responsiveness thought to increase appetitie, and slowing of the basal metabolic rate, which leads to weight gain and type 2 diabetes mellitus (Citrome, Blonde & Damatarca 2005; Holt, Bushe & Citrome, 2005; Nihalani, et al., 2011).

Abdominal (central) or visceral fat weight increases are highly associated with an increased risk of developing insulin resistance, glucose intolerance, hyperinsulinaemia, type 2 diabetes, dyslipidaemia and cardiovascular disease(Pi-Sunyer, 2004; Millar, 2008). As previously mentioned, people with serious mental illness have been reported as having increased abdominal girth, even before commencing treatment with antipsychotic medications (Thakore et al., 2002). Central obesity, dyslipidaemia, glucose intolerance and hypertension, when combined comprise what is now commonly known as Metabolic Syndrome (MetS). MetS is a cluster of metabolic abnormalities that are associated with an increased risk of cardiovascular disease and diabetes (IDF, 2006). The current worldwide definition for Mets, comes from the International Diabetes Federation (IDF) which is outlined in Table 2.3.

Table 2.3 Metabolic Syndrome Clinical Parameters

For a person to be diagnosed with Metabolic Syndrome they must have:

Central obesity (defined as waist circumference ≥ 94cm for Europid men and ≥ 80cm for Europid women, with ethnicity specific values for other groups) plus any two of the following four factors:

- Raised Triglycerides level: ≥ 150 mg/dL (1.7 mmol/L), or specific treatment for this lipid abnormality
- Reduced High-density lipoprotein cholesterol: < 40 mg/dL (1.03 mmol/L*) males and < 50mg/dL (1.29 mmol/L*) in females, or specific treatment for this lipid abnormality
- Raised blood pressure: systolic BP ≥ 130 or diastolic BP ≥ 85 mm Hg, or treatment of previously diagnosed hypertension
- Raised fasting plasma glucose (FPG) ≥ 100 mg/dL (5.6 mmol/L), or previously diagnosed type 2 diabetes If above 5.6 mmol/L or 100 mg/dL, OGTT is strongly recommended but is not necessary to define presence of the syndrome.

(Adapted from International Diabetes Federation, 2006, p. 10).

Significant weight gain, particularly central obesity, is the most noticeable sign of MetS and people with serious mental illness are known to have higher rates of obesity and abdominal girth measurement, than the general population (Loh, et al., 2008; McEvoy, et al., 2005; Thakore et al., 2002). The impact of weight gain for the person with serious mental illness cannot be underestimated. There are reports of some consumers ceasing the antipsychotic medication due to the weight gain, and associated demoralisation and stigma experienced due to their increasing obesity (Lambert, 2009). Weight gain has also been linked to reduced quality of life and further social retreat for people with a psychotic disorder (Tschoner et al., 2007).

2.5 Prevalence of Metabolic Syndrome for people with schizophrenia

Metabolic syndrome, as previously discussed, is becoming increasing prevalent for people with serious mental illness. The seminal and influential Clinical Antipsychotic

Trials of Intervention Effectiveness study (CATIE), came about due to the increasing use of SGAs and the belief that few studies demonstrated the “real world effects” of SGAs (Stroup et al., 2003). The CATIE trial, undertaken over 18 months in the U.S.A., assigned 1500 people to different phases of a randomised control trial. The results found prevalence rates of MetS for people prescribed and taking SGAs to be 36.6% for males and 54.2% for females (McEvoy et al., 2005). Cohn et al., (2004) found similar prevalence rates in Canada for people with serious mental illness prescribed SGAs; of 42.6% for males and 48.5% for females (Cohn et al., 2004). However, De Hert et al., (2006) found the prevalence of MetS for people with serious mental illness prescribed SGAs in Belgium to be statistically lower than Canada and America; 30.5% for males and 35.8% for females (DeHart et al., 2006).

The prevalence rates for MetS in Australia for people with serious mental illness prescribed SGAs have been reported in two studies, which found similar results to prior studies. Tirupati and Chua (2007) reported results from a study of 221 people taking antipsychotic medication. People with schizophrenia or schizoaffective disorder comprised 205 of the 221 participants of the study, with a MetS prevalence rate of 68% reported. A further study by John, Koloth, Dragovic and Lim (2009), found that the prevalence of MetS was 51% in 92 participants with schizophrenia. Both the studies used the IDF definition of MetS for diagnostic and reporting purposes (see Table 2.3 for MetS parameters).

With the high incidence of MetS reported for people with serious mental illness, it is not surprising that diabetes is reported up to be up to three times more prevalent for people taking either first generation and second generation antipsychotics than in the

general population (Holt, Bushe & Citrome, 2005). Table 2.2 clearly shows that there is an increased risk for diabetes associated with most of the SGAs. While the relative increased risk for developing diabetes is reported to be lower for people prescribed FGAs than SGAs, the overall risk for developing diabetes must be considered increased simply due to the higher incidence of obesity reported for people with serious mental illness regardless of antipsychotic treatment (Loh, et al., 2008; McEvoy, et al., 2005; Thakore et al., 2002; Tschoner et al., 2007).

While debate in the literature continues regarding the causative factors for MetS in people with serious mental illness, the confirmation of the high incidence and prevalence of MetS are of significant concern for health professionals involved in psychiatric assessment and treatment. The high prevalence rates discussed above provide robust support for the introduction of nursing interventions that ameliorate or prevent weight gain that can lead to MetS for people with serious mental illness.

2.6 Assessment and management of Metabolic Syndrome

Metabolic syndrome is diagnosed when a person has an abdominal girth measurement higher than the recommended measurement and any two of the following, either raised triglycerides or reduced high density lipoprotein cholesterol, or raised blood pressure or raised fasting plasma glucose (IDF, 2006). See Table 2.4 for exact measurements and parameters. Assessment of MetS includes abdominal girth measurement, blood pressure measurement, and blood chemistries. The tests required for diagnosis of MetS can be undertaken, requested and assessed by a General Practitioner, however, only 18% of respondents in a recent Australian study indicated that their waist measurements had been taken by the doctor during the

previous 12 months, and only 50% had received blood tests for cholesterol, glucose levels and liver function (SANE, 2007). Further, a recent report of a retrospective chart audit found that 32 of 136 first episode people with schizophrenia were not assessed for metabolic abnormalities before or during early treatment for serious mental illness (Curtis et al., 2011). The need for correct assessment of these issues is essential and required if correct diagnosis, treatment and management of MetS is to occurr.

Management of MetS is dependent on the individual's particular circumstances. For example, the person with high blood pressure or high cholesterol blood chemistries may require treatment with additional medication, while the person who has increased girth measurements only may need to make lifestyle changessuch as improving nutrition and increasing exercise. However, ongoing monitoring of blood pressure and glucose and lipid levels is essential. In 2006 Usher et al., published nursing guidelines for the assessment and management of MetS. The guidelines are summarised in Table 2.4. Implications and guidelines for nursing practice have been reported recently (Edward, Rasmussen & Munro, 2010) urging mental health nurses to be involved in physical health monitoring, education and referral to specialists, for people who are taking SGAs.

Table 2.4 Guidelines for practice for the person who is taking second generation antipsychotics

Comprehensive baseline assessment including: • Physical examination • Cardiac Investigations • Blood chemistries • Weight • Height • Waist measurement • Body Mass Index (BMI) • Family history • Personal history • Monitoring of BP, BMI and waist circumference at 4, 8 & 12 weeks after commencing treatment is recommended then 3 monthly (Baptista et al., 2004; Masand & Mago 2005)
• If there are no signs or current risk factors for metabolic syndrome indicated the nurse needs to continue regular monitoring of BP, waist circumference and educate the person re: diet and exercise (Antai-Otong 2004; Gupta 2004; Lambert & Chapman 2004; Wirshing *et al.* 2003).
If there is evidence of early indicators (increased waist circumference and elevated Blood Pressure) there is a need to monitor: • waist circumference every 3 months • BP every 3 months • BMI every 3 months (Antai-Otong 2004; Gupta 2004; Lambert & Chapman 2004; Wirshing *et al.* 2003) • Commence treatment e.g. reduction of weight & an increase in physical activity (Antai-Otong 2004; Wirshing *et al*. 2003).
• If there are three or more symptoms of metabolic syndrome need to commence treatment (e.g. reduction of weight & an increase in physical activity & medications Antai-Otong 2004; Wirshing *et al*. 2003), ongoing monitoring and referral to a specialist.

(Usher, Foster & Park, 2006, p.733).

These nursing guidelines are simple to use and assessment that incoporates these factors should become an intergral part of the assessment and management of any person prescribed and taking antipsychotic medications. The effective assessment, monitoring and management of potential physical complications from taking antipsychotic medications is important. Weight gain needs to be regularly monitored for the person commencing antipsychotic medication, as it is a major contributor to

poor health outcomes due to abdominal obesity being closely associated with raised blood pressure, raised triglycerides, reduced HDL cholesterol and raised glucose levels (IDF, 2006; Millar, 2008).

Early monitoring, assessment and intervention for weight gain assoicated with SGA treatment should occur when the person begins taking the medication and should include education on healthy lifestyle choices including reduced calorie intake and increased exercise as these have been shown to have a positive ameliorating effects on weight (Tschoner et al., 2007; Citrome et al., 2005).

2.7 Intervention studies

Studies involving the manipulation of an intervention to determine the effect of that particular intervention in a clinical setting are considered experimental in their design and often the outcomes provide evidence on which to base clinical practice (Schneider et al., 2007). Intervention studies that could potentially influence weight gain/loss for people with serious mental illness have been reported in the literature since the 1960s. Interestingly the first intervention studies reported were not implemented due to concern for the physical health of the person but rather to change behaviour considered abhorrent at the time, like over eating or inactivity. Of further interest is that during the 1960s the link between weight gain and increased risk of cardiovascular disease was first observed (Yallow & Berson, 1960). The following discussion provides an historical overview of systematic reviews and intervention studies reported to date and the influence of their respective findings on the current study. See Table 2.5 Intervention studies for an overview of studies published to date.

Table 2.5 Intervention studies.

Author (year)	Country	Features of the study	Sample size	Main result	Comments
Ayllon (1963)	U.S.A.	First report of behavioural intervention for weight gain in people with mental illness.	1	-32 kg	Withholding food would not occur today due to ethical reasons.
Sletten et al. (1967)	U.S.A.	Calorie restriction, two groups, not randomised.	14	Group A – 3.3 kg; Group B – 4.5 kg	Patients all taking chlorpromazine; demonstrated that calorie restriction can lead to weight loss.
Bernard (1968)	U.S.A.	26 week reinforcement program.	1	-46 kg	Operant conditioning techniques used.
Harmatz et al. (1968).	U.S.A.	RCT, participants assigned to one of 3 groups for 6 weeks: Group A - 1800 calorie diet only; Group B - group therapy +diet; Group C - behaviour modification +diet.	21	Mean weight changes: Group A +0.5 kg Group B -2.7 kg Group C -3.5 kg	Participants randomly allocated; participants all in-patients.
Moore et al. (1969)	U.S.A.	26 week reinforcement program.	1	-16 kg	Uncontrolled operant conditioning techniques used.
Upper et al. (1971)		26 - 28 week incentive program using tokens to reward behaviour.	2	Mean weight change: -28.6 kg	Participants described as “chronic inpatients”.
Klein et al. (1972)		25 week incentive program using tokens to reward behaviour.	5	Mean weight changes: -4.9 kg	Participants described as “chronic inpatients”.
Knox (1980)	U.K.	2 year study, each participant had a 1000 calorie diet for a minimum of 6 months.	74	70% lost weight; 18% attained ideal weight; 24.3% gained weight	Amount of weight lost not reported, there was no control group to compare.
Rotatori et al. (1980).		2 groups – behavioural treatment group and control group; 14 week study.	14	Behavioural treatment group – 3.3 kg Control group + 2.5 kg	Residential setting.

Heimberg et al. (1995)	U.S.A.	3 groups - weight reduction diet (1400-1500 calories) or lipid lowering diet (2200-2500 calories) or non-dieting control group.	40	Mean weight changes: Diet -2.9 kg; Control + 4.1 kg	All participants described as chronic in-patients taking clozapine; no random allocation.
Merriman et al (1995)		Group therapy involving diet, exercise and self-assertiveness training over 12 weeks with 4 week follow-up.	6	Mean weight changes: at end of treatment -0.2kg; at end of follow-up +0.2kg	16% drop out rate reported.
Wirshing et al. (1999)		Retrospective chart audit; participants involved in activities like regular weighing, food diaries, dietary evaluations and exercise classes. with varying lengths (6-18 months).	122	Mean weight changes: Clozapine -1.2 kg Olanzapine - 5.3kg Risperidone – 2.2kg Haloperidol -2.1kg Sertindole-2.3kg	8.8% drop out rate; all participants were male.
Aquila et al. (2000)		18 month trial of healthy diet, dietary counselling with support groups.	32	Mean weight changes: no significant weight loss at 12 months (-0.46%) or 18 months (0.28%)	9.7% drop out; participants were not randomly allocated; participants lived in a residential setting.
Umbricht et al. (2001)	Switzerland	Over 10 weeks, participants attended sessions with a psychologist and dietician.	6	Weight loss ranged from 0-21 kgs.	The sessions were conducted using a CBT approach and people participated in 7-9 sessions.
Ball et al. (2001)	U.S.A.	Over 10 weeks participants attended weight watcher (WW) meetings and exercise sessions and were compared to the control group who had normal treatment.	22	Mean weight changes: WW -2.3 kg Control group +0.2 kg	47.6% participant drop out; all participants on SGAs.

Archie et al. (2003)	Canada	Participants given 6 month pass to YMCA.	10	- 15 kg	90% drop out rate; participants cited lack of motivation as primary reason for noncompliance
Feeney et al. (2003)	Ireland	Outpatients given the option to attend a weight management program, assessed at 3 year follow-up	89	Intervention -1.6 kg/m (BMI) Control +0.2kg/m (BMI)	42.7% drop out rate.
Vreeland et al. (2003)	U.S.A.	12 week weight control program including nutrition, exercise and behavioural interventions: using MI and compared to control group who had normal treatment.	31	Mean weight changes: intervention group - 2.7 kg control group + 2.9 kg	87.1% drop out rate; partial hospitalised program.
Littrell et al. (2003)	U.S.A.	RCT; Quasi-experimental: 16 weeks of diet and exercise education; intervention group compared with usual care; 2 month follow-up.	70	Mean weight changes: Intervention group –0.27 kg (SD 4.28 kg) Usual care group +4.34 kg (SD 5.89 kg)	All outpatients; 8% drop out rate.
Nguyen et al. (2003)	U.S.A.	Healthy lifestyle education for 5 minutes followed by 2 minutes each week for 4-12 weeks.	22	6 of the 22 people lost weight. Mean change: + 2.4 kg	All participants taking olanzapine.
Noone (2004)	U.S.A.	Weekly group sessions “solutions for wellness” focusing on nutrition and fitness.	120	12 month results showed benefits with one group of 10 reporting a mean weight loss of - 6.6 kg (6 months) and - 8.7 kg (12 months)	Participants: 28 male and 92 female.
Menza et al. (2004)		52 week multimodal weight control program incorporating nutrition, exercise and behavioural interventions; compared with a usual care group.	31	Mean weight changes: Intervention -3 kg Usual care +3.2 kg	35.5% drop out rate; p = 0.01.

Tweedell et al. (2004)	Canada	Case series feasibility study - the program was a 6 month weight prevention program involving nutritional counselling and an individualised exercise program with a personal fitness trainer.	14	No statistical significance was found with any of the measures – weight, BMI and diet and exercise instruments. Follow up at 1 year indicated that all 6 completers were involved in some form of physical activity.	57% drop out rate; all inpatients at a tertiary care psychiatric facility
Ohlsen et al. (2004)	U.K.	6 week program involving dietary planning, exercise and motivational interviewing.	44	Mean weight change after 1 year -3.1 kg not significant	Nurse-led intervention; outpatients.
Evans et al. (2005)	Australia	RCT; intervention was 6 one hour nutrition education sessions over 3 months with dietician; participants randomly allocated to control (n=22) or intervention (n=29) group.	51	At 3 months: control group +2.0 kg Intervention group -6.0 kg ($p<0.002$); At 6 months: Control group +2.0 kg Intervention group – 9.9 kg ($p<0.017$).	21% drop out rate; all participants taking olanzapine.
Brar et al. (2005)	U.S.A.	Participants randomly allocated to either: two sessions weekly for 6 weeks, then one session weekly for 8 weeks of diet and exercise education or usual care, for 14 weeks.	72	Mean weight changes: Intervention -2.00 kg (SD 3.79 kg) control -1.10 kg (SD 3.11 kg)	21% drop out rate; Intention to treat analysis; all Participants were switching from olanzapine to risperidone.
Brown et al. (2005)		Participants attended a rehabilitation weight management program.	44	Mean weight changes: intervention group - 2.7 kg usual care group + 0.7 kg.	Participants were randomly allocated.

Alvarez-Jimenez et al. (2006)		Participants were randomly allocated to intervention group and usual care group for 12 weeks. The intervention was flexible education modules, designed to address weight gain and its possible causes.	61	Mean weight gain of >7% was reported as 40.7% intervention group and 77% usual care group (p=0.04)	Participants were all out-patients experiencing their first psychotic episode.
Ganguli et al. (2005)		Participants were randomly allocated to a 16 week stepped behavioural program or usual care within 30 days of commencing antipsychotics.	50	Weight gain was reduced in the intervention group with 17/27 people gaining no weight and in the usual care group 5/23 people gaining no weight (p=0.009).	Study outcome supports weight attenuation.
Pendlebury et al. (2005)	U.K.	Over 3 years patients with schizophrenia attended the weight management programme in a community mental health centre. Sessions were held weekly and included weighing, and education on healthy eating and exercise.	70	Mean weight changes: - 4.97 kg	The mean number of sessions attended was 34.
The Diabetes Prevention Program Research Group (2005)	U.S.A.	From 1996 to 1998 participants who were high risk for type 2 diabetes were randomly assigned to treatment with Metformin (n=587), troglitazone (n=585), double placebo (n=582) and intensive lifestyle intervention (n=589).	2343	The main results established that lifestyle interventions directed at weight reduction and increased physical activity is more effective than Metformin in reducing the risk of diabetes.	RCT; does not include people with serious mental illness.

Kalarchian et al. (2005)	U.S.A.	12 week group behaviour program (included education, activity, self-monitoring), weekly sessions for 12 weeks, then 2 biweekly sessions then 2 monthly sessions over 12 months. Data was collected from October 2000 to July 2003	35	Mean weight change: -3.2 kg (SD=3.4 kg)	All outpatients; 17% drop out rate.
Richardson et al. (2005)	U.S.A.	18 week physical activity intervention	39	Mean weight change: -2.4 kg	43% drop out rate; increasing physical activity can impact on weight gain.
Skrinar et al. (2005)		12 week fitness intervention	30	Mean weight change: -2.2 kg BMI – 0.7 kg/m^2	Increasing physical activity can impact on weight gain.
Centorrino et al. (2006)	U.S.A.	24 week program of diet, exercise and counselling.	17	Mean weight change: - 6.0 kg BMI - 5.7%	29% drop out rate.
Weber et al. (2006)	U.S.A.	RCT; modified after the diabetes prevention program (DPP); participants randomly allocated to intervention group or usual treatment group; the intervention was a 16 week education program including diet and exercise information; participants also kept a food and activity diary.	17	Mean weight changes: Intervention group -2.45 kg usual treatment -0.59 kg (not significant).	Intervention programs incorporating education, diet control and increased exercise can impact on weight gain.

Pendlebury et al. (2006)	U.K.	Participants self referred to weekly group weight management sessions, over 4 years. Participants recorded their diet intake each week.	93	Mean weight changes: -6.2 kg (SD=0.6 kg)	23% drop out rate, no written material given to participants
Kwon et al. (2006)		RCT, 12 week weight program (included healthy lifestyle education, food and exercise diary) based on CBT compared to usual care	48	Mean weight changes: CBT -3.94 kg Usual care -1.48 kg	All outpatients; 25% drop out rate; all participants taking olanzapine.
Brown et al. (2006)	U.K.	RCT, weekly sessions, for 6 weeks, following program - "Meaningful Day" or usual care.	28	Mean weight changes: BMI -0.02 kg/m^2 Weight -0.9 kg	39% drop out rate.
Scocco et al. (2006)	Italy	Participants attended sessions with a nutritionist over 16 weeks. Two groups started program at different times (Group 1 week 1 and Group 2 week 9) and were compared.	20	Mean weight changes: Group 1 + 3.4 kg Group 2 +1.19 kg	All outpatients taking olanzapine.
Smith et al. (2007)	U.K.	2 year nurse led intervention – "well-being support programme" – including health checks, health promotion advice, weight management and physical activity groups.	966	Results are not presented in weight measures.	Nurse-led intervention. Results provide support for healthy lifestyle programs as "most of the group were overweight, with 49% being in the obese range and 24% of the group were severely obese"
Khazaal et al. (2007)		RCT, participants randomly allocated to CBT group or Brief nutritional education (BNE) group.	61	The CBT group showed more progressive weight loss.	13% drop out rate. Data analysis occurred at base line, 12 weeks and 24 weeks.

Poulin et al. (2007)	Canada	Prospective comparative, open naturalist study over 18 months; 2 groups: education on diet and fitness as well as an exercise programme compared to usual care group.	130	Mean weight changes: Usual care group: Body weight +3.6 kg (+4.1%) BMI +1.8kg/m^2(+5.5%) Girth +4.2% Intervention group: Body weight -3.1 kg(-3.5%) BMI 1.4kg/m^2 (-4.4%) Girth -4.6%	All outpatients; 15% drop out rate; participants not randomly allocated.
Wu et al. (2007)	Taiwan	Participants randomly allocated to either calorie control & exercise program for 3x weekly group sessions, or usual care for 6 months.	56	Mean weight changes: Intervention group -4.2 kg Usual care group +1.0 kg	6% drop out rate; all participants taking clozapine; all participants in-patient.
Wu et al. (2008)	China	RCT, participants randomly allocated to 1 of 3 groups for 12 weeks: Placebo, Metformin alone, Metformin & lifestyle intervention, or lifestyle intervention alone.	128	Mean weight changes: Placebo BMI + 1.2 kg/m2 Girth + 2.2 cm Metformin alone BMI – 1.2 kg/m^2 Girth – 1.3 cm Metformin and lifestyle intervention BMI – 1.8 kg/m^2 Girth – 1.3 cm Lifestyle intervention alone BMI – 0.5 kg/m2 Girth – 0.1 cm	RCT, 8% drop out rate.
Weber et al. (2008)	U.S.A.	Participants attended weekly group sessions for 8 weeks.	8	Participants' weight remained stable.	Study outcome supports weight attenuation.
Lee et al. (2008)		Participants attended 12 weekly group sessions on diet and exercise education, and kept food diaries.	232	Mean weight change: -2.6kg	Inpatients and outpatients, no comparison group.

Melamed et al. (2008)		Participants allocated to either intervention group (including weekly healthy education, diet supervision and 5x30 minute walks/week) or usual care group for 3 months.	59	Mean weight changes: Intervention group BMI -2.8kg/m^2 Usual care group BMI -0.2kg/m^2	All inpatients; no random allocation.
Chen et al. (2009)		Weight control program with 10 weekly sessions including healthy lifestyle education, exercise and diaries.	33	Mean weight changes: 10 weeks -2.1kg 24 weeks -3.7kg 48 weeks -2.7kg	All outpatients; 21% drop out rate; no comparison group
Lindenmayer et al. (2009)		Group healthy lifestyle education program for 36 weeks.	275	Mean weight change: -2.2 kg	All inpatients; 28% drop out rate.
Skouroliakou et al. (2009)		Two groups of participants, Group 1 participants with mental illness; Group 2 participants without mental illness. Both groups participated in healthy lifestyle program including healthy lifestyle education, diaries and counselling for 3 months.	204	Mean weight changes: Group 1 -5.9 kg Group 2 -7.4 kg	31% drop out rate; study outcomes support weight reduction.

In 1963 the first published report of the use of behavioural interventions and diet control was released by Ayllon who reported a two year study to determine the effect of behaviour modification, including calorie controlled diet, with one person diagnosed with chronic schizophrenia (1963). The study reported by Ayllon (1963), while unlikely to obtain ethical approval today because it included an intervention of withholding food in order to change behaviour, demonstrated that behaviour

modification strategies can change people with a serious mental illness and a calorie control diet could have an effect on weight. A further study supported the hypothesis that a reduced calorie diet could have a positive effect on weight loss (Sletten, Cazenave & Gershon, 1967).

Further to this, Sletten et al., (1967) allocated people with schizophrenia taking chlorpromazine to either group A or B; unfortunately the allocation to groups was not randomised but participants were allocated to groups as chosen by the researchers. Group A were given a diet of 2000 calories per day and Group B was given a diet of 1000 calories per day. The findings of the reduced calorie intake for each group was a mean reduction in weight of - 3.4 kgs for Group A and a mean reduction in weight of - 4.5 kgs for Group B (Sletten, Cazenave & Gershon, 1967). Further reports supported the findings first found by Ayllon (1963) and Sletten et al., (1967) that behavioural intervention and diet control led to a reduction in mean weight measurements for people with schizophrenia prescribed first generation antipsychotic medications (Bernard, 1968; Harmatz & Lapus, 1968; Moore & Crum, 1969). While these studies do not include second generation antipsychotic medications as they had not been introduced at the time, they did demonstrate that there was concern for weight gain.

The ability of people with serious mental illness to change behaviours is also demonstrated in these studies. It is important however to acknowledge that many studies that occurred in the 1960s and took place in large psychiatric facilities where choice to participate in treatment for the person with serious mental illness was nil or at the very least limited. This is in direct contrast to present day studies where

informed consent forms an essential aspect of participation in an intervention study. Nevertheless, these early intervention studies provided evidence that weight gain was an issue of concern for the person with serious mental illness.

In the 1970s and 1980s there were only four reported studies for weight control in people with SMI. The studies included two weight reduction programs for people with schizophrenia; however both of these studies had very small cohorts of two and five participants respectively (Upper & Newton, 1971; Klein, Simon, Steele & Primavera, 1972). These studies reported weight loss for all participants; however they are both uncontrolled incentive programs (Upper & Newton, 1971; Klein et al, 1972). In 1980, Rotatori, Fox and Wicks reported a weight loss study that for the first time was conducted with participants living in a residential rehabilitation setting. The study findings included a mean loss of – 3.3 kgs for the group who participated in the behavioural treatment strategy (n=7), while the control group (n=7) had a mean gain of + 2.5 kgs (Rotatori et al., 1980). This is significant as all previous studies were in highly controlled psychiatric inpatient settings. It is important to note that second generation antipsychotics were not in use at the time of these studies.

In the 1990s the first weight loss studies that included people prescribed and taking SGAs were reported. The first of these studies was focused on one particular antipsychotic, clozapine, and all participants were hospitalised patients prescribed and taking the drug (Heimberg, Gallacher, Gur & Gur, 1995). The participants were not randomly assigned but rather chosen by the researchers and then allocated to either a “dieting group” or “non-dieting group”. The intention of the study was to determine if diet control could affect weight loss for people taking clozapine. The

findings for the dieting group was a mean reduction in weight of – 2.95 kgs and a mean weight gain of + 4.0 kgs for the non dieting group (Heimberg et al., 1995). This was the first study to discuss the possibility of a link between antipsychotic medications in particular clozapine, and weight gain, and the relationship with the development of other side effects such as diabetes. However, much of the discussion in the literature concurred that people with schizophrenia had premorbid weight issues before commencing antipsychotic treatment and therefore it was their premorbid obesity that led to the increased risk of diabetes rather than commencing treatment with antipsychotic medications (Heimberg, et al., 1995).

Two additional studies in the 1990s provided some evidence to support the introduction of healthy lifestyle education when people are commencing treatment with first or second generation antipsychotic medications. Firstly, Merriman, Riddell and Thrush (1995) reported a 12 week study, which introduced a small sample of participants (n=6) to diet and exercise education along with self assertiveness training. The mean weight loss reported at the end of 12 weeks was only - 0.2 kg (Merriman et al., 1995). This is a small weight loss, but it could be argued that while the participants did not lose large amounts of weight they were at least able to maintain their current weight and possibly attenuate further weight gain. There is evidence that weight gain during treatment with antipsychotic medications can be up to as much as + 2.3 kg per month (Nihalani et al., 2011).

The second study reported in 1999 was a retrospective chart audit of 92 male patients with schizophrenia. The participants (n=92) had the opportunity to join in a variety of weight loss activities, such as regular weighing of food, keeping a food

diary and exercise classes over 6-18 months (Wirshing, Wirshing & Kysar, 1999). The results are reported according to antipsychotic prescription, with the authors concluding that despite involvement in weight loss activities, people taking clozapine continued to experience persistent weight gain (Wirshing et al., 1999). The mean weight changes were reported as: clozapine -1.2 kgs (n=20), olanzapine - 2.3 kgs (n=13), risperidone - 2.2 kgs (n=38), haloperidol - 2.1 kgs (n=43), and sertindole - 2.3 kgs (n=8) (Wirshing et al., 1999). The findings of this study provide evidence to support the notion that some antipsychotic medications have a higher metabolic risk than others.

From 2000 to 2010 a range of studies (Aquila & Emanuel, 2000; Ball et al., 2001; Vreeland et al., 2003; Littrell et al., 2003; Brar et al., 2005; Pendlebury et al., 2005; Richardson et al., 2005; Centorrino et al., 2006; Weber & Wyne, 2006; Kwon et al., 2006; Evans et al., 2006; Pendlebury et al., 2007; Khazaal et al., 2007; Poulin et al., 2006; Wu et al., 2007; Wu et al., 2008) were reported that added to the literature and evidence for weight loss interventions for people with serious mental illness taking antipsychotic medications. Studies included analysis of the impact of nutrition education only, nutrition and exercise education, nutrition and exercise education along with organised exercise sessions, exercise sessions only, counselling sessions only, healthy lifestyle intervention and medication for weight management and a combination of healthy lifestyle education, organised exercise sessions and motivational counselling support. Systematic reviews have added to the literature with the most recent supporting the need for further investigation of weight management interventions to fully understand their effectiveness McCloughen & Foster, 2011).

While the following discussion focuses on the publication of research based study outcomes, the literature also includes systematic reviews of the literature. Werneke, Taylor, Sanders and Wessely (2003) conducted a review with the aim to determine "the effectiveness of behavioural interventions for the prevention and treatment of overweight patients treated with antipsychotic medication and individuals in the general population" (p. 253). The review found 13 studies of behavioural interventions with varying outcomes, while no study met the criteria for a randomised control trial, 7 studies had control groups and of these only 2 studies identified significant results (Werneke et al., 2003). The authors recommended that "management of weight gain will be an important part of the management of psychosis and behaviour interventions will have a major role" (p. 257). However caution is needed as there are many factors identified that can influence the outcome of a study, including: small sample sizes, no comparison group and absence of randomisation (Werneke et al., 2003). Faulkner, Soundy and Lloyd (2003) and Sharpe and Hills (2003) found that small weight reductions are possible but urge caution due to potential bias resulting from non randomised control trials. The authors recommend that improved understanding of the effects of healthy lifestyle interventions will only come from rigorous randomised controlled trials (Faulkner et al., 2003; Sharpe & Hills, 2003; Werneke et al., 2003).

While more recent systematic review reported in 2007, 2009 and 2011 have found similar conclusions authors (Faulkner et al., 2007; Lowe 2008; Galletly & Murray, 2009; McCloughen & Foster, 2011) continue to explain that small weight loss is achievable, while continuing to caution that interpretation of the results are limited by

small sample sizes, short study durations, variability of interventions and limited randomised control trials (Galletly & Murray, 2009). The following discussion focuses on individual research studies.

Of the nutrition education only studies Evans et al., (2005) reported a study conducted in Australia that investigated the impact of six nutritional education sessions over 3 months. The participants were randomly allocated to control and intervention groups. The study reported statistically significant findings (p=<0.002) with the intervention group experiencing a mean weight loss of - 6.0 kg and the control group experiencing a mean weight gain of + 2.0 kg (Evans et al., 2005). The findings of this study provide robust support for nutrition education to be included as part of the management plan for people prescribed antipsychotic medications.

A small healthy lifestyle intervention study reported in 2001 recruited 22 people with schizophrenia who had experienced weight gain after commencing treatment with olanzapine (Ball, Coons & Buchanan, 2001). The participants who completed the program (n=11) attended weekly weight watcher meetings and exercise sessions for ten weeks. The findings reported a mean weight increase of + 0.2 kgs for the comparison group, while the intervention group reported a mean weight loss of – 2.3 kgs (Ball et al., 2001). The results of this study support the use of a combination of healthy lifestyle education and organised exercise sessions.

Another study that adds support to the use of regular healthy lifestyle education and exercise sessions included 70 participants (Littrell, Hilligoss, Kirshner, Petty & Johnson, 2003). The regular sessions included nutrition, exercise and healthy living

education. The study results reported a mean weight loss of - 0.03 kgs for the intervention group and – 4.35 kgs for the control group (Littrell et al., 2003).

A further study of note was conducted in the community and tested the hypothesis that a brief, community based healthy lifestyle intervention could improve weight, diet and exercise for people with serious mental illness (Brown, Goetz & Van Sciver, 2005). The study used a randomised control design to determine the effects of 6 weekly individual health promotion sessions. Participants were randomly allocated to treatment group (n=15) or control group (n=13). Due to a dropout of 11 participants, results were reported as small but significant with a mean weight loss of - 0.9 kgs overall (Brown et al., 2005). The authors report this was the first RCT to evaluate weight, diet and exercise for people with serious mental illness. While caution in evaluating the results is suggested, they nevertheless advocate that health promotion interventions can produce positive health gains for people with serious mental illness (Brown et al., 2005).

The findings of organised exercise sessions only were reported by Archie, Wilson, Osborne, Hobbs and McNiven (2003) who conducted a pilot study with the aim of increasing fitness levels for people with serious mental illness. Each of the participants (n=10) were given a 6 month pass to the YMCA gym. Unfortunately, this study reported a 90% drop out rate; however the one remaining participant had a weight reduction of - 15 kgs (Archie et al., 2003). Interestingly, the findings of counselling sessions only were reported by Umbricht, Flury and Bridler (2001) who conducted a small study of 6 people with schizophrenia who participated in Cognitive Behaviour Training (CBT) sessions with a psychologist and dietician for ten weeks.

The weight loss reported after 10 weeks ranged from 0 - 21 kgs. While this study has a small cohort of participants (n=6) it demonstrates the potential positive effects of counselling on the experience of weight loss. These two studies were small yet they provide evidence that regular organised counselling and organised exercise sessions can have a positive impact on weight loss for people with serious mental illness.

The Diabetes Prevention Program clinical trial (DPP, 2002) in USA was a large scale study that provided robust support for the introduction of healthy lifestyle interventions. This major study enrolled 3,234 non-diabetic people who were overweight and had elevated blood sugar levels. Participants (n=3234) were randomly allocated to different interventions that included lifestyle modifications, such as diet and exercise education, or medication such as Metformin. The findings demonstrated that lifestyle interventions that included diet changes and increasing physical activity were able to prevent the onset of diabetes (Knowler et al., 2002). While this study does not include people with serious mental illness, it does provide robust evidence of the positive impact of healthy lifestyle programs on weight maintenance or reduction and has led to the development of similar programs for people with serious mental illness. One subsequent study that was developed as a result of the diabetes prevention program comes was by Weber and Wynne (2006). Their results from a CBT program for weight loss developed using the diabetes prevention project program was reported in 2006, with the intervention group (n=8) experiencing a mean weight loss of – 2.7 kgs, while the usual care group (n=9) had a mean weight loss of - 0.6 kgs.

There are only a few studies that have reported the effects of a combination of healthy lifestyle education, organised exercise sessions and motivational counselling support. One of these studies is Vreeland et al., (2003) who reported the findings for 46 participants with serious mental illness who were randomly allocated to control and intervention groups. The weight loss intervention tested included nutrition and exercise education as well as motivational interviewing techniques. The findings after 12 weeks were positive with a mean weight loss of - 2.7 kgs for the intervention group and a mean weight gain of + 2.9 kgs for the control group (Vreeland et al., 2003).

A further study with a similar sample size of 51 was reported in 2004. This study randomly allocated participants to the usual care group (n=20) or a combination of nutrition and exercise education along with behavioural interventions (Tweedell, Sutter, Dunphy & Landeen, 2004). The participants in the intervention group (n=31) had a mean weight loss of – 3.0 kgs, while the participants in the usual care group (n=20) had a mean weight gain of + 3.2 kgs over a 52 week period (Tweedell et al., 2004). A further key study is a 6 week nurse-led healthy lifestyle intervention study of 44 people who had experienced antipsychotic-induced weight gain. Ohlsen, Treasure and Pilowsky (2004) reported the findings of this short program that involved diet planning, exercise advice and motivational interviewing. Participants were followed up for one year and a mean weight loss of – 3.1 kgs was reported (Ohlsen et al., 2004). Interestingly this study is one of only two reported in the last 10 years that has nurse involvement. While the authors report that overall the weight loss is considered small, the majority of participants (72.2 %) lost weight (Ohlsen et al., 2004).

Randomised control trials (RCT) were reported in the last 10 years, with some positive outcomes. Kwon, Choi, Bahk, Kim, Kim, Sin et al., (2006) reported the findings of an RCT testing the effects of a healthy lifestyle management program for 48 people with schizophrenia or schizoaffective disorder. The mean weight loss for the intervention group was - 3.9 kgs while the usual care group had a mean weight loss of - 1.48 kgs.

Another RCT tested the effects of a brief health promotion intervention for 28 people with a serious mental illness and found a mean weight loss of only – 0.9 kgs for the intervention group (Brown & Chan, 2006). Whereas Wu, Zhao, Jin, Shao, Fang, Guo, He, Liu, Chen and Li (2008) who reported the results of an RCT with 128 people with schizophrenia that compared the effects of lifestyle intervention with Metformin prescription, found that participants prescribed Metformin had mean BMI decreases of -1.2, the lifestyle intervention group had a mean BMI decrease of 1.0, and the group that received both had mean decreases of BMI of -1.8.

However, of the many healthy lifestyle intervention studies reported in the last 10 years only two studies reported their study setting as being in the community (Feeney, Dempsey, Moynihan & Barry 2003; Evans, Newton & Higgins 2005), and another two identified nurse involvement in the study (Ohlsen, Treasure & Pilowsky, 2004; Smith, Yeomans, Bushe, Eriksson, et al., 2007). This is disappointing as we know that mental health care has moved significantly in the last 20 years from institutionally based care to community based care, and along with this move there has been changes in the roles that nurses play in mental health care. For example

the role of community mental health nurse or case manager has developed in the last 20 years to include assessment and management of people with increasingly complex issues such as serious mental illness and serious physical illness. Disappointingly, a systematic review of 16 healthy lifestyle interventions reported that none of the studies were conducted by nurses, leading the reviewers to conclude that nursing research has "neglected this area" (Bradshaw, Lovell & Harris, 2005, p. 653). However two studies (Ohlsen et al., 2004; Smith et al., 2007) were found that reported nurse involvement in the interventions, lending further support to the need for nurse involvement to increase.

2.8 Summary of key points

As evident in the research to date, significantly greater weight reduction has been found in lifestyle intervention groups versus pharmacological intervention groups or standard care groups in many studies since the land mark DPP study in 1996-1998 (Ball et al., 2001; Evans et al., 2005, Knowler et al., 2005; Littrell et al., 2003; Vreeland et al., 2003; Weber & Wyne, 2006; McCloughen & Foster, 2011). However, the outcomes so far are limited by factors such as the small number of studies, small sample sizes, short study duration, and by variability in the interventions, including their intensity and duration. Further research that distinguishes between weight gain prevention and weight gain attentuation has been recommended for further studies (Faulkner, Cohn & Remington, 2007; McCloughen & Foster, 2011). The current (although limited) literature argues for further investigation of physical health issues, including weight gain, for people with mental health problems, and suggests that provision of evidence-based health care will not only support the individual but has broader implications for the health and well-being

of the general community (Antai-Otong, 2004; Beebe, 2008; Jennex & Gardner, 2008).

2.9 Passport 4 Life: a healthy lifestyle intervention

Thus, in the current study, Passport 4 Life has been developed. Passport 4 Life includes a 12 week healthy lifestyle booklet, weekly group sessions, exercise sessions, support through nurse involvement, and motivational interviewing. Passport 4 Life was developed using best practice government guidelines that incorporate recommendations for healthy eating and exercise for adults. The use of these guidelines provides the participant with well researched advice for healthy eating and exercise (Queensland Government, 2008). For example the 2 fruits and 5 vegetables per day program are incorporated into Passport 4 Life (P4L) along with the recommendation of daily serves of milk and cheese, bread and cereals and fats (NHMRC, 1998). These recommendations provided by the NHMRC (1998) provide the participant with the necessary advice for healthy eating. These same recommendations are also used nationally for advertising campaigns and this will reinforces to the participant that they are making the same healthy choices as the rest of the population. Passport 4 Life is discuss in further detail in Chapter 3.

Passport 4 Life is designed to be delivered in the community. The choice to deliver the program in community settings was consistent with the current mental health policy (Queensland Government, 2008) of community based care for people with mental illness. Delivering the program in the community enables the program to maintain an authentic and realistic approach for participants, as the activities occur in the community, enabling the participant to replicate and integrate the program into

their daily activities. This approach has a twofold benefit in that it enables the person to participate in a support environment while also breaking down the barriers of stigma.

2.10 Summary

This chapter has reviewed the literature and evidence on healthy lifestyle choices and psychotropic medications. MetS is a prominent and serious condition associated with the use second generation antipsychotic medications, and there is a crucial need for effective prevention and intervention for this side effect. The prevalence of MetS for people with schizophrenia is significantly higher than the general population and the importance of acting on the increasing incidence of MetS is essential. Intervention studies from the 1960s to today have found that weight changes can occur when healthy lifestyle interventions are used. However caution is required as many studies so far have been limited by small sample sizes, short duration, and by variability in the interventions. Further research that distinguishes between weight gain prevention and weight gain attentuation has been recommended while the importance of rigourous study design is also required. The important role that healthy lifestyle interventions play in changing people's behaviour cannot be underestimated.

The following chapter discusses the methodology and methods adopted in the study. It begins with the research design, including descriptions of the essential elements of randomised control trials like: randomisation, control, and manipulation. Study protocols are described, along with sampling procedure, participant criteria, and sample size, followed by details for each group setting. The study intervention is

outlined in detail, along with the design of the program. Data collection tools and study procedures are described. Finally ethical considerations are discussed.

CHAPTER 3: RESEARCH DESIGN AND METHOD

3.1 Introduction

In this study, a randomised controlled trial was conducted to test the effect of a nurse-led intervention for weight gain prevention or maintenance for people with schizophrenia prescribed and taking second generation antipsychotic drugs (SGAs). The following chapter describes the research design, setting, participants and sampling technique used in the study. The study protocols and procedures, data collection and ethical considerations, as well as the analytic techniques employed, are discussed in detail. The structure and components of Passport 4 Life, the nurse-led intervention, are also described.

3.2 Research Design

The research used an experimental design to test the effect of a nurse-led intervention, 'Passport 4 Life', on weight gain prevention or maintenance in people with schizophrenia prescribed and taking second generation antipsychotic drugs. Experimental designs include randomisation, control, and manipulation as essential aspects of the research process. As explained by Schneider et al., (2007), "…these designs are used to test 'cause-and-effect' relationships between an intervention and an outcome, and minimise or control any alternative explanations for the study findings" (p. 166). This study tested the relationship between the delivery of a specifically designed nurse-led intervention and weight gain prevention or weight maintenance in people with serious mental illness taking SGAs. The aim of the study was to determine whether a nurse-led intervention can have an impact on weight maintenance or reduction or ameliorate weight gain for people with serious mental illness (SMI) already prescribed and taking SGAs.

Randomised controlled trials (RCT) are considered to have superior status amongst experimental research design studies and are often referred to as the “gold standard” of research methods (Thompson, 2004; Walker, 2005; Schneider et al., 2007). This reputation enables the findings of a well developed and applied RCT to be considered as quality evidence on which to base practice in healthcare (Walker, 2005). The question of healthcare treatment effectiveness can best be answered by a randomised control trial according to Seers and Crichton (2001). The following diagram (Figure 3.1) clearly outlines the RCT design.

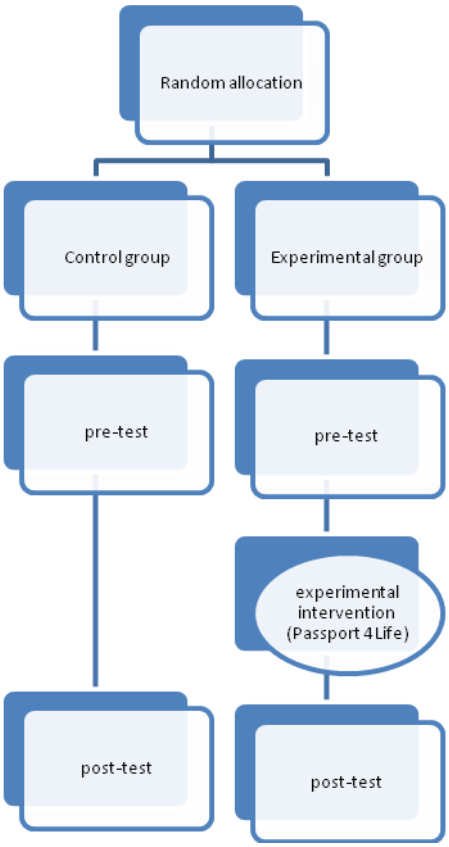


Figure 3.1 RCT design (Adapted from Schneider et al., 2007, p. 168).

For a study to meet the strict requirements of the RCT design, certain standards are needed specifically; randomisation, control, and manipulation (Schneider et al.,

2007). A rigorous approach by the researcher is required to ensure these high standards are maintained. The following discussion demonstrates how these important components were met in this study.

Randomisation, an essential feature of RCT designs, is undertaken to protect against confounding bias. Randomisation ensures each study participant has an equal chance of being allocated to the intervention or control group. This equal chance ensures that all known and unknown factors (variables) are similarly distributed between the groups (Seers & Crichton, 2001). Randomisation must be concealed and unable to be predicted by the participants and the researcher (Seers & Crichton, 2001; Forder, Gebski & Keech, 2005).

In the current study, the random allocation between the two groups occurred when the researcher asked each participant to select an opaque envelope, from a box of envelopes, containing a number and alphabetical letter, for example I = intervention group and C = control group. This process is supported by Seers and Crichton (2001), who explain "ways of achieving concealed random allocation include using consecutively numbered, sealed opaque envelopes" (p. 496). This selection determined to which group the participant was randomly allocated and ensured randomisation in the study. Therefore potential participants, and hence variables, had an equal chance of being randomly allocated to each group. Participants' information was then coded with I for intervention group or C for control group. The researcher had a coding book that was locked and only accessible to the researcher. Participants' names and allocated codes were listed in the coding book. As well as

documenting the groups to which each person was allocated for future reference, this process also helps to maintain participant confidentiality.

Control is the second essential element of the RCT. The ability of the researcher to control a study is observed in the rigour of inclusion/exclusion criteria, blinding of the study, and random sampling (Walker, 2005). The control element of the study design enables the researcher to attribute the outcomes to the intervention tested (Duffy, 1985). The control element of the RCT design also enables the researcher to make statements beyond the sample size to the target population (Seers & Crichton, 2001; Walker, 2005). For this study, control was demonstrated by random allocation of participants (discussed above), the strict application of inclusion/exclusion criteria, the use of study protocols, and the inclusion of a control group for comparison with the intervention group.

Allocation concealment in randomised control trials is important and as Schulz and Grimes (2002), suggests “convey a strong bias prevention message” (p. 697). Forder, Gebeski and Keech (2005), describe allocation concealment as “the procedure used for protecting the randomisation process so that the treatment to be allocated is not known before the patient enters the study”, while blinding is “the masking of treatments after randomisation” (p. 87). Allocation concealment was successful in this study and has been described above. Blinding is not always possible in behavioural intervention studies and this was the case for this study (Schneider et al., 2007). It was not possible to blind the participants to their group allocation as they were required to attend each week (intervention group) or not attend each week (control group).

The study inclusion criteria enabled the researcher to apply explicit characteristics that restricted the sample of the study within a specific population to ensure a homogeneous group of participants. Vital to the RCT, this enables control of extraneous variables (Schneider et al., 2007). The inclusion criteria for this study were: a diagnosis of serious mental illness, 18 years of age or older, not currently psychotic, prescribed and taking second generation antipsychotic medication and living in North Queensland. The rationale and further descriptors of these criteria are discussed under the section 'Participants and sampling procedure'.

3.3 Study protocols

Study protocols were also used to help maintain control in the study and therefore minimise the threat to validity from extraneous variables either antecedent or intervening (Schneider et al., 2007). Antecedent variables are a risk to the study before the study commences and intervening variables are a risk during the study. Both antecedent and intervening variables, if not controlled for, can affect the outcome of the study (Schneider et al., 2007). Study protocols also ensure that all participants receive the same treatment/intervention. The following protocols were developed and used to control any effects of the potential variables.

Protocol for group allocation (random allocation) – Appendix F: 1

Protocol for intervention group – Appendix F: 2

Protocol for control group – Appendix F: 3

Protocol for obtaining consent and collecting measurements – Appendix F: 4

Manipulation is the third element essential for experimental research. Schneider et al., (2007) explain that “manipulation is only relevant in interventional studies, when a researcher manipulates the independent variable by introducing a ‘treatment’ or ‘intervention’” (p. 159). The components of the study included a weekly education program in written form, that incorporated nutrition and exercise education (provided for all participants), weekly group sessions incorporating the concepts and spirit of motivational interviewing (delivered to the intervention group only), and a group exercise program (intervention group only). These study components are discussed further under the section ‘Study intervention’.

In summary, the essential components of experimental research design include: randomisation, control and manipulation. These essential elements have been identified and discussed in relation to the current study and the process of implementation, and ensured rigour for the experimental design.

3.4 Setting

The study was conducted at a variety of settings accessed through established community organisations including non government community agencies and the local area mental health service in north Queensland. The intervention components of the study included a weekly education program in written form, weekly group sessions incorporating the concepts and spirit of motivational interviewing (delivered to the intervention group only), and a group exercise program (intervention group only). These study components are discussed further under the section ‘Study intervention’.

Community settings are where people live their lives. In community settings the principles of health promotion are best situated as proposed in the Ottawa charter that states: “health is created and lived by people within settings of their everyday life; where they learn, work, play and love (WHO, 1986, p. 4). Therefore, as this study aimed to help people to change their lives in ways that would assist them to enhance their health, the setting considered as the most appropriate place to conduct the study was the community in which the participants lived their everyday lives. The majority of the intervention groups in the study were therefore located in community settings. However, as some participants who wanted to be involved in the study were located in inpatients settings, one intervention group included participants from within a locked secure ward of a mental health facility at a local regional hospital.

The motivational/education intervention component of the study required a group room, seating, privacy, and access to amenities such as a place to eat and toilets. Most groups were therefore conducted at premises provided by local non government community organisations. The exercise component of the intervention was conducted in settings located close to the community organisation in which the intervention groups were conducted. For example, one group in the weekly intervention program utilised the local park and swimming pool, while another group utilised a group room and incorporated exercise while watching a DVD, and a further group made use of the space and exercise gym located at the setting.

The exercise component of the intervention was chosen the week prior by the group. If required, the researcher provided a variety of examples of activities and the group

chose an activity that suited them. The suggestions offered by the researcher took into account financial costs associated with activities as well as special clothing or equipment that might be required. The intention of the activity was to introduce the participants to exercise that could be easily incorporated into their daily lives with no or minimal cost.

The groups adapted to the setting provided for the weekly intervention groups. One setting shared a common-room that was used as a walk through to get to an office which resulted in interruptions and limited privacy. While this did limit the discussion of the group, the participants made the most of the setting available. As a way to allow for open discussion in this particular group, the researcher and the participants decided to meet for discussion time at the local beach after their exercise period. The adaptation to the setting became quite popular as it was seen more as an outing than an education session. This example demonstrates that the program can be adapted to different settings, so that participants are able to incorporate their health needs into their everyday life without the requirement for special or expensive equipment.

3.5 Specific setting details for each group

Passport 4 Life was conducted in five different settings over the course of the study. Four were community settings including local day to day living programs and one was a local secure mental health facility. The settings are described below:

1. The first community setting was a local non government organisation that had a day to day living program already in place. This organisation is well known in the local community and was established over 20 years ago. Anyone with a mental illness is able to join the organisation and access the day to day

living rehabilitation program. The day to day program is advertised to local consumers each month via newsletters, posters and word of mouth. The Passport 4 Life program was advertised through the same process and was able to fit into the schedule for the day to day living program. There was a group room available that had access to all amenities for the duration of the program. The exercise activity was undertaken at a local park close to the organisation.

2. The second community setting was a local government run rehabilitation service where participants lived. This service provided a daily group program to consumers living in the rehabilitation units. The program Passport 4 Life became a part of the group program that was offered. The program was advertised to potential participants through a flyer and a group meeting that was held weekly. The participants could voluntarily join the group, by writing their name on the group planner. There was a group room available with access to amenities for the duration of the program. The exercise activity was undertaken at the gym located at the rehabilitation complex.

3. The third community setting was another non government organisation whose core business was supporting and training people with a mental illness to find employment. The program Passport 4 Life was offered at the completion of employment training each week. Passport 4 Life was advertised to participants by the researcher meeting informally with each new group at the commencement of training. Anyone who attended the employment training program was invited to join the Passport 4 Life group. The group was also advertised through the employment consultants to people who were not attending employment training. There was a group room available with access to amenities for the duration of the program. The exercise activity took place in the group room with the use of a walking DVD*.

4. The fourth community setting was the local health service run day to day living program. The Passport 4 Life program was advertised to potential participants through a flyer and a group meeting that was held weekly. The participants could voluntarily join the group, by giving their name to the

coordinator. There was a group room available with access to amenities for the duration of the program. The exercise activity took place at the local park located close to the organisation.

5. The fifth group setting was a secure mental health service. The Passport 4 Life program was advertised via a poster and the researcher meeting with potential participants. The participants could volunteer to participate in the program. There was a group room available with access to amenities for the duration of the program. Due to the requirement of this restricted setting, staff members had to attend the group each week with the participants. The exercise activity took place in the group room with the use of a walking DVD*.

*The walking DVD used for two of the groups was done so at the request of participants. There were some participants who had social phobias and did not want to exercise in public. "Start walking at home" is supported by the American Heart Association and is a 30 minute instructional 'walking' DVD. I was not able to find a similar Australian 'walking' DVD at the time of the intervention component of this study.

3.6 Participants and sampling procedure

The target population for this study was individuals with a diagnosed serious mental illness like schizophrenia living in north Queensland, who were prescribed and taking second generations antipsychotics. People from the target population were invited/recruited to join the study by way of community advertisement in local consumer group newsletters, in person by the researcher attending (by invitation) organised groups, and also by word of mouth of consumers or health care professionals who had joined or read about the study. Posters advertising the study were also placed in local community organisations (see Appendix G).

Community organisations were chosen as the most appropriate recruitment sites as this is where many people with schizophrenia are known to seek assistance for their health care needs rather than from mainstream health services (Muir-Cochrane, 2006). Therefore, sampling and recruitment was conducted at the services where a person with schizophrenia was likely to attend, for example the local mental health service and local non government organisations. This type of sampling is convenience sampling (Creswell, 2009) and is described below. Participants were recruited and then as previously described, randomly allocated to the intervention or control group. Convienience sampling uses the most readily accessible people from naturally formed groups, such as the community mental health organisations used in the study (Creswell, 2009). The sample were selected using the following sample criteria.

3.7 Sampling inclusion criteria

The following identifies the study sampling criteria and outlines the rationales for selecting these criteria.

- **Diagnosed serious mental illness such as schizophrenia**

  Schizophrenia is considered a serious mental illness with potential life changing effects. Schizophrenia is described by Bardwell and Taylor 2009 as “a disorder characterised by a major disturbance in thought, perception, cognition and psychosocial functioning and is one of the most severe mental disorders” (p. 250). The most common treatment for schizophrenia is prescription of second generation antipsychotics (Livingston, 2011).

- **Prescribed and taking second generation antipsychotics**

  The most common treatment for psychosis and schizophrenia is second generation antipsychotics and one of the most common side effects experienced is metabolic effects including weight gain (Usher, Foster & Bullock, 2009).

- **18 years of age or older**

  The age of particpants in the study was 18 years or older. This enables the participant to be considered an adult with the ability to make their own decisions in relation to their health.

- **Not currently psychotic**

  People with serious mental illness can experience the symptoms of psychosis daily. Due to the need for participants in this study to be able to concentrate and retain information, those participants who were currently psychotic could not be included as psychosis is known to impair these mental functions (Bardwell & Taylor, 2009). It was important during the study to recognise this and acknowledge that a person with serious mental illness is able to concentrate, repeat and retain information when they are in control of their psychosis*.

- **Living in North Queensland**

  The study was conducted in the local area, and due to the requirement of the intervention group to attend weekly group sessions it was important that participants lived within an easy traveling distance. The participants were assisted with travel via the use of taxi vouchers if required. Most participants lived within 10-20 minutes travel of the group activity. One participant traveled 30 minutes each week to attend.

*At the beginning of the study participants were asked to identify a person (e.g. a famliy member, case manager or doctor) that could be contacted in the event they became mentally unwell during the study. Participants were encouraged to discuss

their participation in this study with this person. The nurse researcher conducting the intervention program was a mental health nurse who was able to identify mental status changes during the groups, and as required (with consent) was able to contact the support person of the participant with any concerns.

3.8 Sample size

The sample size was determined using the traditional method of power calculation for comparing mean values. With the use of a nomogram the sample size was calculated which enabled the researcher to predict accurate inferences about the relationship between the nurse-led intervention and weight gain prevention or maintenance for people diagnosed with schizophrenia, and prescribed and taking SGAs (Altman, 1991; Schneider, et al., 2007). The importance of the sample size cannot be underestimated as explained by Ingram (1998) who maintains that the findings from the study need to be generalisable to the population and the study should have a reasonable chance of detecting a significant effect.

Using power calculation methods the sample sizes of 47 in the intervention and 47 in the control group were calculated as sufficient to detect the differences in weight and girth measurements specified in the table 3.1 below.

Table 3.1: Anticipated weight and girth changes.

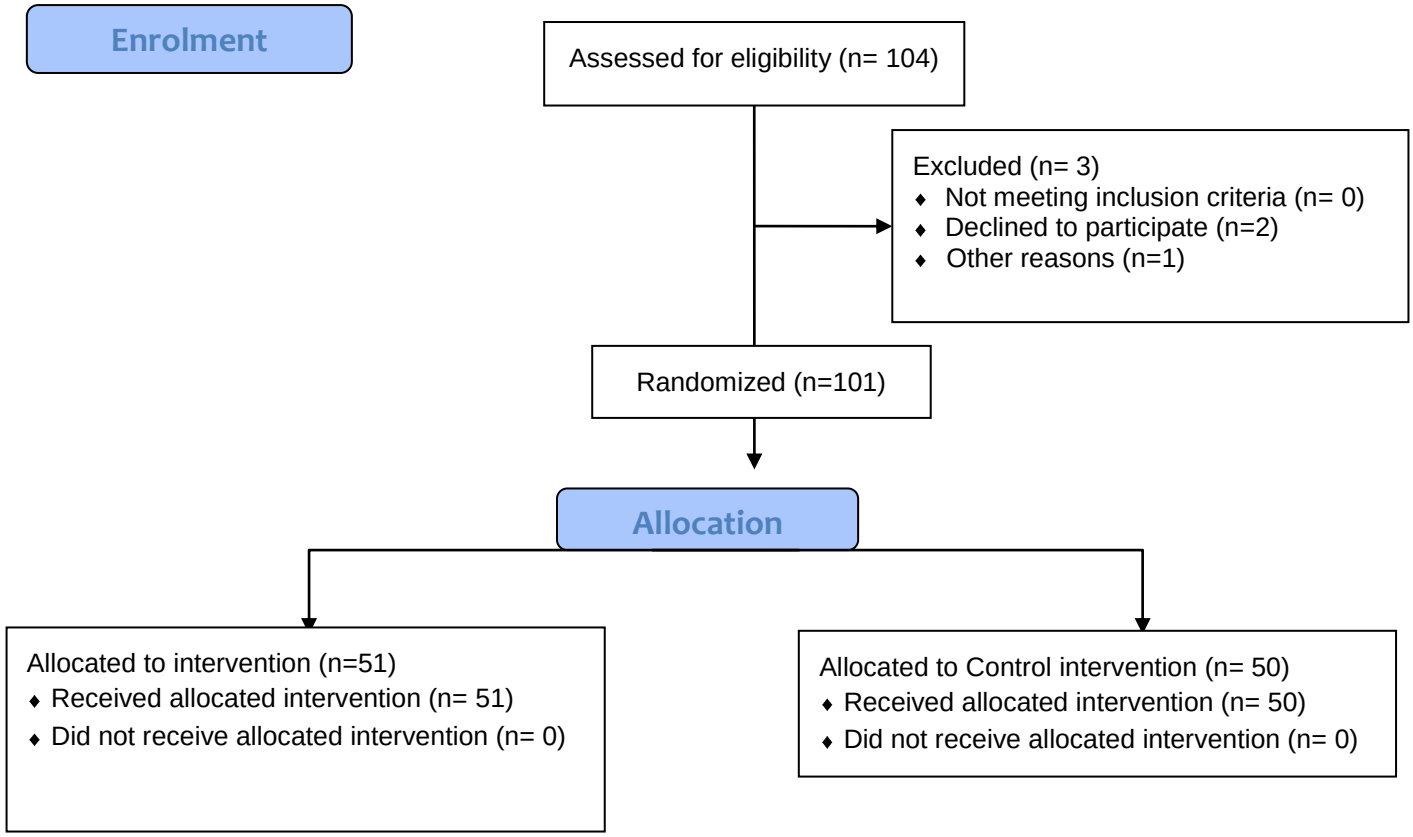
Measurement	**Intervention Group**	**Control Group**
Weight	Loss of 0.5 kg or no gain at 12 weeks	Gain of 1 kg at 12 weeks
Girth	Loss of 1 cm at 12 weeks	Gain of 1 cm at 12 weeks

The power of a study is the ability of the study to detect a difference of a given magnitude and the greater the power of the study, the greater the likelihood that the

study results will be significant (Altman, 1991). Seers and Crichton (2001) also explain that “for a clinical trial to be useful there must be enough research participants to detect a difference between the two groups, this is known as the power of the study” (p. 497).

The power for the study described here is in excess of 80%, with an overall alpha level of 0.05 (Ingram, 1998). Tschoner et al. (2007) reported on eight studies that investigated the effects of various behavioural programs for antipsychotic induced weight gain and found compliance rates for participants varied from 92-69%, with an average attrition of 20% (Tschoner et al., 2007). Given these findings, the sample sizes were inflated to 50 in the intervention group and 51 in the control group. At the completion of the study there were four people who had enrolled but had not completed the intervention. The sample size recruited is demonstrated in Figure 3.2 which outlines the sample, and number randomised to each group (Schulz, Altman & Moher, 2010). The sample was recruited from the North Queensland area.

Figure 3.2 Sample size and randomisation (Adapted from Schulz, Altman & Moher, 2010).



3.9 Study procedure

Potential participants who met the study criteria were invited to attend the first session of each 12 week intervention program. At this initial group, further explanation was given regarding consent, the study, and participant requirements. The participant information form (Appendix 3.6) was given to participants to read. After agreeing to be involved in the study, participants were asked to sign the consent form and were invited to select an opaque envelope which provided the researcher with the random allocation of the participant. The result of the allocation was then explained to the participant.

After the group allocation was complete, participants were given their program bag. The bag contained a water bottle, pedometer, pen and the folder 'Passport 4 Life'. All participants and the researcher spent time discussing the program. The researcher explained the different components of the program and gave examples so that participants could see what each component of the program included. For example, the daily record section required each participant to keep a record of the food they ate, the activity or exercise they did, and how they felt each day. The researcher asked each participant for ideas about how the participant could incorporate this recording task into their daily activities. If participants were not able to offer any suggestions, an example was offered by the researcher. Examples included, keeping daily record next to their tablets and writing in it each day when they took their medication.

After the discussion of how the program would run, each participant was invited to complete the data collection outcome measurement tools. These were undertaken with the assistance of a research assistant. When all survey tools were completed, including demographic data, height, weight and girth measurements were collected by the research assistant. Participants were then informed whether they needed to attend the current series of workshops or return in 12 weeks for further data collection. Finally, participants were reminded of the contact details for the researcher should they need to make contact.

3.10 Study intervention

The study intervention was the program 'Passport 4 Life' and a group exercise session. Passport 4 Life is a 12 week healthy lifestyle written program specifically

developed for this study. It incorporates components that have individually been found to be successful in the maintenance of a healthy weight range. The program design and each component of the study will now be described.

3.11 Designing the Passport 4 Life Program

As previously mentioned the program was designed specifically for this study and includes a variety of components that have previously been found to be effective. To my knowledge there has not previously been a study that incorporated all of the components of the intervention used in this study. It was important to ensure the program developed and used in this study offered a unique set of interventions due to previous studies identifying successful components. Therefore a comprehensive review of previous studies that have tested different components of lifestyle interventions with similar groups of participants was performed. The findings of the review can be found in the previous literature review chapter (Chapter 2).

Significantly greater weight reduction has been found in lifestyle intervention groups versus pharmacological intervention groups or standard care groups (Ball et al., 2001; Knowler et al., 2005; Littrell et al., 2003; Vreeland et al., 2003; Weber & Wyne, 2006). However, the outcomes of these interventions are limited by factors such as the small number of studies, small sample sizes, short study duration, and variability in the interventions, including their intensity and duration.

Passport 4 Life includes a combination of all the components that have individually been shown to have some effect on weight prevention or maintenance. Passport 4 Life incorporates nutrition and exercise education; a motivational interviewing approach in weekly group sessions; nurse participation in groups and a weekly

group exercise activity; provision of healthy snacks as part of the weekly session to help encourage healthy snacking; and supported travel to attend the weekly sessions. Each component of the program will be described. To begin, an overview of how the intervention was developed follows.

3.12 Writing the program

During the development of the Passport 4 Life program it was important that consideration was given to some of the consequences of schizophrenia, particularly cognitive issues such as impaired memory and concentration difficulties, differing levels of literacy, as well as negative symptoms of schizophrenia such as avolition, and a reduction in living and social skills (Robson & Gray, 2007; Bardwell & Taylor, 2009). It was thus important to write the program in a stepped, progressive way, and in an easy to understand, conversational tone. It was also important to incorporate visual reminders, such as healthy eating tips and pictorial representations throughout the program for participants for whom literacy might be a problem. Links to appropriate websites were also included. An example of the reminders used to enhance memory recall and support motivation, is found in Table 3.2 below.

Table 3.2: Example of a healthy eating reminder

Healthy Eating Hint
To be healthy we need to eat each day:
2 serves of fruit
&
5 serves of vegetables
1 serve of fruit = 1 medium apple or 1 cup of chopped/canned fruit
1 serve of vegetables = ½ cup of cooked vegetables or 1 cup of salad
(www.gofor2and5.com.au)

3.13 Components of the Passport 4 Life Program

Passport 4 Life comprises a twelve week program incorporating five interlinked components: Healthy Eating Information; Nurse-led Exercise; Diet and Exercise Records; Goal-Setting, and Motivational Interviewing. At the commencement of each group weight measurements are collected, including height, weight and girth measurements.

3.13.1 Educational information

A healthy eating booklet was developed which integrated the Australian government guidelines for nutrition and exercise. These guidelines provide the reader with easy to understand information to aid the development of a healthy lifestyle. The 2 Fruit and 5 Vegetables a day campaign is an example of one of the recommendations used (Australian Government, 2005). This recommendation is easy to understand and provides simple healthy nutritional advice to people to encourage them to eat 2 serves of fruit and 5 serves of vegetables each day. The Australian Government, State and Territory 2 Fruit and 5 Vegetable initiative has been widely advertised nationally and is easily remembered. The use of a well known campaign normalises the use of the healthy eating booklet and normalises the healthy behaviour (WHO, 1986). Additional reminders are provided with the booklet containing an easy-to-use daily checklist where the person can tick a box for the number of serves they have had each day, along with a reminder example of a serve of fruit or vegetables, see table below.

Table 3.3: 2 Fruit and 5 Vegetables daily checklist

Fruit ☐ ☐ Vegetables ☐ ☐ ☐ ☐ ☐ 1 serve of fruit = 1 medium apple or 1 cup of chopped/canned fruit 1 serve of vegetables = ½ cup of cooked vegetables or 1 cup of salad

Additional healthy nutritional information is provided in the program including common recommendations of serves per day for the other food groups including bread, cereals, rice, pasta and noodles, milk, yoghurt, cheese and meat, fish, poultry, eggs, nuts, and legumes. Examples are also given throughout the program to reflect the recommended serving size for each food group (National Health and Medical Research Council, 1998). Participants were encouraged to read and become familiar with what constitutes healthy snacks. To assist with this goal, each week an example of a healthy snack was brought along by the nurse leader to the group to share with the participants; this also encouraged the participants to try a variety of healthy snacks. Bradshaw et al. (2010), found people benefited from group sharing, with one person stating "it's better done in a group because you can learn from other people's experience…" (p. 479).

Menu planning is a further important aspect of healthy eating that is included in the program. Participants are encouraged to plan their daily and weekly menu; there is a section of the booklet where the participant can do this activity. Examples of healthy menus are also included in the booklet and there are group activities undertaken to plan a healthy menu, and identify the shopping required (see Table 3.4).

Table 3.4: Menu Planning and Shopping Advice

Tips for Menu Planning
Affordability e.g. healthy food does not have to mean expensive, if something is not on your menu plan but is on special, change your menu plan for the week. **Accessible** e.g. if you catch the bus to the shops then it might not be easy to buy in bulk; you might have to shop 2 times a week. **Seasonal** e.g. choose fruit and vegetables when they are in season they are usually cheaper, e.g. bananas **Bulk buying** e.g. buy food when it is on special and freeze in portions. **Tasty** e.g. Add some fresh herbs to your shopping- parsley & lemon go well with grilled fish!

Educational information on exercise is also included in the healthy eating booklet. The Australian Government recommendations for exercise such as “What’s your 30 minutes a day?” and the ‘10,000 steps’ program were used (Queensland Government, 2006; Brown et al*.,* 2005). Either of these programs can be used by participants and to further encourage exercise there is an exercise activity incorporated into each weekly session. Group exercise activities are supported by Johnstone et al., (2009), who investigated barriers to physcial activity experienced by people with schizophrenia. They found organised group exercise to be successful in increasing physical activity with participant comments such as, “ I can get on with a group of people who have mental health problems because I understand what they are going through” (Johnstone et al., 2009, p. 528).

In Passport 4 Life the exercise sessions included a variety of low or no cost activities such as walking, swimming, and group sports, such as cricket. The environment surrounding where the groups were held was used for activities, e.g. the local park or swimming pool, which enabled participants to incorporate exercise into their daily lifestyle without making too many changes or bearing additional costs. The importance of hydration was discussed each week during the exercise session

and participants were given a water bottle and encouraged to drink regularly throughout sessions to maintain adequate hydration.

3.13.2 Inclusion of a nurse leader in exercise activities

An important component of the exercise activity is that the nurse leader of the groups participates in the activity with the participants. Nurse participation is supported by Beebe (2008) who states that the support of a staff member 'buddy' in exercise sessions with clients is a motivator for participation and enhances social interaction. In this study, pedometers were given to each participant when they joined the group as a tool to motivate and monitor their exercise. Participants could choose to use the pedometer to record their steps per day or they could record the length of time and the type of activity they performed. Table 3.5 below provides an example of the advice given to participants on the use of the pedometer.

Table 3.5: Pedometer use

For this first week I want you to try out your pedometer. Put it on when you get up in the morning and check it when you go to bed at night. Now write down how many steps you took today and reset the pedometer for tomorrow. In this first week, try to increase your steps by 100 each day. This might mean walking to the corner shop to get the paper or walking around the block. The eventual aim is to take 10,000 steps per day as this is the number of steps that National Heart Foundation Australia suggests for a healthy heart. If you are not yet taking 10,000 steps each day that is OK, remember this program is about improving your lifestyle (10,000 Steps, Qld Health, 2006).

Participants were asked to record their activity each day and are encouraged to increase their weekly activity over the 12 week period of the program. Suggestions were provided to increase their activity by adding to their normal daily tasks and using their surrounding environment e.g. walk around the block or use the stairs

instead of the lift (Brown, Moorhead & Marshall 2005; Faulkner et al,. 2007; Wand & Murray, 2008).

3.13.3 Diet and exercise record

Daily recording of food intake and activities is an important part of the program and participants were encouraged to record this on a daily basis throughout the 12 weeks of the program (see Table 3.6 and Appendix H for the daily diary record). The records were then used as reinforcement of healthy behaviour changes (Prochaska & Velicer, 1997; Miller & Rollnick, 2002). The Passport 4 Life booklet includes sections where this information can be recorded.

Table 3.6: My daily record

Recording your success Each day take some time to record what you are eating, in your "My daily record" booklet. Remember to be honest with yourself so that you will know for sure what works for you and what doesn't. It is also important to know that being healthier does not happen in 1 day, it will take a few weeks or even months. This program is 12 weeks long so that we can slowly build to success and not try to make it happen all in the first week. This record will be very helpful for you to use when you are evaluating your successes, and evaluating how you are going.

3.13.4 Goal setting

Goal setting was an essential component of the program and was incorporated into each weekly session. Participants were given advice on goal setting; see Table 3.7 and each week of the program in Appendix H for an example. The participants were reminded that goal setting is an individual activity. Each week every person was

encouraged to choose an individual goal that was in keeping with the theme of the week (Prochaska & Velicer, 1997; Miller & Rollnick, 2002).

Table 3.7: Goal Setting Advice

Goal for the week

- Each week you will see this heading with a few blank lines underneath.
- Each week I would like you to choose your own goal in keeping with the theme of the week. For example this week is about "Getting started and planning for Success".
- Remember everyone's goal will be different - maybe you want to increase the amount of vegetables you eat or eat an apple each day.
- One of the most important things to remember when setting your goal is to make sure it is achievable. There is no point in setting a goal like 'I want to run a marathon this week' if you've never tried running before.
- You will find over the coming weeks when you meet each goal you will start to feel better about yourself and when you reach each goal you will also know you are on the way to a healthier you.

Tips for Goal setting

Achievable "I will eat one piece of fruit each day"
Practical "I will eat an apple each day"
Accessible "I will eat a piece of fruit that I can buy at the corner store each day instead of a can of coke"

**Another important part of goal setting is rewarding yourself when you achieve your goal. This is very important as it reminds you that you have been successful.
**Try to think of some healthy rewards that you can use over the coming weeks.

3.13.5 Spirit of Motivational Interviewing

Motivational interviewing (MI) is a cognitive behavioural technique that aims to help people identify and change behaviours that may be placing them at risk of developing health problems including weight gain (Bundy, 2004; Vreeland et al., 2003). MI was selected for the program as it has been shown to be an effective change management strategy for changing risky health behaviours (Miller & Rollnick, 2002). Vreeland and colleagues (2003) implemented motivational interviewing techniques in their study with participants with serious mental illness and reported significant health benefits, including increased amounts of exercise, knowledge of nutrition, and weight loss for the participants of the motivational interviewing group. Littrell et al., (2003) found similar results to Vreeland et al., (2003) with a larger sample size of 70 participants and concluded that "changes in behaviour were

associated with patients acquiring knowledge about healthy lifestyles and developing individualised strategies for behaviour change" (p. 241).

The spirit of motivational interviewing (MI) underpins the philosophy of the delivery of the program. The spirit of MI includes the concepts of collaboration, evocation, and autonomy. These concepts are integral to delivery of MI and provide the foundation for developing healthy behaviour changes. Collaboration is an active process that incoporates both the participant and the researcher with joint decision making as the underlying concept. Evoking the participant's own motivation and resources for change is fundamental to the spirit of MI. Miller and Rollnick (2002) describe evocation further, stating "…a drawing out of motivation from the person...calling forth their intrinsic motivation to change" (p. 34). Honouring the participants autonomy is the third spirit of MI. Miller and Rollnick (2002) suggest an acceptance is required by the researcher that "…people can and do make choices about the course of their lives" (p. 35).

While the spirit of MI is integral to the notion of MI, the following components are designed to increase a person's level of motivation to change behaviour. These include: giving advice, removing barriers, providing choice, decreasing desirability, practising empathy, providing feedback, clarifying goals and active helping. Motivational interviewing practice consists of four guiding principles or conditions for change, including to resist the righting reflex; to understand and explore participants' own motivations; to listen with empathy and to empower the person, and encouraging hope and optimism (Rollnick, Miller & Butler, 2008). The principles are described in Table 3.8.

Table 3.8: Four guiding principles for the practice of Motivational interviewing (Rollnick, Miller & Butler, 2008)

Principle	Description
Resist the righting reflex	People who enter helping professions often have a powerful desire to set things right…given this motivation, the urge to correct another's course often becomes automatic…this can have a paradoxical effect…it is a natural human tendency to resist persuasion(Rollnick, Miller & Butler, 2008, p. 7).
Understand your participants motivations	"be interested in the patient's own concerns, values, and motivations…it is the patient's own reasons for change, and not yours, that are most likely to trigger behaviour change" (Rollnick, Miller & Butler, 2008, p. 9).
Listen to your participant	"When it comes to behaviour change, the answers most likely lie within the patient and finding them requires some listening" (Rollnick, Miller & Butler, 2008, p. 9).
Empower your participant	"Patients in essence become your consultants on their own lives and on how best to accomplish behaviour change" (Rollnick, Miller & Butler, 2008, p. 10).

The intervention group attended weekly sessions of one to one and a half hours incorporating education, demonstrations of healthy food choices, written work on goal setting and planning healthy menus, sharing of ideas, encouragement, and homework from the previous week. During the weekly sessions the spirit and guiding priniciples of MI were incorporated into the group. The researcher developed partnerships with each participant utilising the concept of collaboration with the underlying value that each participant had the right to choose to participate in the group and the activities that were offered, thus supporting the evocation and autonomy of each particpant. In using MI principles, the researcher encouraged individual choice and incorporated the concepts of reflective listening, expressing empathy, acknowledgement of prior ability and ability to change, into each session while encouraging individual choice.

The researcher obtained feedback on the success of these approaches by observing participant behavioural reactions to sessions. For example participant ambivalence or indecision can often be a result of the researcher telling the participant what to do or the participants' reluctance to change (Miller & Rollnick, 2002). If this behaviour is

encountered the researcher uses the technique of ‘rolling with resistance’. This technique enables the researcher to provide information and encouragment to the participant to find the solution that best suits them. An example of this is when a particpant refuses to join in the exercise activity. The researcher acknowledged their choice while identifying the benefits to the participant of the exercise activity. While this occurred throughout the program at different times, the researcher found that participants returned the next week ready to participate in the activity.

MI principles were incorporated into the weekly sessions with the intention of enabling each participant to gain the freedom to make informed individual choices. In order to enhance and individualise the change process necessary for MI to be successful, each participant was asked to identify a goal for each week. This activity validates and reinforces the individual’s healthy choice behaviours. The principles of MI described above were used to provide support and encouragement to the participants of the intervention group, while honouring their autonomy.

3.13.6 Article

The following article has been accepted for publication and provides a description of the development of the intervention ‘Passport 4 Life’.

Publication title
Park, T., Usher, K., & Foster, K. (2011). Description of a healthy lifestyle intervention for people with serious mental illness taking second generation antipsychotics. *International Journal of Mental Health Nursing.* doi: 10.1111/j.1447-0349.2011.00747.x

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Title

Park, T., Usher, K., & Foster, K. (2011). Description of a healthy lifestyle intervention for people with serious mental illness taking second generation antipsychotics. *International Journal of Mental Health Nursing.* doi: 10.1111/j.1447-0349.2011.00747.x

Abstract

Weight gain and obesity has reached epidemic proportions with the prevalence of Metabolic Syndrome (MetS) reaching 20-25% of the global population. MetS is a cluster of metabolic abnormalities, including weight gain, associated with an increased risk of cardiovascular disease, diabetes and stroke. While individuals in the general population are at risk of physical conditions such as MetS, people with mental illness are at even higher risk. The increased incidence of MetS for people with serious mental illness has been linked to the use of second generation antipsychotic (SGAs) medication. This paper describes the content, structure, and development of "Passport 4 Life"- a healthy lifestyle intervention to maintain weight and prevent further weight gain for people with serious mental illness. While there are a number of diet and lifestyle programs available for the general population, "Passport 4 Life" was specifically designed as an intervention to address the needs of people with serious mental illness taking second generation antipsychotics. "Passport 4 Life" comprises 12 weekly group sessions that include the concepts and spirit of motivational interviewing, nutrition and exercise education, combined with a weekly exercise activity.

Key words: antipsychotic medication, healthy lifestyle, metabolic syndrome, motivational interviewing, serious mental illness, weight prevention.

Introduction

In the past decade the physical morbidity and mortality of people with serious mental illnesses has increased, with a concomitant increase in literature addressing the inter-relationship of mental and physical health (Muir-Cochrane 2006; Robson & Gray 2007). In particular, the physical health of people with a serious mental illness is reportedly compromised (Robson & Gray 2007), resulting in a shorter life expectancy than the rest of the population, with between 9 and 25 years of life lost prematurely (Lambert & Newcomer 2009). The reduced life expectancy for the person with serious mental illness has been linked with a range of causative factors, including the use of second generation antipsychotics (SGAs) and their effect on individuals' cardiometabolic and physical health (Goff *et al.* 2005; Hennekens *et al.* 2005; Tschoner *et al.* 2007; Lambert 2009). Antipsychotic medication has long been associated with physical side effects, including cardiovascular and metabolic effects including weight gain (Lieberman *et al.* 2005; McEvoy *et al.* 2005; Robson & Gray 2007).

In Australia, a survey of 350 people with mental illnesses such as schizophrenia (12%), depression (37%) and bipolar disorder (20%) reported that almost all respondents (90%) had a concomitant chronic health problem such as hypertension, diabetes, heart or respiratory disease (SANE 2007). When compared to the general population, the risk of cardiovascular disease is two-three times higher for the person with a mental illness, and respiratory diseases are more prevalent (Robson & Gray 2007). For example in Queensland 7% of adults are diagnosed with diabetes (Queensland Health 2008) in contrast to estimates that 15% of people with serious mental illness have diabetes (Holt *et al.* 2004; Lambert & Chapman 2004; Newcomer 2007).

This paper describes a nurse-led intervention - "Passport 4 Life" - a healthy lifestyle program to maintain weight and prevent further weight gain for people with serious mental illness taking SGAs. The paper aims to provide detailed information on the content, structure and development of the intervention. Unlike most other general healthy lifestyle programs that address diet and exercise, this intervention was purposefully designed to address the needs of consumers with serious mental illness taking SGAs and living in the community. The outcomes of the program are currently being investigated. A further aim of the paper is to advocate the initiation of healthy lifestyle programs at the same time SGAs are prescribed in order to prevent the initial onset of weight gain.

Background

(i) Metabolic Syndrome (MetS)

MetS is a cluster of metabolic abnormalities including hypertension, hyperlipidemia, hyperglycaemia and abdominal obesity which, when experienced together, lead to an increased risk of diabetes and cardiovascular disease. The cause of MetS is not yet clear but insulin resistance and central obesity are considered major factors along with genetic vulnerability, physical inactivity and hormonal changes (IDF 2006). The International Diabetes Federation (IDF) provides a definition and clinical parameters for metabolic syndrome that is currently used worldwide (Table 1). This definition and parameters can be used by the clinician to identify areas of concern for closer monitoring, and for reducing MetS through changing to a healthy lifestyle (Usher *et al.* 2006).

Table 1: MetS Clinical Parameters

According to the IDF (2006), for a person to be defined as having the metabolic syndrome they must have:

Central obesity *(defined as waist circumference* ≥ 94cm for Europid men and ≥ 80cm for Europid women, *with ethnicity specific values for other groups)* **plus any two of the following four factors:**

• ***raised Triglycerides level*****:** ≥ 150 mg/dL (1.7 mmol/L), *or* ***specific treatment for this lipid abnormality***

• ***reduced High-density lipoprotein cholesterol***: < 40 mg/dL (1.03 mmol/L*) in males and < 50 mg/dL (1.29 mmol/L*) in females, ***or specific treatment for this lipid abnormality***

• ***raised blood pressure:*** systolic BP ≥ 130 or diastolic BP ≥ 85 mm Hg, ***or treatment of previously diagnosed hypertension***

• ***raised fasting plasma glucose*** (FPG) ≥ 100 mg/dL (5.6 mmol/L), ***or previously diagnosed type 2 diabetes***
If above 5.6 mmol/L or 100 mg/dL, OGTT is strongly recommended but is not necessary to define presence of the syndrome.

Adapted from the International Diabetes Federation (2006)

(ii) An Australian perspective on MetS

Australia is one of the most overweight of the developed nations (Australian Bureau of Statistics 2008). With a current estimate of 7.4 million overweight or obese adults in Australia, and assuming the current trends continue, an increase to 16.9 million is expected by 2025 (National Preventative Health Taskforce 2008). The health problems associated with overweight and obesity include type 2 diabetes, cardiovascular disease, osteoarthritis and links to breast, uterine, bowel and kidney cancers. These health issues are estimated to cost Australia $1.2 billion per year and impact on individuals, families and communities, leading to substantial health and socioeconomic sequelae (National Preventative Health Taskforce 2008). High risk groups for MetS have been identified nationally with particular reference to Aboriginal and Torres Strait Islander people.

(iii) Weight gain and second generation antipsychotic medication

Weight gain, obesity, and consequently MetS, is a common problem for people with serious mental illness, with Australian studies finding the prevalence rates of MetS for people with serious mental illness range between 51% and 68% (John *et al.* 2009; Tirupati & Chua 2007). Tirupati and Chua (2007) reported the results from a study of 221 patients on antipsychotic medication with a diagnosis of psychotic disorder; people with schizophrenia or schizoaffective disorder made up 205 of the 221 participants and had a MetS prevalence rate of 68%. In a study of 203 patients with a variety of psychiatric disorders including schizophrenia, John *et al.* (2009) found that 51% of the 92 participants with schizophrenia had MetS.

The association between weight gain, diabetes and the SGAs is linked to a number of hypotheses including the blocking of the serotonin receptors (5-HT_2) by the medication, resulting in a decreased serotinergic transmission causing weight gain and obesity , or genetic predisposition or enviromental factors (Citrome *et al.* 2005; Holt *et al.* 2005; Tschoner 2007). Devlin *et al.* (2000) convey "medications that block histamine H_1, serotonin 5-HT_{2c}, and dopamine D_2 receptors tend to be associated with weight gain" (p. 858), while Thakore *et al.* (2002), in a cross sectional study of 30 people, found that patients with schizophrenia who were drug free had higher BMIs (26.7±1.1kg/m^2) than a control group (2.8 ±0.5 kg/m^2) and also had increased fat in the abdominal area. The substantial prevalence of physical health issues, including weight gain, in mental health consumers has prompted calls for nurse-led health prevention and intervention programs and practices (Wand & Murray 2008).

(iv) Previous interventions designed to reduce weight gain associated with SGAs

A number of interventions to prevent or reduce weight gain associated with SGAs have been researched to date. In a study by the Diabetes Prevention Program Research Group (DPP) in the USA (1996 to 1998), a randomised clinical trial found lifestyle interventions focussing on weight reduction and increased exercise were more effective than medication such as metformin, troglitazone or placebo in preventing type 2 diabetes (Knowler *et al.* 2005). While this study did not specifically include people with serious mental illness taking SGAs, the landmark findings provide robust support for the use of lifestyle interventions. In the USA, Weber and Wyne (2006) conducted a pilot study over 16 weeks, basing their lifestyle intervention on the Diabetes Prevention Program intervention, and incorporating cognitive behavioural therapy techniques. The 17 participants of this study were diagnosed with serious mental illness and were taking SGAs. The findings support the use of lifestyle interventions with the intervention group losing an average of 5.4lbs (2.5 kgs) and the control group losing just 1.3lbs (0.6 kgs) (Weber & Wyne 2006). A 12 week study conducted by Vreeland and colleagues (2003) in the USA with 31 participants with serious mental illness incorporated a partial hospital based program of twice weekly sessions that included nutritional counselling, exercise, and motivational counselling techniques. Vreeland *et al.* (2003) found the intervention group lost an average of 6lbs (2.7 kgs) while the control group gained an average of 6.4lbs (2.9 kgs). Ball and colleagues (2001) conducted a 12 week study in the USA with 22 participants with serious mental illness, 11 participants attended weekly Weight Watcher group meetings and attended 3 exercise sessions weekly, while the comparison group of 11 did not participate in the groups but maintained their medication. They concluded that weight loss strategies which included education sessions on nutrition and exercise were successful for people with serious mental illness, reporting weight loss for participants ranged from 0-8.2 kgs.

As evident in the research to date, significantly greater weight reduction has been found in lifestyle intervention groups versus pharmacological intervention groups or standard care groups since the land mark DPP study in 1996-1998 (Ball *et al.* 2001; Knowler *et al.* 2005; Littrell *et al.* 2003; Vreeland *et al.* 2003; Weber & Wyne 2006) However, the outcomes of these interventions are limited by factors such as the small number of studies, small sample sizes, short study duration, and variability in the interventions, including their intensity and duration. Further research that distinguishes between weight gain prevention and weight gain

reversal has been recommended (Faulkner 2007). The current (although limited) literature argues for further investigation of physical health issues, including weight gain, for mental health consumers, and suggests that provision of evidence-based health care will not only support the individual but has broader implications for the health and well-being of the general community (Antai-Otong 2004; Beeb 2008; Jennex & Gardner 2008; Wand & Murray 2008; Bradshaw *et al.* 2010).

Passport 4 Life includes a combination of all the components that have been individually shown to have some effect on weight prevention (i.e. nutrition and exercise education, exercise sessions, support through nurse involvement and motivational interviewing), and is based upon evidence from previous studies (for example Weber & Wyne 2006; Vreeland *et al.* 2003), and available best practice guidelines (for example Australian Government 2005). In addition, it is specifically based on Australian standards for nutrition and exercise and has been tailored for consumers with serious mental illness living in the community. The program can be delivered to small groups (ideally no more than 10 participants) by a mental health nurse in any setting where there is privacy and seating. The activity component is designed to make use of the environment surrounding the group setting rather than a specific area. We anticipate that the combination of these elements into one intervention will elicit successful healthy lifestyle change and weight maintenance or prevention of further weight gain for mental health consumers taking SGAs. Participant outcomes from the program are currently being investigated.

Designing the Passport 4 Life Program

It is important to acknowledge that other healthy lifestyle interventions are available to support healthy lifestyle change in the community at large; these include mainstream programs such as the Weight Watchers program, programs at local gyms or health clubs, and programs intended for mental health consumers such as Mind Body Life (Eli Lilly). However, the Passport 4 Life intervention fills a particular gap as it has been designed for the needs of people with serious mental illness, providing a combination of activity, education and support. The program, based on a primary health promotion approach, incorporates nutrition and exercise education; a motivational interviewing approach in weekly one hour group sessions; nurse participation in groups and exercise activity; the provision of healthy snacks as part of the weekly session; and supported travel to attend the weekly sessions. When joining the program each participant is given a carry bag, water bottle, healthy lifestyle

folder and pedometer. Participants are also able to access financial assistance for transport to attend the weekly groups if required. We argue it is the combination of all these components of the program that may lead to healthy lifestyle change and potential weight attenuation for people with serious mental illness.

The program is theoretically grounded in the principles of health promotion and based on the premise that 'health is created and lived by people within settings of their everyday life; where they learn, work, play and love' (WHO 1986 p. 4). The development of personal skills and an increase in knowledge on healthy lifestyles are fundamental to health promotion and are necessary for changing risky behaviours, including poor nutrition, inactivity and sedentary lifestyles. Passport 4 Life is offered in the community and can be accessed through the local area mental health service or a variety of non government community agencies. The program was added to scheduled activities of community organisations, and this enabled participants to join the program with little disruption to their weekly plans.

The program is also premised on the understanding that any lifestyle change requires changes in behaviour, which are challenging for most people. It is important to acknowledge the different stages of change that a person may experience and to recognise how these can affect a person's involvement in changing their behaviours. Thus, Passport 4 Life is underpinned by Prochaska and DiClemente's (1983) theoretical model of change. The Transtheoretical Model (TTM) identifies six stages of change – precontemplation, contemplation, preparation, action, maintainence and termination. A brief summary of the stages is included in Table 2. Throughout the stages of TTM, motivational interviewing approaches can be incorporated and assist a person where there is the intention to change (Prochaska & Velicer 1997). The incorporation of the TTM model in the development of the Passport 4 Life program was designed not only to elicit behaviour change but also to support behaviour change. With this in mind the spirit of Motivational Interviewing (MI) has been incorporated into the weekly sessions.

Table 2: Summary of Stages of Change (Prochaska & DiClemente, 1983).

Stage of Change	Description
Precontemplation	The person is not currently considering change: not aware of or contemplating healthy lifestyle changes.
Contemplation	The person is intending to change: aware of pros and cons of healthy lifestyle changes.
Preparation	The person has a plan of action: started attending the P4L group.
Action	The person has made changes/modifications: healthy lifestyle changes are occurring.
Maintenance	The person is working to prevent relapse: confidence in the healthy lifestyle changes that have occurred.
Termination	The person has no temptation & will not return to unhealthy lifestyle choices.

Motivational interviewing (MI) is a cognitive behavioural technique that aims to help people identify and change behaviours that may be placing them at risk of developing health problems including weight gain (Bundy 2004; Vreeland *et al.* 2003). It was selected for the program as MI has been shown to be an effective change management strategy that is commonly used for changing risky health behaviours (Miller & Rollnick 2002). Vreeland and colleagues (2003) implemented motivational interviewing techniques in their study and reported significant health benefits, including increased amounts of exercise, knowledge of nutrition, and weight loss for the participants of the motivational interviewing group. Littrell *et al.* (2003) found similar results with a larger sample size of 70 participants and concluded that 'changes in behaviour were associated with patients acquiring knowledge about healthy lifestyles and developing individualised strategies for behaviour change' (p. 241).

During the development of the Passport 4 Life intervention it was important that consideration be given to some of the consequences of serious mental illness, particularly cognitive issues such as impaired memory and concentration difficulties, and a range of levels of literacy, as well as negative symptoms including avolition, and reduced living and social skills (Robson & Gray 2007). It was thus important to write the program in a stepped progressive way, and in an easy to understand, conversational tone. It was also important to incorporate visual reminders such as healthy eating tips and pictorial representations throughout the program. Links to appropriate websites were also included. An example of the reminders used to enhance memory recall and support motivation, is found in Table 3.

Table 3: Example of a healthy Eating reminder from the Passport 4 Life

Healthy Eating Hint
To be healthy we need to eat each day:
2 serves of fruit
&
5 serves of vegetables
1 serve of fruit = 1medium apple or 1 cup of chopped/canned fruit
1 serve of vegetables = ½ cup of cooked vegetables or 1 cup of salad
(www.gofor2and5.com.au)

Components of the Passport 4 Life intervention

Passport 4 Life comprises a twelve week program incorporating five interlinked components: Healthy Eating Information; Nurse-led Exercise; Diet and Exercise Records; Goal-Setting, and Motivational Interviewing. At the commencement of each group weight measurements are collected, including height, weight and girth measurements, along with current medications. The weekly group session of one hour incorporates a 30 minute discussion and 30 minutes of activity. The groups were led by one nurse, but case managers and carers were encouraged to join in when able to provide additional support.

(i) Educational information

A healthy eating booklet was developed which integrated the Australian government guidelines for nutrition and exercise. These guidelines provide the reader with easy to understand information to aid a healthy lifestyle. The 2 Fruit and 5 Vegetables a day campaign is an example of one of the recommendations used (Australian Government 2005). This recommendation is easily understood and provides simple healthy nutritional advice to encourage the eating of 2 serves of fruit and 5 serves of vegetables each day. This Australian government, State and Territory initiative has been widely advertised nationally and is easily remembered. The use of a well known campaign normalises the use of the healthy eating booklet and normalises the healthy behaviour (WHO 1986). Additional reminders are provided with the booklet containing an easily used daily checklist where the person can tick a box for the number of serves they have had each day, along with a reminder. See Table 4 for an example.

Table 4: 2 Fruit and 5 Vegetables daily checklist

Fruit □_ _□ Vegetables _ _ _ _ _ □□□□□ 1 serve of fruit = 1 medium apple or 1 cup of chopped/canned fruit 1 serve of vegetables = ½ cup of cooked vegetables or 1 cup of salad

Additional healthy nutritional information is provided in the program including the recommendations for serves per day for the other food groups including bread, cereals, rice, pasta and noodles, milk, yoghurt and cheese and meat, fish, poultry, eggs, nuts and legumes. Examples are given throughout the program of the recommended serve size for each food group (National Health and Medical Research Council 1998). Participants are encouraged to become familiar with what constitutes healthy snacks. To assist with this, each week an example of a healthy snack is brought along by the nurse leader to the group to share with the participants; this also encourages the participants to try a variety of healthy snacks. Bradshaw *et al.* (2010) found people benefited from group sharing, with one person stating 'it's better done in a group because you can learn from other people's experience…' (p. 479).

Menu planning is another important aspect of healthy eating. Participants are encouraged to plan their menu; there is a section of the booklet where the participant can write their menu plan. Healthy menu examples are included in the booklet and there are group activities used to practice planning a healthy menu, along with shopping advice. See Table 5 for an overview of menus.

Table 5: Menu Planning and Shopping Advice

Tips for Menu Planning
Affordability e.g. healthy food does not have to mean expensive, if something is not on your menu plan but is on special, change your menu plan for the week. **Accessible** e.g. if you catch the bus to the shops then it might not be easy to buy in bulk, you might have to shop 2 times a week. **Seasonal** e.g. choose fruit and vegetables when they are in season they are usually cheaper e.g. bananas **Bulk buying** e.g. buy food when it is on special and freeze in portions. **Tasty** e.g. Add some fresh herbs to your shopping- parsley & lemon go well with grilled fish!

Educational information on exercise is included in the healthy eating booklet. The Australian government recommendations for exercise including "What's your 30 minutes a day?" and the "10,000 steps" program are incorporated (Queensland Government 2006; Brown *et al.* 2005). Either of these programs can be used by participants and to encourage exercise there is an exercise activity incorporated into each weekly session. Group exercise activities are supported by Johnstone *et al.* (2009), who investigated barriers to physcial activity experienced by people with serious mental illness. Johnstone *et al.* (2009) found organised group exercise successful in increasing physcial activity with one participant stating " I can get on with a group of people who have mental health problems because I understand what they are going through" (p. 528). In Passport 4 Life the exercise sessions include a variety of low or no cost activities such as walking, swimming, and group sports such as cricket. The environment surrounding where the groups are held is used for activities, for example the local park or swimming pool, which enables participants to incorporate exercise into their daily lifestyle without making too many changes or bearing additional costs. The importance of hydration is discussed each week during the exercise session and participants are given a water bottle and encouraged to drink regularly throughout sessions to maintain hydration.

(ii) Inclusion of a nurse leader in exercise activities

An important component of the exercise activity is that the nurse leader of the groups participates in the activity with the participants. Nurse participation is supported by Beebe (2008) who states that the support of a staff member buddy in exercise sessions with clients is a motivator for participation and enhances social interaction. Pedometers are given to each participant when they join the group as a tool to motivate and monitor their exercise.

Participants can use the pedometer record their steps per day or they can record the length of time and the type of activity they perform. Table 6 provides an example of the advice given for the use of the pedometer.

Table 6: Pedometer use

For this first week I want you to try out your pedometer. Put it on when you get up in the morning and check it when you go to bed at night. Now write down how many steps you took today and reset the pedometer for tomorrow. In this first week try to increase your steps by 100 each day. This might mean walking to the corner shop to get the paper or walking around the block. The eventual aim is to take 10,000 steps per day as this is the number of steps that National Heart Foundation Australia suggests for a healthy heart. If you are not yet taking 10,000 steps each day that is OK, remember this program is about improving your lifestyle (10,000 Steps, Qld Health, 2006).

Participants are asked to record their activity each day and are encouraged to increase their weekly activity over the 12 week period of the program. Suggestions are provided to encourage an increase in activity by adding to normal daily tasks and using the surrounding environment e.g. to walk around the block or use the stairs instead of the lift (Brown, Moorhead & Marshall 2005; Faulkner *et al.* 2007; Wand & Murray 2008).

(iii) **Diet and exercise record**

Daily recording of food intake and activities is an important part of the program and participants are encouraged to complete their records. See Table 7. The records are then used as reinforcement of healthy behaviour changes (Prochaska & Velicer 1997; Miller & Rollnick 2002). The Passport 4 Life booklet includes sections where this information can be recorded.

Table 7: My daily record

Recording your success
Each day take some time to record what you are eating, in your "My daily record" booklet.

Remember to be honest with yourself so that you will know for sure what works for you and what doesn't.

It is also important to know that being healthier does not happen in 1 day, it will take a few weeks or even months. This program is 12 weeks long so that we can slowly build to success and not try to make it happen all in the first week.
This record will be very helpful for you to use when you are evaluating your successes, and evaluating how you are going.

(iv) Goal setting

Goal setting is an essential component of the program and is incorporated into each weekly session. Participants are given advice on goal setting, see Table 8 for example. The participants are reminded that goal setting is an individual activity. Each week individuals are encouraged to choose a goal that is in-keeping with the theme of the week (Prochaska & Velicer 1997; Miller & Rollnick 2002).

Table 8: Goal Setting Advice

Goal for the week
Each week you will see this heading with a few blank lines underneath.

Each week I would like you to choose your own goal in keeping with the theme of the week. For example this week is about "Getting started and planning for Success".

Remember everyone's goal will be different - maybe you want to increase the amount of vegetables you eat or eat an apple each day.

One of the most important things to remember when setting your goal is to make sure it is achievable. There is no point in setting a goal like 'I want to run a marathon this week' if you've never tried running before.

You will find over the coming weeks when you meet each goal you will start to feel better about yourself and when you reach each goal you will also know you are on the way to a healthier you.

Tips for Goal setting
Achievable "I will eat one piece of fruit each day"
Practical "I will eat an apple each day"
Accessible "I will eat a piece of fruit that I can buy at the corner store each day instead of a can of coke"

Another important part of goal setting is rewarding yourself when you achieve your goal. This is very important as it reminds you that you have been successful.
Try to think of some healthy rewards that you can use over the coming weeks.

(v) Motivational Interviewing

The spirit and priniciples of MI are incorporated throughout Passport 4 Life. The spirit of MI involves the three core concepts of collaboration, autonomy and evocation. These concepts would be familiar to mental health nurses as they are the foundation of building therapeutic relationships (Rollnick, Miller & Butler 2008). The nurse group leader develops partnerships with each participant with the underlying belief that each person has the right to choose to participate in the group and associated activities that are offered, thus supporting the evocation (intrinsic motivation to change) and autonomy of each participant (Miller & Rollnick 2002). In using MI principles, the nurse group leader incorporates the concepts of reflective listening, expressing empathy, acknowledgement of prior ability and ability to change, into each session, while encouraging autonomy. In order to enhance and individualise the change process necessary for MI to be successful, each participant is asked to idenfiy a goal each week. This activity validates and reinforces the individual's healthy

choice behaviours. Thus, the spirit of MI are used to provide support and encouragement, while supporting autonomy and behaviour change.

Discussion

Medical co-morbidity for people with serious mental illness is a major health concern because of the increasing risk of developing physical health problems, especially those associated with the use of SGAs (Lambert *et al.* 2003; McEvoy *et al.* 2006; Muir-Cochrane 2006). One of the main problems associated with the ongoing use of SGAs is the weight gain and concomitant risk of developing MetS. Passport 4 Life has been designed as a nurse-led intervention with the intention of assisting people taking SGAs to adopt a healthy lifestyle and maintain or reduce their weight. The program includes healthy eating and increased physical activity, which can lead to improved health outcomes.

The intention of the program is not rapid or large weight loss in the short term but rather healthy lifestyle changes that lead to attenuation of weight gain and maintenance of current weight, and/or a slow sustainable change which eventually leads to weight loss of 1- 4 kgs or 10% (NHMRC 2003). This is important as weight loss of 10% of body weight can lead to a decrease in blood pressure and cholesterol rates. This particular goal is supported by the NHMRC Clinical Practice Guidelines for the Management of Overweight and Obesity in Adults (2003) which indicate a weight loss of 1-4kgs or 1-4cm of waist circumference per month is a realistic weight loss goal, while a 5-10% loss overall can result in metabolic improvements. Recommendations from the NHMRC Clinical Practice Guidelines for the Management of Overweight and Obesity in Adults (2003) describe the benefits of weight loss in quantitative terms suggesting that for each 1% of body weight lost a fall of 1mmHg in systolic blood pressure and 2mmHg in diastolic blood pressure can be expected along with a 1% decrease in Low Density Lipoprotein (LDL) cholesterol for every kg lost. For successful weight loss to occur the NHMRC (2003) propose that treatment goals should be realistic, and include health improvements and behavioural changes as well as weight loss.

Passport 4 Life is a nurse-led program which has potential to be offered by nurses working in a range of inpatient and community mental health settings. Brunero and Lamont (2009) have previously proposed a new role - the cardiometabolic mental health nurse- who would be tasked with prevention, detection and treatment of cardiac and metabolic disorders in people with a mental illness. In addition to specialist roles such as this for mental health nurses, we

argue that nurses working across a range of healthcare settings can offer healthy lifestyle programs such as Passport 4 Life. Nurses working in inpatient and community mental health settings, and in primary health settings, can incorporate physical health prevention and intervention into their practice and actively support mental health consumers to work towards adopting a healthy lifestyle.

Physical health prevention and intervention by nurses in mental health is particularly relevant in the context of mental health nurse role development in Australia, including the introduction of the Mental Health Nurse Incentive Program (MHNIP) in 2007 which aimed to improve community access to mental health care (Council of Australian Governments 2006). The MHNIP enables credentialed mental health nurses to take referrals from general practitioners, private psychiatrists, and other organizations (Happell *et al.* 2010), and as a primary health care intervention Passport 4 Life could be offered as a healthy lifestyle option by nurses, including practice nurses, to consumers with serious mental illness taking SGAs. Passport 4 Life can be delivered in a variety of settings and was developed to be run in the community where people live (WHO 1986). The promotion of health in the community needs to be embraced by all nurses, including credentialed mental health nurses. Passport 4 Life has included individuals who have been taking SGAs, most of whom have already sustained weight increases. This group is one of significant need. However, it is important that future programs also address the needs of drug naive consumers and are implemented at the time they are prescribed SGAs in order to diminish the initial onset of weight gain. Given the substantially increased morbidity and mortality of mental health consumers there is an urgent need to offer them nutrition and exercise education, along with comprehensive physical and mental health assessment and supportive counselling.

Conclusion

This paper has provided a description of the content, structure, and development of a healthy lifestyle program for people with serious mental illness taking SGAs. SGAs are known to be linked to metabolic syndrome and weight gain. The program has been based on the best available evidence to assist people with a serious mental illness to develop healthy lifestyle change leading to weight maintenance or loss. The Passport 4 Life program offers an opportunity for nurses to be involved in improving the physical and mental health of people with serious mental illness. The outcomes for mental health consumers in the program are currently being researched and there is a need for further research into mental health nurses'

roles and practices in physical health prevention and intervention for mental health consumers.

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3.14 Data collection

Data collected from participants during the study included: age, gender, ethnicity, diagnosis, current medication, and previous weight prevention strategies. All participants had baseline measures (weight, height and girth) followed by the same measures repeated at 12 weeks. The participants in the control group had identical measures taken at the same time periods as the intervention group.

- **Weight, height and girth measurements**

The NHMRC Clinical Practice Guidelines for the Management of Overweight and Obesity in Adults (2003) suggests a weight loss of 1-4 kgs or 1-4 cm of waist circumference per month as a realistic weight loss goal; while a 5-10% overall weight loss can result in metabolic improvements. Recommendations from The NHMRC Clinical Practice Guidelines for the Management of Overweight and Obesity in Adults (2003) include the benefits of weight loss in quantitative terms, suggesting that for each 1% of body weight lost a fall of 1mmHg in systolic blood pressure and 2mmHg in diastolic blood pressure can be expected along with a 1% decrease in Low Density Lipoprotein (LDL) cholesterol for every kilogram lost. For successful weight loss to occur the NHMRC (2003) propose that treatment goals should be realistic, and include health improvements and behavioral changes as well as weight loss. In this study, body weight was assessed at baseline and 12 weeks by use of a balance scale. Participants were weighed in light clothing without shoes and after urination. The same set of callibrated scales was used for all participants. The anticipated weight changes for each group are identified in the Table 3.1 Anticipated weight and girth changes.

Considering the guidelines from the National Health and Medical Research Council (2003), the following Table 3.9 of weight changes could reasonably be expected during the 12 weeks of the program.

Table 3.9: Potential weight and girth changes (NHMRC, 2003).

Duration	Weight	Girth
Short term	1-4kgs/month	1-4cm/month
Medium term	10% of initial weight	5% after 6 weeks
Long term (1-5 years)	10-20% of initial weight	88cm (females) 102cm (males)

- **Diet adherence**

Each participant, in both the control and intervention groups, was asked to maintain a diary of their food intake and write down and check off as required. This booklet was discussed each week in the intervention group.

- **Exercise performance**

Individuals were assessed on exercise undertaken during the intervention. They were provided with a checklist style of booklet for every day of the week and encouraged to fill out the checklist as they undertook the activity. Exercise such as walking, and swimming, were included as were other activities such as team sports. Environmental activities such as climbing the stairs instead of using the lift were also suggested as regular activities to be undertaken by the participants. This information was discussed at the weekly intervention groups.

- **Medication Compliance Questionnaire (MCQ)**

The medication compliance questionnaire (MCQ) is composite measure of medication compliance with a seven point scale ranging from 'complete refusal' to 'active participation' was used to assess medication compliance in the participants (Kemp et al., 1996). The MCQ was chosen for this study because it was a simple design that could easily be understood by participants.The person's compliance was assessed at baseline, and 12 weeks in both groups. The MCQ is scored according to the response given: complete refusal=1; partial refusal= 2; reluctant acceptance= 3; occasional reluctance about treatment= 4; passive acceptance= 5; moderate participation= 6; active participation= 7.

- **Drug Attitude Inventory - 10©(DAI-10)**

The DAI-10 is a self report inventory on the subjective effects of neuroleptic medications. The person is asked to answer 10 questions choosing either *true* or *false*. The DAI-10 is reported as having good internal consistency with high test-retest reliability with the developer reporting that "the primary advantage of this inventory is that it is simple, easy to administer and patients typically do not find the inventory intrusive" (Awad, 1993, p. 613). This outcome assessment was measured at baseline, and 12 weeks in both groups. The DAI-10 questionnaire is scored according to the true or false answer given, as either +1 or -1. The final score is the sum of the total of pluses and minuses. A positive total score means a positive subjective response (compliant). A negative score means a negative subjective response (non-compliant).

- **Liverpool University Neuroleptic Side Effect Rating Scale (LUNSERS)**

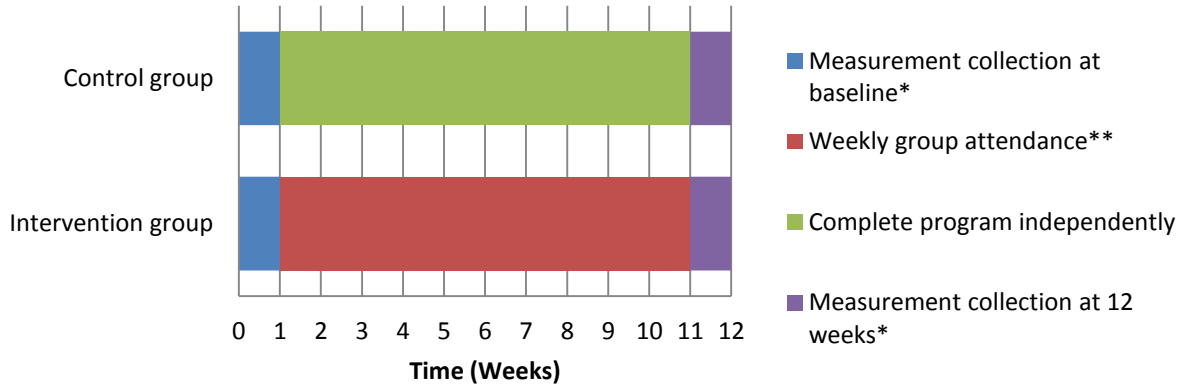
The LUNSERS is a self report questionaire for the reporting of general neuroleptic side effects, with 51 questions which can be grouped under the following categories: extrapyramidal side effects, psychic side effects, hormonal side effects, anticholinergic side effects, miscellaneous side effects, other autonomic side effects, allergic reactions and red herrings. Using a 5 point Likert scale, the person rates each item as *not at all, very little, a little, quite a lot or very much*. Kim et al., (2006) report "the LUNSERS has been used as a useful rating scale to assess subjective tolerability of antipsychotics in previous studies" (p. 302). This outcome assessment was measured at baseline and 12 weeks in both groups. The LUNSERS has eight categories of potential medication side effects. To obtain a final score each category is added together (excluding the red herring score) and then the red herring score is subtracted for the final score to be obtained. The final score is then classified: 0-40 = low; 41-80 = medium; 81-100 = high; > 101 = very high. A red herring score above 20 is considered high and may indicate individuals who over score in general.

- **Medical Outcomes Study Short Form 36 (SF-36)**

The SF-36 Version 2 is a generic well-validated multipurpose health measure (Turner-Bowker, Bartley, & Ware 2002). Described as an ever present measurement tool the SF-36 is used across all health care industry sectors and was constructed to measure physical and mental health status. The questionnaire measures indicators of health including: behavioural function and dysfunction, distress and wellbeing, objective and subjective ratings and favourable and unfavourable self evaluations of general health (Ware, Kosinski, & Dewey, 2002). Validity and reliability of the tool is well documented and the SF-36 is considered a

useful benchmark when comparing well and unwell populations to estimate the burden of specific conditions (Turner-Bowker et al. 2002). This outcome assessment was measured at baseline and 12 weeks in both groups. The SF-36v2 is scored according to clusters of questions and provides a physical health and mental health summary score. The following Figure 3.2 identifies the components of the study applicable to each group.

Figure 3.3 Components of the study



* Weight, height & girth measurements, Medication Compliance Questionaire, Drug Attitude Inventory -10©, Liverpool University Neuroleptic Side Effect Rating Scale, Medical Outcomes Study Short Form 36. ** Weekly group meetings incorporating motivational interviewing, review of food and exercise diary and 30 minutes of exercise.

3.15 Data analysis

All characteristics, for intervention and control group, were described using percentages for categorical variables. Distribution of numerical variables was assessed for normality and mean and standard deviation was used to describe the characteristic in case of approximate normality. Median and inter-quartile range is used when numerical data is skewed. All characteristics assessed at baseline were compared between intervention and control groups to evaluate the effectiveness of randomisation. Differences in primary outcome measures between baseline and 12 weeks follow-up were compared between intervention and control group using

standard bi-variate statistical tests (e.g. Chi-square tests, Fisher's exact tests, Chi-square test for trend, and t tests). Statistical analysis was conducted using SPSS version 18. The results are reported in Chapter 4.

3.16 Ethical Considerations

James Cook University and National Health and Medical Research Council (NHMRC) ethical criteria were adhered to throughout the study. Ethics approval to conduct the study was obtained from the James Cook University and Townsville Health Service District Human Ethics Committees (see Appendix A and B). Ethical approval was obtained to conduct the study in a number of settings including the School of Nursing, Midwifery and Nutrition building at James Cook University, a variety of non government organisations, and various sites within the Townsville Health Service District, particularly the mental health units. The exercise component of the study required that a short 30 - 40 minute walk or swim be undertaken during each group which could occur at all the settings listed or the group could travel to a suitable setting such as the local gardens or swimming pool.

Participants were given a plain language statement (Appendix C) that outlined their participation in the study and provided them with the names of contacts in the case any concerns arose during the study period related to their participation. Participants were assured that all attempts would be taken to ensure their anonymity and confidentiality and reminded that they had the right to withdraw from the study at any time. Those participants who agreed to take part in the study were asked to sign a consent form (Appendix D). All identifying information was accessible only by the research team. Participant information was coded and stored in locked filing

cabinets. All data resulting from the study will remain in storage for a minimum of five years after the publication of results. After five years the stored data will be destroyed in keeping with JCU confidential data destruction guidelines. The participant consent forms will be stored for a period of 15 years after the completion of the study as outlined in the JCU policy "Code for the responsible conduct of research", adapted from the Australian code for the responsible conduct of research (NHMRC, 2007). Access to the original documentation is restricted to the researcher and the research supervisors.

As participants in this study were deemed vulnerable people due to their diagnosis of schizophrenia (NHMRC, 2007), their consent to take part was only negotiated if they were deemed free of any symptoms of psychoses at the time of entering the study. This was determined by an experienced mental health nurse, a member of the research team, who interviewed all participants presenting to take part in the study. If an individual was not suitable for the study when assessed, they were offered the oportunity to be re-assessed at a later time if they so desired. With the consent of the individual, the outcomes of their participation in the nurse-led program were provided to their nominated GP at the end of the program.

3.17 Summary

This chapter included description of the study design and methods including, study setting, participants, protocols, intervention and outcome measurements. Ethical considerations were also described. Information on the protocols used in the study, the participant information sheet and consent form, demographic data collection

forms, and examples of the survey tools used in the study, are included in the appendices.

The following chapter outlines the results of the study. Initially, an overview of participant recruitment is provided followed by descriptions of participant demographic characteristics. Finally, comparison of participant outcomes stratified by intervention and control group is reported.

CHAPTER 4: RESULTS

4.1 Introduction

This chapter describes the results of the study. The CONSORT 2010 guidelines have been used to guide reporting of the findings and to assist in the provision of "clear, complete and transparent" reporting (Moher, Hopewell, Schultz et al., 2010, p. 2). The chapter begins with an overview of the participants and recruitment strategies, followed by the demographic and health characteristics of the participants, and finally the weight related characteristics. The chapter then provides a description of the control and intervention group characteristics, comparing the intervention and control group at baseline and 12 weeks. Finally, the results of the outcome measures are presented.

4.2 Recruitment of participants

There were 104 people recruited to participate in the study, of these 2 people attended only the information session and one person left the study due to medical reasons, resulting in a total of 101 participants; 51 in the control group and 50 in the intervention group. Participants were recruited to the study via posters displayed at local community mental health services, word of mouth and by invitation for the researcher to visit mental health services. The participants were recruited from five different local mental health services over the course of the study. Specific details of the settings are described in Chapter 3. Table 4.1 shows participant numbers and group allocation from the different settings. The 101 participants were randomly

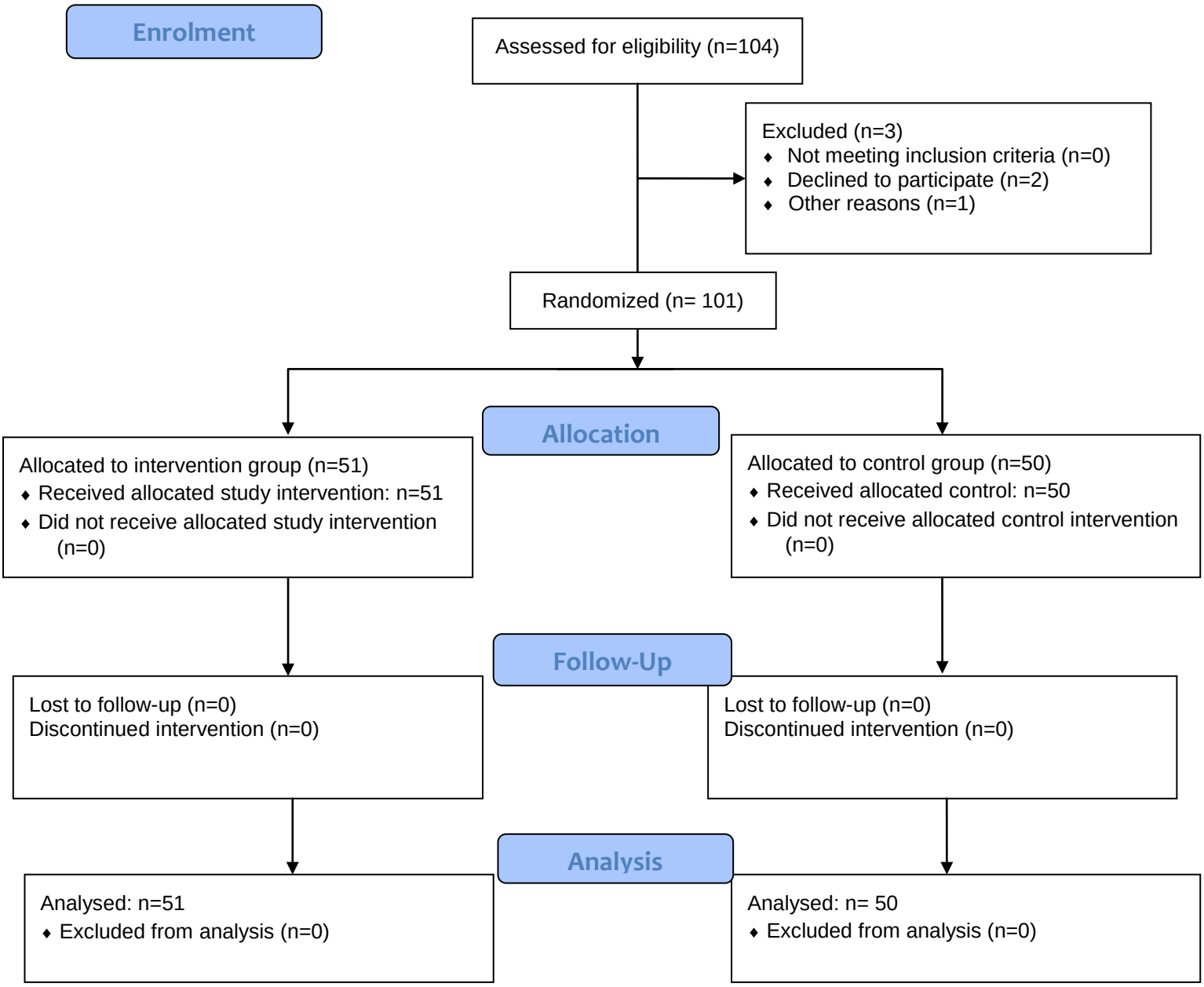
allocated, by the use of opaque envelope selection, to either the control or intervention group. Figure 4.1 provides a flow chart of participant enrolment and allocation to the control or intervention group using the CONSORT Guidelines (Schulz, Altman & Moher, 2010).

Table 4.1 Participant numbers stratified by recruitment setting and by control and intervention allocation (n=101).

Recruitment setting *	Intervention group (n=50)	Control group(n=51)
1. Community NGO**	19	17
2. Community rehabilitation service	11	14
3. Community NGO**	5	8
4. Community government service	7	6
5. Secure mental health service	8	6

*full description of recruitment groups in Chapter 3, **Non government Organisation

Figure 4.1 Participant numbers
(adapted from CONSORT 2010 Flow Diagram, Schulz, Altman & Moher, 2010)



4.3 Description of participants' demographic characteristics

Table 4.2 provides detailed demographic information for all participants (n=101) collected at the commencement of the study. There were slightly more male participants than females, with male participants making up 53.5% of the group. The marital status of the majority of the participants was single (80.2%). The self reported ethnicity of the participants was Caucasian Australian 71.3%, Aboriginal or Torres Strait Islander 13.9%, and another 14.9%, which included Maori, Papua New Guinea, British and Italian nationalities. The first language spoken by most participants, 96.0%, was English, while 4% identified English as their second language. The definitive education level reached by participants was difficult to determine as many participants did not finish high school, with 53.5% reporting this was the case. The education level completed by participants was reported as 20.8% completing high school and 15% of participants reported completing TAFE or university courses. Overall 5.0% of participants identified as in "current paid work". A majority (78.2%) were not currently employed.

Table 4.2 Participant demographic characteristics (n=101)

Item	Category	Frequency	%
Gender	Male	54	53.5
	Female	47	46.5
Marital status	Single	81	80.2
	Married	3	3.0
	Divorced	11	10.9
	Separated	6	5.9
Ethnicity	Caucasian Australian	72	71.3
	Aboriginal or Torres Strait Islander	14	13.9
	Other	15	14.9
First language spoken	English	97	96.0
	Other	4	4.0
Education level reached	Completed high school	21	23.0
	TAFE	11	10.0
	Did not complete high school	54	49.1
	University graduate	4	3.6
	Current student	5	3.6
Current employment	Paid work	5	4.9
	Volunteer	12	11.8
	Combination (paid and volunteer)	3	2.9
	Not working	79	78.2

4.4 Description of participants' health characteristics

There were 101 participants in the study. The majority of participants, 84.2%, self reported a diagnosis of schizophrenia, with 15.8% of participants self reporting bipolar disorder, depression or anxiety as their psychiatric diagnosis. Almost all participants, 99%, were currently prescribed and taking a second generation antipsychotic medication, with 36.6% taking Olanzapine, 23.8% taking Risperidone, 18.8% taking Clozapine, and 14.9% taking Seroquel. There were 62.4% who identified a mental health worker as their case manager, which included nursing and allied health staff, non government employees and general practitioners, while 35.6% stated they did not have a case manager. There were 40.6% of participants

who self reported a medical problem and 16.8% self reported a surgical problem. The medical conditions reported included diabetes, asthma, hypertension and epilepsy.

Table 4.3 Description of participants health characteristics (n=101)

Item	Category	Frequency	%
Diagnosis	Schizophrenia	85	84.2
	Depression	7	6.9
	Bipolar disorder	7	6.9
	Anxiety	2	2.0
	Other	2	2.0
Current psychiatric medication	Olanzapine	37	36.6
	Clozapine	19	18.8
	Risperidone	24	23.8
	Quetiapine	15	14.9
	Amisulpride	2	2.0
	Aripiprazole	3	3.0
	Mirtazapine	1	1.0
Medical problems	No	60	59.4
	Yes	41	40.6
Surgical problems	No	84	83.2
	Yes	17	16.8
Case manager	Mental health worker	63	62.4
	None	36	35.6
	Other	2	2.0

4.5 Description of participants' weight related characteristics

Table 4.4 provides a description of the participants' weight related characteristics. Sixty-five of the 101 participants (64.4%) reported having a weight problem, while 80.2% reported previous attempts to lose weight. The most common weight loss method previously tried by the participants was a combination of exercise and diet (29.8%), while 21.1% reported they had tried exercise only, and 22.1% dietary changes alone. Table 4.5 provides the mean weight measures of participants

(n=101) at baseline. The mean weight was 97.4 kg (SD= 19.1), while the mean girth was 110.4 cm (SD=13.0). The mean BMI was 33.5 kg/m^2 (SD=7.1). The range of weight measurements at baseline for participants was 44.7-142.8 kg for weight, 77-142 cm for girth and 18.13-56.72 kg/m^2 for BMI.

Table 4.4 Description of participants weight characteristics (n=101)

Item	Category	Frequency	%
Weight problem	No	36	35.6
	Yes	65	64.4
Have you tried to lose weight	No	20	19.8
	Yes	81	80.2
How have you tried to lose weight	Exercise	22	21.1
	Diet change	23	22.1
	Exercise and diet	31	29.8
	Not applicable	20	19.2

Table 4.5 Participant weight characteristics at baseline (n=101)

Item	Mean (SD)*[Range]
Weight (kg)	97.4(19.1)[44.7-142.8]
Girth (cm)	110.4(13.0)[77-142]
BMI (kg/m^2)**	33.5(7.1)[18.13-56.72]

*SD=standard deviation, **BMI=body mass index

4.6 Description of control and intervention demographic characteristics

The control group had 50 participants, and the intervention group had 51 participants randomly allocated. Table 4.6 and Table 4.7 provide detailed demographic information for the control group (n=50) and the intervention group (n=51). The control group had an equal gender distribution, with 50% male and 50% female, while the intervention group had 56.9% males and 43.1% females. The control group included 80.0% with a self reported diagnosis of schizophrenia, while the intervention group included 88.2% with a self reported diagnosis of schizophrenia. Weight problems were identified by 62.0% of participants in the control group and 66.7% of participants in the intervention group.

Table 4.6 Control group participant characteristics (n=50)

Item	Category	Frequency	%
Gender	Male	25	50.0
	Female	25	50.0
Diagnosis	Schizophrenia	40	80.0
	Depression	5	10.0
	Bi Polar disorder	3	6.0
	Anxiety	2	4.0
Self-reported weight problem	No	19	38.0
	Yes	31	62.0

Table 4.7 Intervention group participant characteristics (n=51)

Item	Category	Frequency	%
Gender	Male	29	56.9
	Female	22	43.1
Diagnosis	Schizophrenia	45	88.2
	Depression	2	3.9
	Bi Polar disorder	4	7.8
Self-reported weight problem	No	17	33.3
	Yes	34	66.7

4.7 Comparison of participants stratified by intervention and control

The control group (n=50) and the intervention group (n=51) were compared at baseline. Table 4.8 outlines the comparison of the participants (n=101) at baseline stratified by intervention and control group. These comparisons were necessary to assess whether the randomisation process was successful. If baseline characteristics were different between intervention and control groups then statistical analysis would be required to adjust the main outcome analysis for confounding.

Participants in the control group had a mean age of 40.8 years with a standard deviation of 12.5 years while the intervention group had a mean age of 40.8 years with a standard deviation of 11.5 years. The control group had an equal gender distribution, with 50% female, while the intervention group had 43.1% females. The control group had 82% living alone while the intervention group had 78.4% living alone. The most commonly identified ethnicity for both groups was Caucasian Australian, control group 70.0% and intervention group 72.5%. The majority of participants in both groups identified English as their first language, control 98.0% and intervention 94.1%. There was a high level of unemployment in both groups with 77.6% in the control group and 82.0% in the intervention group identified as not currently working.

Table 4.8 Comparison of the participants (n=101*) at baseline stratified by intervention and control

Descriptor	Control (n=50)	Intervention (n=51)	p-value
Mean age (SD)** [years]	40.8 (12.5)	40.8 (11.5)	p=0.982
Female n (%)	25 (50.0%)	22 (43.1%)	p=0.489
Living single n (%)	41 (82.0%)	40 (78.4%)	p=0.363
Caucasian Australian n (%)	35 (70.0%)	37 (72.5%)	p=0.628
First language English n (%)	49 (98.0%)	48 (94.1%)	p=0.617
Did not complete high school n (%)	28 (58.3%)	26 (55.3%)	p=0.982
Not currently working n (%)	38 (77.6%)	41 (82.0%)	p=0.748

*Not all participants answered all questions; **SD = standard deviation

4.8 Comparison of health characteristics stratified by intervention and control

The health characteristics of the control (n=50) and the intervention group (n=51) were compared. Table 4.9 presents an outline of the comparison of the participants (n=101) health characteristics at baseline stratified by intervention and control group. The majority of participants, control 80.0% and intervention 88.2%, self reported a diagnosis of schizophrenia. There were 38.0% (control) and 43.1% (intervention) of participants who reported a medical problem while less reported surgical problems (control 14.0%; intervention 19.6%).

Table 4.9 Comparison of health characteristics at baseline stratified by intervention and control

Descriptor	Control(n=50)	Intervention(n=51)	p-value
Schizophrenia n (%)	40 (80.0%)	45 (88.2%)	p=0.323
With medical problems n (%)	19 (38.0%)	22 (43.1%)	p=0.599
With surgical problems n (%)	7 (14.0%)	10 (19.6%)	p=0.451

4.9 Comparison of weight related characteristics stratified by intervention and control

Table 4.10 presents the comparison of the participants (n=101) weight related characteristics at baseline stratified by intervention group (n=51) and control group (n=50). 62.0% of the control group and 66.7% of the intervention group self reported a weight problem. 74.0% of the control group and 86.3% of the intervention group self reported trying to lose weight previously. The most common weight loss method previously attempted was a combination of exercise and diet with 29.8% (n=101).

Table 4.10 Comparison of weight related characteristics at baseline stratified by intervention and control

Descriptor	Control(n=50)	Intervention(n=51)	p-value
Self-reported weight problem n (%)	31 (62.0%)	34 (66.7%)	p=0.624
Self-reported weight loss attempt n (%)	37 (74.0%)	44 (86.3%)	p=0.122

*Not all participants answered all questions; **SD = standard deviation

Table 4.8, 4.9, and 4.10 show that differences at baseline between intervention and control groups with respect to demographic, health, and weight related characteristics were mostly small and not statistically significant. These results indicate that the randomisation process was successful and there was no requirement to adjust the main outcome analysis for confounding.

4.10 The Outcome Measures

There were seven outcome measures collected in this study including self reported questionnaires, and body measurements. The seven outcome measures were: weight (kg), girth (cm), BMI (kg/m^2), Drug Attitude Inventory-10 questionnaire (DAI-10), Liverpool University Neuroleptic Side Effect Rating Scale (LUNSERS), Medication Compliance Questionnaire (MCQ), and SF-36v2 Health Survey. The body measurements were recorded as numbers and compared using means and standard deviations (SD). The questionnaires require different interpretation; the process for this is outlined in Chapter 3.

4.11 Comparison of outcome measures at baseline stratified by intervention and control

The control group (n=50) and intervention group (n=51) were compared using outcome measures. Table 4.11 presents the comparison of the participants (n=101) at baseline stratified by intervention group (n=51) and control group (n=50). The control group had a mean weight of 97.7 kg (SD=20.7) at baseline, while the intervention group had a mean weight of 97.2 kg (SD=17.4) at baseline. The control group had a mean girth of 109.7 cm (SD=14.1) at baseline, while the intervention group had a mean girth of 111.0 cm (SD=11.8) at baseline. The control group had a mean BMI of 34.0 kg/m^2 (SD=8.1) at baseline, while the intervention group had a mean BMI of 33.3 kg/m^2 (SD=6.1) at baseline.

The MCQ score for both groups was active participation, with 50.0% in the control group and 50.0% in the intervention group choosing this answer. The DAI-10 score for both groups was positive. The LUNSERS final score for both groups was low with the control group scoring a median of 25 (IQR 13, 57) and the intervention group scoring a median of 28 (IQR 17, 47). There were 3 participants (2 from the intervention group and 1 from control group) who had a score above 20 for the red herring category of LUNSERS. The mean SF36-v2 physical health score for the control group was 55.6 (SD=9.4) and intervention group was 57.4 (SD=8.5), and the mean mental health score for the control group was 43.4 (SD=5.8) and for the intervention group 43.2 (SD=6.3).

Table 4.11 Comparison of the participants (n=101*) at baseline, stratified by intervention and control

Outcome measure	**Control(n=50)**	**Intervention(n=51)**	**p-value**
Mean weight (SD) [kg]	97.7 (20.7)	97.2 (17.4)	p=0.891
Mean girth (SD) [cm]	109.7 (14.1)	111.0 (11.8)	p=0.628
Mean BMI (SD) [kg/m^2]	34.0 (8.1)	33.3 (6.1)	p=0.601
Self-reported medication compliance: active participation n (%)	23 (50.0%)	23 (50.0%)	p=0.811
LUNSERS median of final score (IQR)***	25 (13, 57)	28 (17, 47)	p=0.952
DAI median score (IQR)	4 (0, 8)	4 (0, 6)	p=0.954
SF36v2 Mean physical score (SD)	55.6 (9.4)	57.4 (8.5)	p=0.303
SF36v2 Mean mental health score(SD)	43.4(5.8)	43.2(6.3)	p=0.958

*Not all participants answered all questions; **SD = standard deviation;***IQR = inter-quartile range

The baseline results of Table 4.11 show that there were only small differences between intervention and control participants at the beginning, indicating that the randomisation process was successful.

4.12 Comparison of outcome measures at 12 weeks stratified by intervention and control

The control group (n=50) and intervention group (n=51) were compared using outcome measures at 12 weeks. Table 4.12 presents the comparison of the participants (n=101) at 12 weeks stratified by intervention group (n=51) and control group (n=50). The control group had a mean weight of 97.5 kg (SD=20.7), while the intervention group had a mean weight of 96.4 kg (SD=17.2) at 12 weeks. The control group had a mean girth of 109.6 cm (SD=14.6), while the intervention group had a mean girth of 109.8 cm (SD=11.5) at 12 weeks. The control group had a mean BMI of 33.9 kg/m^2 (SD=8.1), while the intervention group had a mean BMI of 33.0 kg/m^2 (SD=6.0). The MCQ score for both groups was active participation, with 52.2% in the control group and 46.8% in the intervention group choosing this answer. The DAI-10 score for both groups was positive. The LUNSERS final score for both groups was low with the control group scoring a median of 15 (IQR 7.5, 26.5) and the intervention group scoring a median of 25(IQR 13, 37). There were 3 participants who had a score above 20 for the red herring category of LUNSERS. The mean SF36-v2 physical health score for control was 57.5 (SD=8.8) and for the intervention was 57.9 (8.0), and the mean mental health score for the control group was 44.3 (SD=5.7) and 44.0 (SD=6.2) for the intervention.

Table 4.12 Comparison of the participants (n=101*) at 12 weeks, stratified by intervention and control.

Outcome measure	Control (n=50)	Intervention (n=51)	p-value
Mean weight (SD) [kg]	97.5 (20.7)	96.4 (17.2)	p=0.772
Mean girth (SD) [cm]	109.6 (14.6)	109.8 (11.5)	p=0.944
Mean BMI (SD) [kg/m^2]	33.9 (8.1)	33.0 (6.0)	p=0.507
Self-reported medication compliance: active participation n (%)	24 (52.2%)	22 (46.8%)	p=0.365
LUNSERS median final score (IQR)***	15 (7.5, 26.5)	25 (13, 37)	p=0.012
DAI median score (IQR)	6 (2.5, 8)	6 (2, 8)	p=0.534
SF36v2 Mean physical score (SD)	57.5 (8.8)	57.9 (8.0)	p=0.986
SF36v2 Mean mental health score (SD)	44.3(5.7)	44.0(6.2)	p=0.803

*Not all participants answered all questions; **SD = standard deviation; ***IQR = inter-quartile range

4.13 Comparison of baseline and 12 weeks outcome measures separately for intervention and control

The body measurements were compared at baseline and 12 weeks. Table 4.13 presents the comparison of the outcome measures at baseline and 12 weeks separately for intervention group (n=51) and control group (n=50). The intervention group had a mean weight loss of - 0.74 kg (SD=3.78 kg, p=0.167) while the control group had a mean weight loss of - 0.17 kg (SD=3.36, p=0.729). The intervention had a mean girth loss of - 1.23 cm (SD=5.24, p=0.101) while the control group had a mean girth loss of - 0.15 cm (SD=3.22, p=0.743). The intervention group had a mean BMI loss of - 0.25 kg/m^2 (SD=1.34, p=0.181) and the control group had a mean BMI loss of - 0.06 kg/m2 (SD=1.16, p=0.733).

Table 4.13 Comparison of BEFORE and AFTER outcome measures separately for intervention and control group

Group	Outcome measure	Mean	Standard deviation	p-value
Intervention	Weight at start (kg) - Weight at 12 weeks (kg)	0.74	3.78	p=0.167
	Girth at start (cm) - Girth at 12 weeks(cm)	1.23	5.24	p=0.101
	BMI at start(kg/m^2) - BMI at 12 weeks(kg/m^2)	0.25	1.34	p=0.181
Control	Weight at start (kg) - Weight at 12 weeks (kg)	0.17	3.36	p=0.729
	Girth at start (cm) Girth at 12 weeks(cm)-	0.15	3.22	p=0.743
	BMI at start (kg/m^2) - BMI at 12 weeks(kg/m^2)	0.06	1.17	p=0.733

4.14 Conclusion

This chapter presented the results of the study. The CONSORT statement Flow diagram (2010) was used to show participant recruitment. The participants' demographic, health and weight characteristics were described. The control and intervention group characteristics were compared demonstrating that the randomisation process was successful. The health characteristics and outcome measures were described and compared, stratified by control and intervention group. Finally, comparison of baseline and 12 week outcome measures were described.

The following chapter provides a discussion of the results of the study in regard to previous studies. Initially, a summary of the study outcomes is provided followed by a discussion of the characteristics of the study participants. Finally, the results of the control group and intervention group are discussed, and compared with the results of previous studies.

CHAPTER 5: DISCUSSION

5.1 Introduction

This chapter provides a discussion of the study results. The chapter begins with a summary of the study, an overview of the participants and the baseline participant data. The chapter then discusses the statistical results, identifies how the results of this study confirm results from previous studies, and offers insights that may account for the difference of outcomes from this study and others. Finally, the chapter outlines the new knowledge identified as a result of this study.

5.2 Summary of the study

This study was a randomised control trial undertaken to test the effect of a nurse-led healthy lifestyle intervention program on weight related outcomes for people with serious mental illness (SMI) taking second generation antipsychotics (SGAs). The study recruited 104 participants from the local area. After initial withdrawals the study had 51 people randomly allocated to the control group and 50 people randomly allocated to the intervention group. The sample size required to detect a statistical difference was 47 in the control group and 47 in the intervention group and this predication was based on sample size calculations using a nomogram (Altman, 1991; Schneider, et al., 2007). As the aim of the study was to test the effect of a nurse-led healthy lifestyle intervention program on weight related outcomes for people with serious mental illness prescribed second generation antipsychotic medication, the hypothesis was that a healthy lifestyle program would cause a weight loss of 1 kg and girth measurement loss of 1 cm for participants in the intervention group.

The healthy lifestyle program components have been described earlier in Chapter 3, along with the components applicable to the control and intervention group. The outcome measures of the study included weight (kg), girth (cm), BMI (kg/m^2), and questionnaire data. The outcome measures are described in detail in Chapter 3. Baseline and 12 week outcome measures were collected from the intervention and control group and compared. Demographic data was also collected at baseline and compared for randomisation of variables.

5.3 Study participants

The study participants (n=101) were almost equally male (n=54, 53.5%) and female (n=47, 46.5%), and the majority of participants were single (n=81, 80.2%), Caucasian Australian (n=72, 71.3%) and unemployed (n=79, (78.2%). These demographic data are similar to a recently published multi-component health education intervention study for people with schizophrenia where the participants (n=45) are described as "predominately male, white, single and economically inactive" (Bradshaw, Lovell, Bee & Campbell, 2010, p. 478). The mean age of participants in the present study was 40.8 years. This is slightly higher than the reported mean age of 37 years by Bradshaw et al., (2010), and lower than the reported mean age of 46 years in a large study (n=966) assessing health status and providing healthy lifestyle education by Smith et al., (2007). The demographic characteristics of this present study demonstrate the broad characteristics of people living in the community with serious mental illness. The high number of participants that didn't finish school (n=54), when considered alongside the high number of unemployed participants (n= 79), could be reflective of missed opportunities to develop career pathways due to the symptoms of serious mental illness. The early phase of a psychotic illness that is referred to as the prodrome phase, often develops gradually in the teenage years. It is during this phase that a person may

experience a gradual deterioration in functioning that affects education and relationship development (Dodd, 2011).

The study participants (n=101) mostly self reported a diagnosis of schizophrenia (n=85, 84.2%), while 6.9% reported a diagnosis of bipolar disorder or depression. One hundred participants reported taking second generation antipsychotics, while one participant reported taking Mirtazepine only. The most commonly prescribed antipsychotic medications were Olanzapine (n=37, 36.6%), Clozapine (n=19, 18.8%), and Risperidone (n=24, 23.8%). These findings differ from a similar study by Bradshaw et al., (2010) who reported only 78% of participants in their study taking SGAs, with the rest taking first generation antipsychotics or a combination of both first and second generation antipsychotics. This may reflect the difference in prescription of antipsychotics in different countries as Bradshaw et al., (2010) conducted their study in the UK. Interestingly, in the last few years the prescription of SGAs in Australia has changed from requiring a diagnosis of psychotic disorder or schizophrenia to include bipolar disorder and depression (Usher, Foster & Bullock, 2009). This is important to note as this change led to a change in the inclusion criteria for the study. That is, the change in antipsychotic prescription for psychotic disorders meant the study inclusion criteria needed to be broadened to include people with serious mental illness rather than just a diagnosis of schizophrenia as the aim was to work with people who had experienced weight gain due to the use of SGAs.

40.6% of study participants (n=101) of this study reported medical problems including diabetes, asthma, hypertension and epilepsy. These results are significantly lower than an Australian survey conducted in 2007 that found 90% of 350 people with a mental illness also had a physical illness (SANE, 2007). While these results could be taken optimistically to mean the health of people with serious mental illness is improving, it

could also reflect the inability of people with a mental illness to access health services and the lack of opportunity to be assessed, diagnosed, and treated, which may be more relevant in regional areas. In 2006 SANE identified barriers that people with mental illness experienced in attempting to remain well. These included the cost of health care, difficulty accessing services, and lack of motivation to be involved in health care (SANE, 2006). The results of this present study could be also reflecting these barriers to physical health care. There could be other explanations for the lower reported incidence of medical conditions in this present study. For example, the group of participants recruited to this study may be overall more physically healthy than the group recruited to the SANE (2006) study. While this is offered as a possible explanation of the results, the weight measurements collected show that the participants of this study are mostly in the overweight category (88.9%) and we know this factor increases the risk of physical health problems. It is more likely that the group of participants in this study may not be aware of the state of their physical health due to limited access to health services in regional areas as indicated. Alternatively, it is also possible that the participants may have been a group of people who are more aware of their physical health and that is one of the reasons that drew them to volunteer for the study.

The majority of study participants (n=101) at baseline self reported a weight problem (n=65, 64.4%), while a substantial proportion reported having previously tried to lose weight (n=81, 80.2%), with participants equally attempting exercise (n=22, 21.1%), diet change (n=23, 22.1%), and exercise and diet combined (n=31, 29.8%), in an attempt to lose weight. Loh, Meyer and Leckband (2008) found similar results in their study of weight perception in people with schizophrenia, which found 58% of participants (n=50) had attempted weight loss, with 28% attempted diet change only, 32% tried exercise only, while 22% tried exercise and diet combined. In a survey of 261 people with a mental illness, exercise was identified as an important factor in improving health

although almost half of the 261 participants did not participate in any exercise (SANE, 2006). Soundy, Faulkner and Taylor (2007) found similar results in a study using semi structured interviews; they explored perceptions of physical activity with people with serious mental illness. Their findings showed that “walking was part of a regular routine” for some but “overall, most were ambivalent about becoming more active, receiving little or no support to do more” (p. 493).

The participants’ weight measurements at baseline show that the majority of participants have a girth higher than the recommended healthy girth and their BMI was above the normal recommended ranges. The mean weight of the present study participants was 97.4 kg (SD=19.1). The mean girth of the present study participants was 110.4 cm (SD=13.0) and the mean Body Mass Index (BMI) of the present study participants was 33.71 kg/m^2 (SD=7.1).

The current recommended healthy girth for men is < 102 cm and for women < 88 cm and the normal range recommendation for BMI is 18.50-24.9 kg/m^2 (IDF, 2006). BMI of 25.00 – 29.9 is overweight, 30.00 – 34.9 is moderate obesity, 35.00 – 39.9 is severe obesity and > 40.00 is very severe obesity (IDF, 2006). Table 5.1 shows the percentage of participants for each category of BMI.

Table 5.1 BMI categories for all participants at baseline (n=101)

BMI range	**Frequency (n=101)**
Normal range BMI 18.50-24.9 kg/m^2	n=12 (12.1%)
Overweight range 25.00 – 29.9 kg/m^2	n=25 (25.3%)
Moderately overweight 30.00 – 34.9 kg/m^2	n= 21 (21.2 %)
Severe obesity 35.00 – 39.9 kg/m^2	n=26 (26.3 %)
Very severe obesity >40.00 kg/m^2	n=17(17.2 %)

The BMI rates of this study can be compared to a study by Smith et al., (2007) who reported a higher overall baseline BMI of 46 kg/m^2, but found similar groupings within the BMI ranges; with 19% in the normal BMI range, 32% in the overweight BMI range, 25 % in the moderately overweight BMI range and 24 % with a BMI > 35 kg/m^2.

A healthy lifestyle intervention study with 70 participants reported BMI for the intervention group of 26.26 kg/m^2 (SD=3.68) and the control group 27.17 g/m^2 (SD = 5.79) (Littrell et al., 2003). A further study (Wu et al., 2008) comparing healthy lifestyle interventions (n=128) reported baseline weight characteristics of weight 64.6 kg, BMI 24.5 kg/m^2 and girth 83.7 cm. While these weight measurements fall within the normal ranges, the participants for this particular study were all people experiencing their first psychotic episode who had gained 10% of their pre-drug body weight (Wu et al., 2008). This inclusion criteria for Wu et al. (2008) of first psychotic episode, could account for the lower mean weight, BMI and girth as participants had not previously experienced antipsychotic induced weight gain. The studies described above, excluding Wu et al.

(2008), all reported baseline weight characteristics for participants outside of the normal recommended weight ranges.

The higher incidence of obesity for people with a mental illness has been investigated by Loh, Meyer and Leckband (2008), who reported on the accuracy of body image perception for people with serious mental illness. They compared 50 people with schizophrenia to 50 people without schizophrenia and found that the BMI for the 50 people with schizophrenia was 29.06 kg/m^2 (SD = 6.23), while the group of people without schizophrenia (n=50) had a BMI of 27.03 kg/m2 (SD= 4.15), thus demonstrating that people with schizophrenia were significantly more likely to be obese than the general population (46% vs. 18%). Loh et al. (2008) do not offer any suggestions as to why there is this significant difference in weight measurements but the participants of their study did report a willingness to join education groups on weight loss. These findings add further support to the urgent need to include weight management strategies as part of 'normal care' for someone with serious mental illness. High BMI rates are known to increase the risk for the individual for cardiovascular disease and diabetes (IDF, 2006). The majority of the participants of this present study have BMI and girth measurements above the normal recommended range, indicating that they are all at a higher risk for cardiovascular disease and diabetes.

The comparison of baseline characteristics for the control group (n=50) and intervention group (n=51) demonstrated that the randomisation process was successful. Randomisation of participants to groups is designed to distribute the essential study variables evenly within the control and intervention groups, thus enabling the study findings to be attributed to the intervention and not to issues of variability (Schneider et al., 2007). The variables that were important to randomly allocate in this study included: demographic characteristics, mental illness diagnosis and antipsychotic medication

prescription. Demographic characteristics of participants in the control group (n=50) and intervention group (n=51) were compared using mean and standard deviation values.

The mean age of participants in the control group and intervention group was the same at 40.8 years, with a SD=12.5 years for the control group, and a SD=11.5 years for the intervention group. The self reported diagnosis of schizophrenia for the control group (n=50) was 80.0% (n=40) and for the intervention group (n=51) was 88.2% (n=45). Participants with self reported medical problems in the control group (n=50) was 38.0% (n=19) and for the intervention group (n=51) was 43.1% (n=22).The majority of participants in both groups reported their status as living single (82.0%; (n=41 for the control group and 78.4% (n=40) for the intervention group). There was also an equal distribution of unemployed participants between the two groups; 77.6% (n=38) in the control group and 82.0% (n=41) in the intervention group.

The comparison of self reported current weight problems found equal results in both groups with 62.0% (n=31) in the control group (n=50) and 66.7% (n=34) in the intervention group (n=51) self reporting a weight problem at the time of recruitment into the study. There were slightly less participants in the control group that reported attempting to lose weight (74.0% n=37, when compared to the intervention group of 86.3% n=44). In summary, the randomisation process was successful.

5.4 Study results

The data analysis of the outcome measures for the control group (n=50) and intervention group (n=51), although not statistically significant, demonstrated small positive changes in the predicted direction. The control and intervention group were compared using statistical tests.

5.5 Weight measurements

The comparison of control and intervention groups at baseline and 12 weeks was not statistically significant. There were, however, small positive changes that are outlined below. There was a mean weight loss change of - 0.74 kg (SD=3.78 kg, p=0.167) at 12 weeks for the intervention group (n=51), while the control group (n=50) had a mean weight loss change of - 0.17 kg (SD=3.36, p=0.729) at 12 weeks. The girth measurement for the intervention group had a mean change of - 1.23 cm (SD=5.24, p=0.101) at 12 weeks, while the control group girth measurement change was - 0.15 cm (SD=3.22, p=0.743) at 12 weeks. The BMI change for the intervention group at 12 weeks was a loss of - 0.25 kg/m^2 (SD=1.34, p=0.181) at 12 weeks while the control group had a loss of -0.06 kg/m^2 (SD=1.17, p=0.733). These results, while promising, do not fully support the hypothesis of the study: that the healthy lifestyle program would cause a weight loss of 1 kg and 1 cm in girth measurement for people in the intervention group.

While the results of the study are not statistically significant, other studies have had similar results from healthy lifestyle interventions. An earlier and similar study of a 16 week healthy lifestyle program that met weekly found the intervention groups (n=35) mean BMI range (0.01 kg/m^2 to 0.13 kg/m^2) and weight range (-0.03 kg to -0.37 kg) changed very little, while the standard care group (n=35) had mean increases of BMI (+1.01 kg/m^2 to +1.37 kg/m^2) and weight (+3.26 kg to +4.35 kg) (Littrell et al., 2003). Littrell et al., (2003) proposed that differences in BMI and weight gain experienced by the standard care group when compared to the intervention group can be attributed to the increase in knowledge that the intervention group could have gained while participating in the healthy lifestyle education group. The authors concluded “the results of this study showed positive outcomes of an educational intervention to ameliorate the weight gain of patients with schizophrenia for whom antipsychotics are prescribed”

(Littrell et al., 2003, p. 241). A similar conclusion can be drawn from this present study where the control and intervention group both had small weight losses. The weight losses experienced by the control group could be attributed to the increase in knowledge that resulted from reading and undertaking the nutrition and exercise changes suggested in the Passport 4 Life booklet.

Ball, Coons and Buchanan (2001) evaluated the effects of a 12 week publicly available healthy lifestyle program on weight measurements of people with schizophrenia taking olanzapine (n= 11). They found no significant difference in weight measures when control and intervention group were compared, although participants of the intervention group (n=8) lost more weight than the control group (- 2.3 kg vs. - 0.2 kg), which is similar to the current study. In contrast, a similar 12 week healthy lifestyle program to the present study was tested by Vreeland and colleagues (2003), with comparison of the control (n=15) and intervention (n=31) group showing a statistical difference (p=0.004) in weight measurements with the intervention group showing a mean weight loss of - 2.7 kg vs. a mean weight gain of + 2.9 kg for the control group. The study design, however, was different to the present study in that the participants were not randomly allocated to groups and the authors reported a high potential for selection bias of participants who *"*were already motivated to lose weight" (Vreeland et al., 2003, p. 1157).

In 2004, a study of 44 people on SGAs was conducted using a naturalist audit of a standardised weight loss programme, which utilised three motivational interviewing sessions with participants during one month (Ohlsen, Treasure & Pilowsky, 2004). The results of the Ohlsen et al. (2004) study support the present study results. They recommended further research using a randomised control trial design. Similarly to the present study the authors reported no significant changes in overall weight, however, like Loh et al. (2008) they support the provision of weight management strategies as

part of ‘normal care’ at the commencement of antipsychotic medication (Ohlsen et al., 2004).

A further healthy lifestyle program, albeit with a very small sample size, also found positive results over 16 weeks, with the intervention group (n=8) having a mean loss of 2.45 kg and the control group (n=9) losing 0.6 kg (Weber & Wyne, 2006). Weber and Wyne (2006) developed their 16 week program to include cognitive behavioural intervention and educational sessions including goal setting, problem solving, and plans to increase exercise. This program has some similarities to Passport 4 Life as it also includes behavioural intervention, goal setting, and planning. The authors concluded that a longer intervention could yield greater weight loss and that their study shows weight loss is possible with behavioural interventions for people with SMI (Weber & Wyne, 2006). Similarly, a longer intervention in the current study may have revealed a significant result. However, the length of the intervention in the present study was limited due to the time limits of a PhD study and available funding.

The results of the present study suggest that the length of the intervention could be increased in follow up studies. It is possible that if the intervention were conducted over a longer time, it would be expected that increasingly significant results could be detected as the results of the present study are promisingly moving in a positive direction. Further, the fact that the control group was also provided with the Passport 4 Life workbook, part of ethical considerations when including human participants in RCTs, could also mean that the control group behaviour was influenced resulting in a diminished difference in weight loss between the two groups. Unfortunately, the outcomes of the study could in part reflect the ethical difficulties in conducting RCTs with people in the real world environment (Sanson-Fisher, Bonevski, Greene et al., 2007).

In summary, the healthy lifestyle program Passport 4 Life can be compared in parts to the studies discussed above, but the present study is different as it included not only healthy lifestyle education but also exercise sessions, food examples and samples, the spirit of motivational interviewing, and nurse involvement in each weekly community group over 12 weeks. While the weight measurements were not statistically significant, there were small promising changes for the intervention group of - 0.74 kg (SD=3.78) weight loss and -1.23 cm (SD= 5.24) girth loss.

These small changes in the predicted direction indicate that for some of the participants the program was beginning to show successful weight losses. It is important to also realise that while the results may not have been statistically significant, there were some considerable weight losses for individuals within the group. For example one participant had a commencement weight of 115.2 kg and at the completion of the 12 week program in the intervention group their weight had decreased by -5.0 kg. While weight loss may occur individually, weight gain can also occur and this will affect the study results. For example one participant had a commencement weight of 89.6 kg and their completion weight was 95 kg, a gain of + 5.4 kg. These examples demonstrate the range of differences experienced by individuals who participated in the program. These differences can be understood in terms of the differing individual experience of weight, and serious mental illness, for participants. For example, often people with serious mental illness experience lack of motivation as a symptom of their illness, and if this were happening during the course of the program it would therefore be quite difficult for the person to change their unhealthy behaviour.

5.6 Questionnaire results

The self reported medication compliance questionnaire (MCQ) found that 50.0% of the control group (n=50) and 50.0% of the intervention group (n=51) at baseline reported

‘active participation in their medication intake’. At 12 weeks 52.2% of the control group (n=50) and 46.8% of the intervention group (n=51) reported ‘active participation in their medication intake’. This result represented a slight decrease for the control group (50.0% to 46.8%) and slight increase for the intervention group (50.0% to 52.2%) to the questions ‘active participation in their medication intake’ when comparing baseline results with 12 week results, but there was no statistical difference between baseline (p=0.811) and 12 weeks (p=0.365). These small changes could be attributed to the experience of ambivalence or tolerance that people with a mental illness often experience regarding their treatment, particularly medication treatment. Medication participation or compliance has long been an issue for discussion, and linked with psychiatric morbidity (Gray, Wykes & Gournay, 2002). The person’s compliance can be influenced by different factors, including knowledge of their disorder and the potential benefits of long term treatment with antipsychotics. Side effects such as tardive dyskinesia, extrapyramidal symptoms, and anticholinergic that can be long lasting effects can be particularly influential in decisions related to compliance with antipsychotic treatment. Medication compliance is considered an essential component of treatment for the person with a serious mental illness taking second generation antipsychotic medication, leading to decreased hospital admissions and relapse prevention (Gray et al., 2002). However, it is not surprising to find that people taking antipsychotic medication experience ambivalence at times, and choose to not actively participate in their medication treatment regime. The self reported findings of participation in medication in this present study are very similar to literature reports of non-compliance with antipsychotic medication in 50% of people prescribed antipsychotics (Gray, et al., 2002).

The Liverpool University Neuroleptic Side Effect Rating Scale (LUNSERS) results are reported using a median –“the median is the value that comes half-way when the data is

ranked in order" and inter-quartile range (IQR) – the IQR is the "numerical difference between the 25th and 75th centiles" (Altman, 1991, pp. 22-33). The median of the LUNSERS for the control group (n=50) was 25 (IQR 13, 57) and 28 (IQR 17, 47) for the intervention group (n=51) at baseline, while the scores at 12 weeks for the control group (n=50) was 15 (IQR 7.5, 26.5), and for the intervention group (n=51) 25 (IQR 13, 37). There is a decrease from 25 to 15 for the median score for the control group, but this was not statistically significant; baseline (p=0.952) and 12 weeks (p=0.012). The median scores for the LUNSERS are all in the 'low' category at baseline and 12 weeks. This 'low' score indicates that all the participants in this study were able to 'tolerate' their antipsychotic medication and any side effects experienced. An interesting observation was that one participant who was assisted by a research assistant (RA) to complete the LUNSERS questionnaire had noticeable involuntary leg movements while sitting. However, when asked Question 48: *"Have you experienced parts of the body moving of their own accord, e.g. foot moving up and down",* the participant answered "not at all". The research team discussed this at the completion of the survey, and decided to go back and ask the participant again. Again the person responded "not at all". This answer was a complete contrast to what we were observing. This observation and the statistical results of this questionnaire have led to further consideration of the ability of some people with a mental illness to tolerate and acknowledge side effects that may at first seem intolerable, such as involuntary movements. Another explanation could be that the person did not interpret their body movements as involuntary but rather saw them as voluntary. While much of the literature discusses the adverse consequences of medication side effects (Morrison, Gaskill, Meehan, Lunney, Lawrence & Collings, 2000; Usher, Foster, Bullock, 2009) there is limited discussion on the person's ability to tolerate side effects, particularly if there is the perception of limited interference with daily life. For the participant mentioned above, it was observed that the involuntary movements were most noticeable when the person was sitting still.

Should we consider that it might be possible for a person to no longer recognise their side effects if they have learnt to tolerate them? The results of the LUNSERS scores for this study demonstrate that all the participants experienced side effects from their medication but overall their personal experience and ability to tolerate the side effects was higher than expected. Kim, Kim, Ahn and Kim (2006) found similarly non-statistically significant results and concluded that while the self report nature of the LUNSERS should be considered there are advantages to "understanding symptoms on the part of patients" (p. 303). Kim et al., (2006) go further to suggest alternative explanations like that *there can be a* "difference of severity between the subjective symptoms and objective signs of EPS", and this can lead to differing evaluations of side effects, as discussed above (p. 304). Further qualitative exploration of participants' perceptions and views of side effects may extend understandings of apparent disparities between observed and reported symptoms.

The Drug Attitude Inventory - shortened version - (DAI-10) results are reported using medians and inter-quartile range (IQR). The DAI median score for the control group (n=50) was 4 (IQR 0,8) and for the intervention group (n=51) was 4 (IQR 0,6) at baseline, with both groups making the same improvement to have a median score of 6 at 12 weeks, with IQR 2.5,8 for the control group and IQR 2,8 for the intervention group. This represents an increased median positive score from 4 to 6 for both the control and intervention groups. The DAI is reported as either a positive or negative score. In all cases, intervention or control group, baseline and 12 weeks assessment the scores were always positive. This result is interpreted as a positive subjective response in respect to medication compliance. When comparing control and intervention group, the results were not statistically significant; baseline (p=0.954) and 12 weeks (p=0.534). This positive result demonstrates that the participants of both control and intervention

group in this present study were mostly compliant with their psychotropic medication at baseline. The positive score increase at 12 weeks indicates for the control and intervention groups, an increasing compliance.

The SF-36v2 score is reported in two parts, the mean mental health score and the mean physical health score. The mean physical health score for the control group (n=50) was 55.6 (SD=9.4) and for the intervention group was 57.4 (SD=8.5) at baseline, while the 12 week score for the control group increased to 57.5 (SD=8.8) and the intervention group increased to 57.9 (SD=8.0). The mean mental health score for the control group (n=50) was 43.4 (SD=5.8) and for the intervention group was 43.2 (SD=6.3) at baseline, while the 12 week score for the control group increased to 44.3 (SD=5.7) and the intervention group increased to 44.0 (SD=6.2). The comparative scores for SF-36v2 for the physical health component summary is mean = 50.0 (SD=10.0) and for mental health component summary is mean = 50.0 (SD=10.0) (Ware, Kosinski & Dewey, 2002). The scores for the participants in the present study, in both control and intervention group at baseline and 12 weeks, are within the ranges suggested as normative ranges for Australian scoring. The participants of this study can then be described as being within the normal population range for self care, physical, social and role activities, psychological distress and emotional problems (Ware, Kosinski & Dewey, 2002).

Australian normative data from the SF-36v2 collected in 2004 from 3015 participants can also be used to compare to the findings from the control and intervention groups of the present study (Hawthorne, Osborne, Taylor & Sansoni, 2007). The Australian data includes population norm scores of 50.27 (SD=9.70) for physical health and 52.92 (SD=10.17) for mental health (Hawthorne, Osborne, Taylor & Sansoni, 2007). The mean age for the present study is 40.8 (SD = 12.5) for both control and intervention group, therefore the SF-36v2 can be compared to the norm scores for the age group 35-44

(n=553). For people in the 35-44 age group (n=553), the population norm scores include: physical health component summary of 52.65 (SD=7.78) and for mental health component summary 49.42 (SD=9.63).

At baseline, the mean physical health score for the control and intervention group when compared was not statistically significant. However when the scores are compared to the norm scores for the age group 35-44, both the intervention and control group have higher scores. The baseline scores for both intervention and control group were higher than the population norm score 55.6 (control) and 57.4 (intervention) versus 52.56 (population norm score).This higher score demonstrates that people in the present study have self scored their physical health higher than the norm score for the age group 35-44. At 12 weeks the mean physical health score for the control and intervention group when compared again is not statistically significant. However the scores for both groups in the present study remain higher than the physical health score for the age group 35-44. The 12 week scores for both intervention and control group were higher than the population norm score 57.5 (control) and 57.9 (intervention) versus 52.56 (population norm score).

The participants of this study at baseline and 12 weeks have self rated as 'physically healthy', thus scoring higher than the norm for age in the physical health score. This scoring is consistent with the participants' self reporting of medical problems (40.6%) that were significantly lower than previous studies. However, the weight measurements of participants of the present study showed that the majority of participants had a girth higher than the recommended healthy girth and their BMI is above the normal recommended ranges. As previously identified, the higher than recommended weight measurements of the participants, indicate a higher risk for physical health problems.

The mental health score for participants in the present study however is different to the physical health score. The mental health score at baseline and 12 weeks for the control and intervention groups when compared is statistically not significant. However when the participants' mental health score is compared to the norm score for age 35-44, the participants of this study self reported lower mental health scores than the age score at baseline and 12 weeks. The baseline scores for both intervention and control group were lower than the population norm score 43.4 (control) and 43.2 (intervention) versus 49.42 (population norm score). The 12 week scores for both intervention and control group remained lower than the population norm score 44.3 (control) and 44.0 (intervention) versus 49.42 (population norm score). As all the participants of the present study have a self reported serious mental illness diagnosis, it could be expected that they would score lower than the norm score for age 35-44.

The present study can be compared to a recently reported study of a 12 month lifestyle intervention by Forsberg, Bjorkman, Sandman and Sandlund (2010). Forsberg et al., (2010) similarly found no statistically significant changes with the SF-36 scores when the control group (n=17) and intervention group (n=24) were compared after a 12 month lifestyle intervention.

5.7 Article

The following article is currently under review and presents the findings of the research.

Publication title
Usher, K., Park, T., Foster, K., & Buettner, P. (under review). A randomised 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. *Journal of Advanced Nursing.*

Title: A randomised 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.

Abstract

Aim: To test the effect of a nurse-led intervention on weight gain in people with serious mental illness (SMI) prescribed and taking second generation antipsychotic medication.

Background: Weight gain and obesity has reached epidemic proportions with the prevalence of Metabolic Syndrome (MetS) reaching 20-25% of the global population. While individuals in the general population are at risk of physical conditions such as MetS, people with serious mental illness are at even higher risk, particularly those taking second generation antipsychotic (SGAs) medication.

Method: A randomised control trial (RCT) conducted which 104 randomly allocated participants. The control group received a 12 week healthy lifestyle booklet. In addition to the booklet, the intervention group received weekly nutrition and exercise education, exercise sessions, and nurse support. Participants were assessed at baseline and 12 weeks. Seven outcome measures were used: body measurements included girth (cm), weight (kg), height (cm) and BMI (kg/m^2); questionnaires included the medication compliance questionnaire (MCQ), the Drug Attitude Inventory (DAI-10), the Liverpool University Neuroleptic Side Effect Rating Scale (LUNSERS), and the Medical Outcomes Study Short Form 36 (SF-36v2). Differences in primary outcome measures between baseline and 12 weeks follow-up was compared between intervention and control group using standard bi-variate statistical tests (Chi-square tests, Fisher's exact tests, Chi-square test for trend, and t tests).

Results: The analysis of outcome measures for the control group (n=50) and intervention group (n=51) were not statistically significant. There was a mean weight change of - 0.74 kg (SD=3.78 kg, p=0.167) at 12 weeks for the intervention group (n=51), while the control group (n=50) had a mean weight change of - 0.17 kg (SD=3.36, p=0.729) at 12 weeks.

Conclusion: The study was conducted between 2008 and 2010. The results, while not statistically significant, did show small positive changes in the intervention group.

Key words: metabolic syndrome; weight gain; serious mental illness; second generation antipsychotic medications.

Introduction

While antipsychotic medication remains the mainstay of treatment for schizophrenia and other serious mental illnesses, the increased use of the newer second generation antipsychotics has led to concerns about their association with weight gain and other metabolic symptoms (Usher, Foster & Bullock 2009). The second generation antipsychotics (SGAs) are known to be linked to marked and predictable weight gain which is rapid in the initial period after commencement of the medication followed by a period where it continues but at a reduced rate. A meta-analysis of weight change by Allison, Mentore, Heo, Chandler, Cappelleri, Infante and Weiden (1999) identified the following weight gain over 10 weeks of treatment with a standard dose of the following SGAs:- Clozapine, 4.45 kg; Olanzapine, 4.15 kg; Risperidone, 2.10 kg; and Ziprasidone, 0.04 kg. The weight gain associated with SGAs usually occurs rapidly during the first 4-12 weeks of treatment. After the initial period the weight gain continues at a lower level over a prolonged period of time (Tschoner et al., 2007).The weight gain linked to second generation antipsychotic drugs is typically associated with abdominal obesity (McEvoy et al., 2005), enhanced adiposity, which is linked with increased morbidity and mortality as well as reduced quality of life (McEvoy et al., 2005). Together these changes make up what is referred to as metabolic syndrome, a cluster of metabolic abnormalities including hypertension, hyperlipidemia, hyperglycaemia and abdominal obesity which, when experienced together, lead to an increased risk of diabetes and cardiovascular disease (IDF, 2006). Australian studies report prevalence rates of MetS for people with serious mental illness ranging between 51% to 68% (Brunero *et al.* 2009; John *et al.* 2009; Tirupati & Chua 2007). Thus, weight gain and metabolic disturbance linked to the second generation antipsychotics has become a major concern for clinicians and consumers (Wand & Murray 2008). Interventions have been introduced in an attempt to manage the weight gain linked to these medications. Interventions including lifestyle, education, weight loss medications, and exercise have all been tried and evaluated. Research to date indicates significantly greater weight reduction in lifestyle intervention groups versus

pharmacological intervention groups or standard care groups (Littrell et al. 2003, Vreeland et al. 2003 & Weber & Wyne 2006).

Background

Early intervention for weight gain with SGAs should be the first priority when a person with a serious mental illness commences taking SGA medications and when antipsychotic medication changes occur. Interventions at that time should include healthy lifestyle education, reduced calorie intake and increased exercise (Tschoner et al., 2007; Citrome et al., 2005). However, for those who have been taking SGAs for sometime and have put on a significant amount of weight as a result, a number of interventions have been implemented in order to help with weight management and reduction.

Single mode intervention studies range from 12 -36 weeks duration and tend to be drug based. For example, the adminitration of metformin has been successful in arresting weight gain and leading to significant BMI reductions in many participants (Morrison et al. 2002). Education programs that deliver information on nutrition, wellness, fitness, and exercise, have also had some success. A 12 week study by Ball and colleagues (2001), included 22 participants with serious mental illness of whom 11 attended weekly Weight Watcher group meetings, 3 attended weekly exercise sessions, while a comparison group (n=11) did not participate in the groups but maintained their medication. The study reported successful outcomes with weight loss ranging from 0-8.2 kgs. Other studies have found disparite results. For example, Lindenmayer et al. (2009) found a significant mean weight and BMI reduction of approximately 2 kg over nine months but a similar study conducted over six months reported no weight loss.

Multimodal interventions range from 12-weeks to 18-months duration and used a comination of approaches such as education, exercise, dietary management, and lifestyle programs (McCloughen & Foster 2011). For example, 12-week programs with educational and behavioural components have achieved significant weight reductions (Melamed et al. 2008; Kwon et al. 2006; Skouroliakou et al. 2009). Studies using amantadine (a dopamine agaonist that decreases appetite) and metformin combined with lifestyle education, diet, and exercise, appeared to

achieve weight stabilisation in the intervention group rather than weight loss and weight gain in the control group (Graham et al. 2005). However, weight loss was achieved in a study with a larger number of participants (Wu et al. 2008). Studies conducted over longer duration tended to have better outcomes. For example, the study by Poulin et al. (2007), conducted over 18 months with education followed by structured weekly fitness classes, had a significant weight and BMI reduction.

In summary, significantly greater weight reduction has been found in lifestyle intervention groups versus pharmacological intervention groups or standard care groups since the land mark DPP study in 1996-1998 (Ball et al., 2001; Evans et al., 2005, Knowler et al., 2005; Littrell et al., 2003; Vreeland et al., 2003; Weber & Wyne, 2006). However, the outcomes so far are limited by factors such as the small number of studies, small sample sizes, short study duration, and by variability in the interventions, including their intensity and duration. Further research that distinguishes between weight gain prevention and weight gain reversal has been recommended for further studies (Faulkner, Cohn & Remington, 2007).

The study

Aim

The aim of this study was to test the effect of a nurse-led intervention on weight gain in people with serious mental illness (SMI) prescribed and taking second generation antipsychotic medication.

Design

An experimental randomized controlled trial was undertaken.

Participants

There were 104 people recruited to participate in the study. Two people attended the information session only and one person left the study due to medical reasons, resulting in a total of 101 participants; 51 in the control group and 50 in the intervention group. Participants were recruited to the study via posters displayed at local community mental health services, non-government organizations (NGOs), word of mouth and as a result of presentations on the topic in the local

area. Participants were from a combination of five local mental health services and members of NGOs. All participants had a diagnosis of a serious mental illness, were over 18 years of age, were assessed by the team as well and thus able to consent to participate, and able to read English.

Data collection

Data were collected by the researchers between March 2008 and December 2010. Demographic data collected from participants included: age, gender, ethnicity, diagnosis, current medication, BMI, and previous weight prevention strategies. All participants had baseline measures (weight, height and girth) assessed by a research assistant which were repeated at at 12 weeks. The participants in the control group had identical measures taken at the same time periods as the intervention group.

Instruments

The *Medication Compliance Questionnaire (MCQ)* is a measure of medication compliance with a seven point scale ranging from 'complete refusal' to 'active participation' used to assess medication compliance in the participants (Kemp et al., 1996). The person's compliance was assessed at baseline, and 12 weeks in both groups. The MCQ is scored according to the response given: complete refusal=1; partial refusal= 2; reluctant acceptance= 3; occasional reluctance about treatment= 4; passive acceptance= 5; moderate participation= 6; active participation= 7.

The Drug Attitude Inquiry-10 (DAI-10) is a self report inventory on the subjective effects of neuroleptic medications. The person is asked to answer 10 questions choosing either *true* or *false*. The DAI-10 is reported as having good internal consistency with high test-retest reliability (Awad, 1993). This outcome assessment was measured at baseline, and 12 weeks in both groups. The DAI-10 questionnaire is scored according to the true or false answer given, as either +1 or -1. The final score is the sum of the total of pluses and minuses. A positive total score means a positive subjective response (compliant). A negative score means a negative subjective response (non-compliant).

The *Liverpool University Neuroleptic Side Effect Rating Scale* (LUNSERS) is a self report questionaire for the reporting of general neuroleptic side effects, with 51 questions which can be grouped under the following categories: extrapyramidal side effects, psychic side effects, hormonal side effects, anticholinergic side effects, miscellaneous side effects, other autonomic side effects, allergic reactions and red herrings. Using a 5 point Likert scale, the person rates each item as *not at all, very little, a little, quite a lot or very much*. The LUNSERS has been used as a useful rating scale to assess subjective tolerability of antipsychotics in previous studies (Kim et al. 2006). This outcome assessment was measured at baseline and 12 weeks in both groups. The LUNSERS has eight categories of potential medication side effects: psychic, anticholinergic, hormonal, extrapyramidal, miscellaneous, allergic, other autonomic and red herrings. To obtain a final score each category is added together (excluding the red herring score) and then the red herring score is subtracted for the final score to be obtained. The final score is then classified: 0-40 = low; 41-80 = medium; 81-100 = high; > 101 = very high. A red herring score above 20 is considered high and may indicate individuals who over score in general.

The *Medical Outcomes Study Short Form 36* (SF-36) is a generic well-validated multipurpose health measure (Turner-Bowker, Bartley, & Ware 2002). The questionnaire measures indicators of health including: behavioural function and dysfunction, distress and wellbeing, objective and subjective ratings and favourable and unfavourable self evaluations of general health (Ware, Kosinski, & Gandek, 1993). Validity and reliability of the tool is well documented and the SF-36 is considered a useful benchmark when comparing well and unwell populations to estimate the burden of specific conditions (Turner-Bowker et al. 2002). This outcome assessment was measured at baseline and 12 weeks in both groups. The SF-36v2 is scored according to clusters of questions and provides a physical health and mental health summary score.

Procedure

Potential participants who met the study criteria were invited to attend the first session of each 12 week group series. After consenting to participate, all in attendance were invited to select an opaque envelope which provided the researcher with the random allocation of the participant.

The result of the allocation was then explained to the participant. After a discussion about the conduct of the program, participants were invited to complete the data collection tools which were completed with guidance from the research assistant. When all survey tools were completed, height, weight and girth measurement and other questionnaire data was collected. Participants in the intervention group were provided with a copy of the education booklet, met every week for 12 weeks, and the measures repeated at the completion of the program. An overview of the program has already been published (Park, Usher & Foster 2011). Control groups participants were provided with a copy of the education booklet and asked to return in 12 weeks for further assessments.

Ethical consideration

The study was approved by the relevant ethics committees and all participants received an explanation of the study before providing written consent. Participants in this study were deemed vulnerable due to their diagnosis of serious mental illness. Therefore, their consent to take part was only negotiated if they were deemed free of any symptoms of psychoses by an experienced mental health nurse at the time of entering the study.

Data analysis

All characteristics assessed at baseline were compared between intervention and control participants to evaluate the effectiveness of randomization. Differences in primary outcome measures between baseline and 12 weeks follow-up was compared between intervention and control group using standard bi-variate statistical tests (Chi-square tests, Fisher's exact tests, Chi-square test for trend, and t tests or non-parametric Wilcoxon tests, as appropriate). Statistical analysis was conducted using SPSS version 18.

Results

Table 1 provides a detailed overview of the demographic information for all participants (n=101) collected at the commencement of the study. There were slightly more male participants than females, with male participants making up 53.5% of the group.

Table 1: Participant demographic characteristics (n=101)

Item	**Category**	**Frequency**	**%**
Gender	Male	54	53.5
	Female	47	46.5
Marital status	Single	81	80.2
	Married	3	3.0
	Divorced	11	10.9
	Separated	6	5.9
Ethnicity	Caucasian Australian	72	71.3
	Aboriginal or Torres Strait Islander	14	13.9
	Other	15	14.9
First language spoken	English	97	96.0
	Other	4	4.0
Education level reached	Completed high school	21	23.0
	TAFE	11	10.0
	Did not complete high school	54	49.1
	University graduate	4	3.6
	Current student	5	3.6
Current employment	Paid work	5	4.9
	Volunteer	12	11.8
	Combination	3	2.9
	Not working	79	78.2

The majority of participants, 84.2%, self reported a diagnosis of schizophrenia, with 15.8% of participants self reporting bi polar disorder, depression, or anxiety as their psychiatric diagnosis. Second generation medications taken by the participants included Olanzapine (36.3%), Risperidone (23.8%), Clozapine (18.8%), and Seroquel (14.9%) (see Table 2 for further health characteristics).

Table 2: Description of participants health characteristics (n=101)

Item	**Category**	**Frequency**	**%**
Diagnosis	Schizophrenia	85	84.2
	Depression	7	6.9
	Bi Polar disorder	7	6.9
	Anxiety	2	2.0
	Other	2	2.0
Current psychiatric medication	Olanzapine	37	36.6
	Clozapine	19	18.8
	Risperidone	24	23.8
	Seroquel	15	14.9
	Amisulpride	2	2.0
	Abilify	3	3.0
	Avanza	1	1.0
Medical problems	No	60	59.4
	Yes	41	40.6
Surgical problems	No	84	83.2
	Yes	17	16.8

Case manager	Mental health worker	63	62.4
	None	36	35.6
	Other	2	2.0

The control group had 50 participants randomly allocated and the intervention group had 51 participants randomly allocated. The baseline results outlined in Table 3 indicate only small differences between intervention and control participants at the commencement of the study, indicating that the randomisation process was successful.

Table 3: Comparison of the participants (n=101*) at baseline, stratified by intervention and control

Outcome measure	**Control(n=50)**	**Intervention(n=51)**	**p-value**
Mean weight (SD) [kg]	97.7 (20.7)	97.2 (17.4)	p=0.891
Mean girth (SD) [cm]	109.7 (14.1)	111.0 (11.8)	p=0.628
Mean BMI (SD) [kg/m^2]	34.0 (8.1)	33.3 (6.1)	p=0.601
Self-reported medication compliance: active participation n (%)	23 (50.0%)	23 (50.0%)	p=0.811
LUNSERS median of final score (IQR)***	25 (13, 57)	28 (17, 47)	p=0.952
DAI median score (IQR)	4 (0, 8)	4 (0, 6)	p=0.954
SF36 Mean physical score (SD)	55.6 (9.4)	57.4 (8.5)	p=0.303
SF36v2 Mean mental health score(SD)	43.4(5.8)	43.2(6.3)	p=0.958

*Not all participants answered all questions; **SD = standard deviation;***IQR = inter-quartile range

The control group (n=50) and intervention group (n=51) were compared using outcome measures at 12 weeks. Table 4 presents the comparison of the participants at 12 weeks stratified by intervention group (n=51) and control group (n=50). The control group had a mean weight of 97.5 kg (SD=20.7), while the intervention group had a mean weight of 96.4 kg (SD=17.2); the control group had a mean girth of 109.6 cm (SD=14.6), while the intervention group had a mean girth of 109.8 cm (SD=11.5); the control group had a mean BMI of 33.9 kg/m^2 (SD=8.1), while the intervention group had a mean BMI of 33.0 kg/m^2 (SD=6.0); the MCQ score for both groups was active participation (52.2% in the control group, 46.8% in the intervention group); DAI-10 score for both groups was positive; LUNSERS final score for both groups was low with the control group scoring a median of 15 (IQR 7.5, 26.5) and the intervention group scoring a median of 25(IQR 13, 37); and, the mean SF36-v2 physical health score for control was 57.5 (SD=8.8) and for the intervention was 57.9 (8.0), and the mean mental health score for the control group was 44.3 (SD=5.7) and 44.0 (SD=6.2) for the intervention.

Table 4: Comparison of the participants (n=101*) at 12 weeks, stratified by intervention and control.

Outcome measure	Control (n=50)	Intervention (n=51)	p-value
Mean weight (SD) [kg]	97.5 (20.7)	96.4 (17.2)	p=0.772
Mean girth (SD) [cm]	109.6 (14.6)	109.8 (11.5)	p=0.944
Mean BMI (SD) [kg/m^2]	33.9 (8.1)	33.0 (6.0)	p=0.507
Self-reported medication compliance: active participation n (%)	24 (52.2%)	22 (46.8%)	p=0.365
LUNSERS median final score (IQR)***	15 (7.5, 26.5)	25 (13, 37)	p=0.012
DAI median score (IQR)	6 (2.5, 8)	6 (2, 8)	p=0.534
SF36 Mean physical score (SD)	57.5 (8.8)	57.9 (8.0)	p=0.986
SF36v2 Mean mental health score (SD)	44.3(5.7)	44.0(6.2)	p=0.803

*Not all participants answered all questions; **SD = standard deviation;***IQR = inter-quartile range

Discussion

The results of the study were not statistically significant. However, small changes in the predicted direction did occur for the intervention group. Individual or group lifestyle approaches have been reported as achieving modest weight loss and are recommended at the commencement of treatment with second generation antipsychotic medications (Álvarez-Jiménez et al. 2008). Multi-modal approaches which include a combination of education, healthy lifestyle, behavioural, and exercise interventions are more likely to be effective in reducing weight in the longer term (Poulin et al. 2007). The intervention used in the study included a healthy lifestyle, exercise, and motivational interviewing approach. The failure to find a significant result can be attributed to a number of factors. The participants in the study had all been taking SGAs for some time. It is possible that their weight had reached a plateau which may have made weight loss less likely. Further, interventions that combined a variety of weight loss techniques, such as exercise, diet, and education, that were conducted over a longer period of time, 16 weeks (Weber & Wyne 2006), 18 weeks (Richardson et al. 2005), six months (Chen et al. 2009; 18 months (Poulin et al. 2007), were more likely to report a significant result. Perhaps the study reported here would have a significant result if the intervention was conducted over a longer period of time. It is also possible that change in the control group had an impact of the study outcome. Both the intervention and control group were provided with a specially designed educational booklet that provided the participant with healthy eating hints, menu planning tips, as well as weekly menu planners (Park et al. 2011). This information may have influenced the control group behaviour and resulted in weight loss in that group overall.

In addition to the weight loss results, the participants at baseline and 12 weeks scored higher than the norm for age in regard to physical health. This result indicates that the participants considered themselves to be 'physically healthy'. However, the physical measurements of the participants at baseline and 12 weeks indicate that the majority has a girth higher than the recommended healthy girth and a BMI above the normal recommended range. Therefore the participants of this study were already overweight; this is similar to findings from previous studies such as Smith et al., (2007) who reported a study of 966 people with serious mental illness and found overall the BMI of participants was higher with a mean of 46 kg/m^2.

Study limitations

The study was not blinded as both the researcher who delivered the intervention and the participant knew whether they were in the intervention or control group. Failure to blind the researcher and participants in intervention studies is common (Schneider et al., 2007), and in this study it was only possible to blind the research from the data collected by using a research assistant to collect measurements.

Location of the study groups was also a limitation of the study. Some of the interventions groups were conducted close to parks and areas where recreation activities were easy to find while others were in less than ideal locations. For example, one group was conducted at a rehabilitation setting and while there is a gym located on-site, it is not air-conditioned and was not always available for use by the participants.

The participants were recruited via advertisement at local non-government organizations and through the local health service. It is possible the sample may have been skewed towards a particular representation of people with serious mental illness as a result and perhaps other recruitment procedures would lead to different outcomes.

Conclusion

The study reported was developed due to the increasing body of evidence in the literature linking weight gain for people with serious mental illness to the prescription of second generation

antipsychotics. The results of the study demonstrated that healthy lifestyle changes will have a positive effect on weight. The observations of the researcher found a willingness of the participants to be engaged in healthy lifestyle changes. It is imperative that mental health nurses act on the mounting body of evidence and start to include healthy lifestyle education at the commencement of antipsychotic medications.

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Conflict of interest

No conflict of interest is declared.

Author contributions

KU, KF and TP were responsible for the study conception and design. KU, KF, TP and PB drafted and submitted funding applications. TP performed the data collection. TP and PB undertook the data analysis. KU and TP were responsible for drafting the manuscript and KF and PB made critical revisions to the paper.

What is already known about this topic:

- Weight gain has reached epidemic proportions in the general population but people with mental illness are at greater risk of weight gain, especially those taking second generation antipsychotic medications;
- People taking second generation antipsychotic medications gain weight at a predictable rate and lifestyle interventions designed to help manage weight gain are more effective than pharmacological interventions or standard care groups;

What this paper adds:

- A lifestyle, education and weight loss intervention undertaken in combination with motivational interviewing conducted over 12 weeks did not result in significant weight loss;
- A similar intervention should be undertaken over an extended period of time as the results indicated weight change in the predicted direction even though not significant.

Implications for practice and/or policy

- Mental health nurses must to take the lead in assessment and management of physical health concerns for people with serious mental illness.
- Individual components of the program could be implemented in different settings, such as the education component could be delivered as a group program in inpatient and community settings.
- Mental health nurses need to increase their knowledge of assessment and management of medication side effects, such as weight gain for people with serious mental illness.
- Future research should involve qualitative studies to gain a deeper understanding of the experience of medication induced weight gain.

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5.8 Researcher observations

The weight outcome measurement results of this study, while not statistically significant, did show some positive improvements for participants. While administering the intervention component of the study I was able to observe the participants and the following discussion, while not a formal component of the results of the study, provides some valuable observations on other, unmeasured benefits and outcomes for participants. These observations suggest there may be a number of aspects of participants' experience of healthy lifestyle programs that warrant further exploration.

Participants at the rehabilitation facility where there was free access to a gym did not use the gym before starting the program Passport 4 Life; at the end of the 12 week program the participants were using the gym 2-3 times per week as well as the scheduled group time with the Passport 4 Life group. Staff reported that participants were asking for access to the gym and were going there as a group. Another group that met weekly in the community enjoyed the group so much that at the last Passport 4 Life group they arranged to continue meeting each week to support each other in their healthy lifestyle choices. I have been told that this group continues to meet weekly. There were friendships that were developing from within the groups, and I know of four women who have continued their friendship with each other even though they no longer attend the community program. I initially found the engagement of participants with each other a little surprising due to the expectation that the impact of the negative symptoms of psychotic disorders might lead to minimal interpersonal engagement.

During the 12 week program I observed participants that were initially reluctant to join in activities come along to groups and actively join in the group, and sharing suggestions of healthy meals with other group members. I also observed participants to walk taller,

appearing to stand up straighter and look at me when they were talking. This was in contrast to when they started the group and they would sit around the table looking down at the table and only engaging with me when directly addressed. I interpreted this as their gaining a greater confidence and trust in me and their fellow group participants. This is similar to the findings from a study by Loh, Meyer and Leckband (2008) who concluded at the completion of their study that “patients diagnosed with schizophrenia disorder are willing to engage in treatment for weight loss and lifestyle improvement” (p. 131). Faulkner and Biddle (2002), in a study of staff attitudes to physical activity for patients, found that “physical activity was also seen as beneficial in terms of social interaction with other clients” (p. 662).

The benefits of the group interaction during the exercise component of the program, as observed in the present study, were the forming of friendships, and increased confidence in individual abilities to participate in activities, as well as the therapeutic relationship that developed between participants and the group leader. The building of therapeutic relationships is considered by many to be the foundation on which mental health nursing is established and as previously identified I believe that it was the trust that developed during this relationship that led participants to join in the group activities, and this cultivated confidence that led to the founding of further groups.

Often at the beginning of the program Passport 4 Life, participants would need to be reminded to bring their folders, walking shoes and water each week. However after a few weeks I watched as participants needed little or no reminding of what to bring each week. I was also surprised on many occasions to find the participants arriving early for the group, and start setting up the room or the activity. All of these actions I considered to show commitment, initiative and motivation to be involved in change and wanting to join in. Similar observations have been discussed in the literature with behaviour

changes being associated with knowledge acquisition and confidence building (Littrell, Hilligoss, Kirshner, Petty & Johnson, 2003; Weber & Wyne, 2006). These observations are in contrast to the negative symptoms of serious mental illness, such as amotivation, anhedonia and often a general inability to join in. The participants of the present study were observed to display similar behaviours to the participants from previous studies (Littrell, Hilligoss, Kirshner, Petty & Johnson, 2003; Weber & Wyne, 2006) such as commitment, initiative and wanting to join in.

5.9 Summary

The statistical results of this study, while not statistically significant, have shown a positive outcome for participants in the intervention group, with weight measurements indicating small weight losses of - 0.78 kg (SD= 3.78). The comparison of baseline characteristics for the control group (n=50) and intervention group (n=51) demonstrated that the randomisation process was successful. The questionnaire results showed that participants of this study were mostly compliant with their psychotropic medication (DAI-10) were able to 'tolerate' their antipsychotic medication and any side effects experienced (LUNSERS), and were active participants in their medication management as reported (MCQ). The SF-36v2 results showed the participants in the study self reported their physical health as higher than the population norm for age 35-44 and the mental health score was lower than the population norm for age 35-44. The subjective observations of the researcher revealed a willingness to be engaged and motivation by participants to be involved in healthy lifestyle changes.

The next chapter outlines the strengths and limitations of the study followed by an overview of the implications for practice, research, and education. Finally, researcher reflections related to the research process are presented.

CHAPTER 6: CONCLUSION

6.1 Introduction

This chapter presents the strengths, limitations, and implications of the study. As the study was a randomised control trial I did not formally collect qualitative data on the experience of weight gain for people with a serious mental illness prescribed and taking second generation antipsychotic medication. However, a reflective journal was kept and excerpts from the journal will be used within this chapter.

6.2 Strengths of the study

The strengths of this study include:

1. The success of the randomisation process. This process ensured that all variables were randomly allocated between the control and intervention group. The success of randomisation of variables means that the groups are comparable and that confounding has not influenced the findings (Altman, 1991).

2. All aspects of previously successful weight prevention programs were incorporated together for the first time, to the best of my knowledge. This intervention, Passport 4 Life, included education sessions, exercise sessions, nurse involvement, support to attend the groups, examples of healthy snacks and motivational interviewing. The program was delivered in the community and included the best available Australian guidelines for nutrition and exercise. The program was designed for people with serious mental illness and included specific tools that could be used to counteract the consequences of serious mental illness including memory impairment and concentration difficulties, for

example visual reminders were used throughout the written program to enhance memory recall and reinforce healthy choices.

3. The study was conducted across a variety of sites enabling a heterogeneous sample to be recruited. The differing sites enabled diversity in the sample that was recruited, for example some of the participants were living in rehabilitation facilities while others were living at home with families. The variety of community sites enabled the researcher to recruit a diverse participant sample using the inclusion criteria from the local area.

4. All intervention groups were conducted by the researcher who is an experienced mental health nurse. This continuity of program delivery was also supported by the use of an instructor's manual for Passport 4 Life. This continuity and consistency during the delivery of the program provides safety for the findings from internal validity threats (Schneider et al., 2007).

5. A research assistant was employed to collect all baseline and follow up data including weight measurements and assisting with questionnaire completions. The use of a research assistant enabled a consistent approach to data collection.

6.3 Limitations of the study

The limitations of this study include:

1. Challenges to blinding of interventions studies are identified in the literature and it is common for intervention studies to only achieve single blinding due to the inability to blind participants from the intervention they are involved in (Schneider

et al., 2007). For this study it was only possible to blind the researcher from the data that was collected through the use of a research assistant to collect data.

2. Due to time constraints the program was delivered weekly for only 12 weeks, with data collection occurring at the beginning and end of each rotation of each 12 week program. A different result may have occurred if the group could have met two – three times per week and/or if the program was delivered over 24 weeks or longer. The literature suggests that significant outcomes are more likely when these programs are conducted over longer periods of time.

3. Different group settings may also impact on the success of the program. For example access to exercise equipment was an issue for some participants who lived in rehabilitation facilities. Their access to the gym was limited by staff availability and willingness to 'open' and supervise gym time. The location of the gym also changed during the course of the program due to room availability and the gym was moved to a shed, with no air conditioning, that still contained gardening equipment. Another group setting located in the community was close to a local park and this was utilised successfully for exercise during each weekly session.

4. The cognitive impact of serious mental illness cannot be underestimated and the lack of motivation that is often persistent can lead to non involvement. Group activities have been shown to be beneficial for people with similar experiences, serious mental illness and can lead to increased involvement and encouragement to make positive health changes (Johnstone et al., 2009). This research project involved groups meeting once per week. While this was beneficial, improved results may have occurred if the group could have met two – three times per

week. In addition, the study was limited by the fact that the consumers were unwilling to be excluded from the intervention group when assigned to the control group. To overcome this issue, participants were invited to re-enrol in the study when the next recruitment session was conducted. However, some participants continued to turn up each week to the intervention group. Their data was collected and analysed using intention to treat analysis. Unfortunately, this may have impacted on the study results.

5. Working with people with serious mental illness can be challenging due to differing symptoms experienced, and the impact of the illness on the choices made by participants. For example in one of the groups that I conducted during this study there were many people with phobias and this impacted on the exercise/activity that we could do each week. One person in the study had agoraphobia and refused to exercise in public, while another person had issues with cleanliness and refused to exercise outside on pathways used by others. These issues, while impacting on the group's choice of exercise, also impacted on individual activity choices and their ability to make healthy food choices. For example there was one person in the group that experienced severe agoraphobia and was not able to shop for themselves; this person was reliant on a family member purchasing their food each week.

6. When working with people in the real world it is difficult to undertake research that fits entirely with a RCT process. This is why many adaptations of RCTs have now been designed (Sanson-Fisher et al., 2007). However, rather than avoid the use of the gold standard RCT in this study, consideration was given to those assigned to the control group. The control group participants were also provided

with the Passport 4 Life workbook. It is possible this action also limited the results of the study.

6.4 Implications for practice

Implications for *future research* include consideration of:

1. Conducting the program over a longer period, such as 24 weeks, and limiting the components of the program.

A similar study conducted over a longer period of time may find positive results. As this intervention was only conducted over 12 weeks, it is recommended a future study implement the intervention over a period of 24 weeks or more. It may also be feasible to limit the complexity of the program and aim for less outcomes overall.

2. Use of the Transtheoretical Model of Change

Research utilising Prochaska and Di Clemente's (1983) Transtheoretical Model of Change (TTM) and the six stage process – pre-contemplation, contemplation, preparation, action, maintenance and termination- would enable the researcher to design a program that was cognisant of the change stage relevant to each participant. Assessing the individual's stage of change before they enter the program could enable the researcher to use strategies targeted for the stage of change that the person was in.

3. Individual support for participants

Supplementary individual support for participants, such as shopping support or cooking classes, could also increase the participants' ability to choose healthy lifestyle behaviours.

4. Qualitative research

Qualitative research using a narrative analysis would offer deeper understanding of the experience of weight gain while taking antipsychotic medication. This deeper understanding could lead to the development of individual programs designs.

Implications for *practice* include consideration of:

1. Individual components of the program

Individual components of the program could be implemented in different settings. The education component of the program could be delivered as a group program in private practice settings where groups form an integral part of the inpatient treatment.

Implications for *education* include consideration of:

1. Knowledge development on group process and the spirit of motivational interviewing

Knowledge is required by the person delivering the program in the areas of group process, program content and motivational interviewing. The spirit of motivational interviewing is essential when assisting people to choose behavioural change.

2. Nurse education

Information about the topic of weight management and health related issues for people with serious mental illness should be included in all undergraduate and postgraduate nursing and allied health curricula. Further, continuing or professional development sessions on the potential physical health side effects of antipsychotic medication and the assessment and management of these issues, such us, metabolic syndrome need to be conducted for practising nurses in mental health facilities.

6.5 Reflections

This research project utilised a quantitative design and analysis, and the design was therefore influenced by the scientific paradigm. Reflective journaling was used throughout the project by the researcher, and this enabled the researcher to work through situations that occurred that had not been expected in the research design, for example the impact of the participants stories on the researcher and the research project. Reflective practice and reflexivity processes are commonly discussed in qualitative research where researchers are expected to become immersed in the world of the participant (Creswell, 2009; Usher, Foster & Stewart, 2010). For quantitative studies the opposite is expected and researchers are required to maintain objectivity. In this research project reflective practice and reflexivity enabled the researcher to continue to be objective during the data collection phase of the project but also remain connected with the participants, as this was an essential component of the intervention.

6.5.1 Article

The following article is currently under review and discusses the experience of reflexivity within a quantitative study.

Publication title
Park, T., Foster, K., & Usher, K. (under review). Unexpected Moments': reflexivity and participant/researcher relationships in a randomised controlled trial. *The Collegian.*

Abstract

Reflexivity, the process of researcher self- reflection, evaluation and self-awareness, is a common feature in qualitative research. The importance of acknowledging the role the researcher plays in the research project, and the impact of the self, is recognised as an essential element in the interpretive/constructivist paradigm. Quantitative research, however, requires the researcher to take an objective, detached stance, controlling for the researcher's impact on the research through the use of study protocols. This paper discusses reflexivity within the context of a randomised controlled trial where the novice researcher, a mental health nurse, experienced unexpected moments with study participants during data collection. These moments included relational encounters with research participants and novice nurse researcher. We conclude that the use of a reflexive approach can positively influence data collection and participant involvement in quantitative research and that greater attention to researcher-participant encounters in these studies is needed.

Keywords
Reflexivity, quantitative research, mental health nursing, serious mental illness, participant/researcher relationship

Introduction

Reflexivity is based on the notions of self-awareness and self-reflection. However, while reflection infers a process of review that occurs after the event (Usher and Holmes 2010), reflexivity is different. Reflexivity requires the researcher to engage in an overt level of awareness during the research process "…as a way of aiding the production of knowledge from experience by examining the impact on one's position and actions" (Lipp 2007 p. 19). A process of continual reflection and evaluation, reflexivity occurs when the researcher raises their awareness of how their research impacts on the world and vice versa (Lipp 2007) and where the researcher maintains an ongoing questioning self-awareness for the duration of the project (Usher, Foster and Stewart 2010). Ultimately it results in the researcher attaching meaning to the experiences encountered in the act of self-reflection, and acknowledging the impact on data collection and analysis. As Foster *et al* (2006) identify, "a reflexive orientation is to be self-conscious about how the researcher plays a part in constructing meaning in the research" (p. 46). In this way, reflexivity acknowledges the central role the researcher has in the research project and its progression (Liamputtong 2008).

This paper discusses how unexpected moments between researcher and participants in a quantitative study with people with serious mental illness revealed the importance of researcher reflexivity. The aim is to extend the understandings and application of reflexivity in research, and to add to the knowledge-base for supporting novice researchers in managing 'self' and 'other' in the field. To begin, we provide an overview of the study.

The Research Project

The study was a randomised control trial to test the effect of a nurse-led intervention on weight gain in people with serious mental illness (SMI) taking second generation antipsychotic medication. Experimental designs utilise randomisation, control and manipulations as essential components of the research process. Due to these elements, randomised control trials (RCT) are considered to have superior status amongst experimental design studies, and are often referred to

as the "gold standard" of research methods (Thompson 2004; Walker 2005; Schneider Whitehead & Elliot 2007). The reputation of RCTs enable the findings of a well developed and applied RCT to be considered high level evidence on which to base practice in healthcare (Walker 2005; Seers & Critelton 2001). RCTs are conducted within the scientific paradigm. In the post-positivist worldview, the researcher conducting a randomised controlled study is able to apply findings regarding the sample population to the whole population. Statistical results enable universal explanation of the sample population, and therefore generalisations, of observable phenomena. These concepts are supported by the use of manipulation, randomisation and control, enabling the phenomena to be developed and replicated. Generalisations are a fundamental tenet of this paradigm and allow explanations to be developed with validated statistical consistency (Schneider *et al* 2007). In the current study, participants were randomly allocated to the control or intervention group. The intervention was a 12 week healthy lifestyle program developed specifically for people with SMI taking second generation antipsychotic medication. The intervention aimed to ameliorate weight gain often experienced by people with SMI taking second generation antipsychotics (Park Usher & Foster, 2011).

The participants

The participants were people with a SMI taking second generation antipsychotics. All participants were recruited from the community. The participants in the intervention group were required to attend weekly sessions.

People with a serious mental illness are considered a vulnerable group in research due to the effects their illness can have on their thoughts, feelings and behaviour (NHMRC 2007). Vulnerability is discussed by Liamputtong (2007) as potentially leading to invisibility, marginalisation, fear, stigma and 'scepticism about being involved in research' (p. 4). Vulnerability is recognised as an ethical concern that the researcher needs to take into account when planning and conducting research (NHMRC 2007). Important considerations include individuals' autonomy, beneficence, justice, respect, research merit and integrity (NHRMC 2007). These often complex considerations warrant careful reflection by the researcher when the

researcher enters the participants' world. They remain vital issues throughout all aspects of the research activity.

Nurse-led Intervention

In the study, each week for twelve weeks the participants in the intervention group joined the researcher for a one hour session to discuss the healthy lifestyle topic of the week and their progress with choosing to implement healthy lifestyle components of the program into their everyday life. After the group discussion, a 30 minute exercise activity, led by the researcher, was also undertaken. The weekly intervention sessions were an integral component of the project. Groups met at the same time and place. Group sessions enable people with a common goal – for example wanting to learn about healthy lifestyles – to come together to learn and share their individual experiences (Luffman 2009). Groups also allow people to provide support for each other, such as acknowledging and encouraging achievements like healthy lifestyle choices. In this case the sharing and discussion within the group, assisted people with a common problem - weight gain caused by antipsychotic medications - to come together and to know, that they were not alone in their experience. In group theory this is referred to as *reducing isolation* and *universality* respectively (Luffman 2009).

The weekly group sessions were underpinned by the spirit of motivational interviewing (MI). MI enabled the researcher to develop partnerships with participants and the group, while incorporating the essential concepts of collaboration, evocation, and autonomy (Miller & Rollnick 2002).

Dual identities – mental health nurse and researcher

In the study, the researcher was also a mental health nurse. This professional identity provided her with the knowledge and experience to perform the group intervention. An essential component of mental health nursing is the development of therapeutic relationships. This relationship is fundamental to the role of the mental health nurses and considers all aspects of the person. The partnership developed within the therapeutic relationship facilitates the achievement

of individual health goals within a supportive and authentic relationship (Akerjordert & Severinsson 2004).

On the other hand, experimental research requires the researcher to take a position that is distant, and focuses on measurement using instruments or tools. The objective of experimental research is concise and narrow, and involves searching for truth in an objective and controlled manner (Schneider *et al* 2007). Thus, in this study the mental health nurse researcher was faced with a situation where, due to their professional nursing identity and function they were expected to work with participants and develop therapeutic relationships that enable the individual to improve their health status. At the same time, as the nurse researcher conducting a controlled trial they were expected to distance themselves for the sake of objectivity.

However, Chesney (2001) argues that "the nurse-nurse researcher role conundrum does not concern how close or distant the researcher is to participants, but rather how reflexive the researcher is in recognising the impact of the 'me' of the researcher" (p. 300). While this may be the case in qualitative research, in our experience it differs in quantitative research, where the researcher is expected to collect data using measurement tools that reduce answers to numbers analysed statistically to produce research findings (Creswell 2009). As a result the researcher needs to consider the options of developing relationships that are distant or developing relationships that involve authentic partnerships of sharing and self-disclosure (Colbourne & Sque 2004).

This dual role and tension of nurse and nurse researcher experienced by the novice researcher in the current study is highlighted in this brief journal extract; *I often found during the groups that I was asked by participants to draw on knowledge from areas of my nursing. I would be asked for advice such as …What do you think this rash is? What should I do about the flu? Should I get this mole checked? Should I tell my case manager about the voices? Why do I have to take antipsychotic medication?* Colbourne and Sque (2004) had a similar experience, stating "even after careful explanation of my role, participants regularly and directly requested specific information and expected caring, knowledgeable and honest responses" (p. 299). Johnson and

Clarke (2003) describe such an experience as "stepping out of the researcher role" and suggest that the pressures to do so often occur when the participant knows the researcher is a nurse. Further to this perception of external pressure to cross the conventional researcher/participant barrier, is the internal socialisation of nurses to provide care. However, we agree with Colbourne and Sue (2004) that, rather than attempting to remove the 'nurse' from the nurse- researcher, "if the nurse cannot be removed from the researcher *then* why pretend otherwise" (p. 303).

Unexpected moments – relational encounters

Very early on in the data collection phase of the project the first author began to experience unexpected moments. These were moments of being drawn into participants' stories and experiencing feelings of vulnerability that hadn't been anticipated or envisaged when I embarked on the study. In these moments I would be drawn into a participant's story, listening and reflecting on their experience of weight gain, and found I would have to stop and remind myself why I was there and what my role was – nurse-researcher. During the recounting of many a person's tale I found myself experiencing feelings of helplessness, vulnerability, sadness, and amazement and wondered quietly to myself more than once whether I could make a difference to these participants' lives.' I reminded myself I was doing a quantitative study, and thought*, 'it's all about the numbers and statistics; it's not meant to be about the stories. Isn't that what qualitative researchers do?* I reminded myself I was simply here to deliver an intervention, to run a group and to collect measurements.

But it was during the collection of the measurements and the running of the groups that the participant stories were shared and heard. These were poignant and often disturbing stories full of pathos - about loves lost, abandonments, family tensions, and feelings of being invisible to others. These stories impacted on me and I found that the sharing of the stories in the groups each week reminded me of the often painful reality of living with a chronic illness such as mental illness, the daily challenges faced by people with serious mental illness, the feelings of not 'fitting in', of stigma and not being accepted in society, and the experience of not being heard. These stories impacted on me emotionally and cognitively as I grappled to manage my empathic

responses to their accounts while also maintaining my professional role and performance as the group leader. Such an ongoing challenge led me to undertake regular reflexivity as a way of managing my emotional responses and enhancing my awareness of the impact of these on the project, and vice versa. The following constructed story of Billie provides an example of the complex and layered accounts shared by participants which I grappled with.

The story of Billie (gender neutral pseudonym)
Billie had been diagnosed with paranoid schizophrenia 25 years ago and would probably be classified in the mental health system as "treatment resistant". Billie was prescribed a combination of first and second generation antipsychotics and experienced daily denigrating auditory hallucinations. Billie lived in supported accommodation. When I first met Billie there were whispers from the staff, *"...Billie might join your group but probably won't turn up each week...."* I spoke to Billie and invited Billie to join the group. Billie replied with a tentative "Yes", and started completing the paperwork. During the next 12 weeks Billie turned up to the group each week and started contributing, offering suggestions about healthy living.
Each week, Billie refused to join in the exercise activity, until week 6 when Billie asked to speak to me alone, after the rest of the group had started the activity. Billie then told me his/her reluctance to join the exercise was because the 'voices' said constantly to 'go walk in front of a bus' and Billie wasn't sure if we would see any buses when we were doing the activity, so thought it best not to join in. Billie said to me *"I wouldn't want you to see me do that to myself"*. I explained to Billie that there were no buses where we exercised and Billie decided to join in the activity. After this interaction, each week Billie would join in the whole group – education and exercise session. During the course of the 12 week program Billie talked about lost love - "I had a partner once" - but then said "but who would stay with someone who looks like this (referring to weight gain) and talks to themself all day long?" The day Billie told me about the auditory hallucinations and their affect on Billie's ability to join in the activity was a pivotal moment for me. I reflected on the reason Billie had given and concluded that I couldn't imagine a more profound reason not to exercise and therefore subsequently to be 'left out' of group interaction.
Contemplating this, I started to question how Billie's story would be heard in my research. How could the statistics give voice to Billie's experience? Was it important that Billie's and others' stories were heard? While the RCT continued, I and my supervisors agreed that a separate qualitative study on the experience of weight gain with consumers and carers was needed.

Reflexivity and quantitative research

Reflexivity is considered an essential aspect of rigour in qualitative research, however there is remarkably little literature that discusses reflexivity and quantitative research. Finlay (1998) argues that the experience of the researcher within every research project should be considered as primary evidence. Yet as identified previously, this is not always the case in some types of research such as experimental studies. Incorporating reflexivity may not be considered appropriate when conducting an RCT given that objectivity is required and bias is considered a threat to validity of the findings. If the primary intent of quantitative research is to investigate casual relationships by analysing statistical data then how can reflexivity be included?

We contend that self-reflection during the reflexive process enables the researcher in both qualitative and quantitative studies to acknowledge and manage their personal impact on the developing relationship of researcher and research participant. Self-reflection can lead to maintaining the 'human connection' or 'authenticity' that nurses use when developing relationships with patients/participants. Without 'stepping out' of the researcher role to explore and listen to 'Billie' I would have continued to interpret 'Billie's' non involvement in the exercise activity as a personal choice and accepted 'Billie's' autonomy to so choose. However due to 'Billie's' self disclosure I was able to be reflexive in my approach and use my nursing skills of support, empathy and encouragement with 'Billie' to join in the activity. In doing so, I acknowledged the importance of 'stepping out' and examining subjective reactions and relationship dynamics *as they occur* (Finlay 1998). This is described by Dowling (2006) as 'being aware in the moment' of what is influencing the researcher, the research participant and the research project.

Throughout this project the novice researcher also kept a reflective journal from which much of the discussion of this paper has been drawn. Jasper (2005) supports the use of reflective writing in research, suggesting reflective writing enables the writer to rearrange their thoughts in different ways that can lead to refocusing and bringing to light different perspectives. The use of reflective processes for reflexive work is also supported by Finlay (2002) who describes reflection and reflexivity as occurring on a continuum. In this study the use of reflection enabled the novice researcher to be responsive within the data collection phase of the research project.

Discussion

The use of a reflexive approach in quantitative studies could influence data collection and participant involvement in a number of ways, particularly in sensitive research where the researcher has contact with vulnerable people. Johnson *et al* (2003) suggest that in terms of the researcher-participant relationship a reflexive approach, enabling the researcher to "step out" of the researcher role, may facilitate increased access to participants and data, but they caution the researcher to be alert for coercion and exploitation.

The use of a reflexive approach as described by Finlay (1998), which encompasses continual evaluation of subjective responses and research method, was essential for the healthy lifestyle intervention in this study to proceed due to the underpinning of the spirit of motivational interviewing in the intervention. The development of authentic partnerships between researcher and participant is a requirement of the spirit of MI (Miller & Rollnick 2002). If the typical objective researcher stance had prevailed during the data collection phase of the project (group intervention), participants may not have engaged for the full 12 weeks and the role tension between 'nurse' and 'nurse researcher' may not have arisen.

Carolan (2003) recognises the increasing credibility that a reflexive approach can bring to qualitative studies. We contend it is possible that a reflective approach could offer similar benefits for quantitative studies where researchers are delivering an intervention. We suggest that, contrary to views that reflexivity could contaminate the research process in quantitative research; these studies can be enriched by the reflexive process through disciplined self-awareness and self-management by the researcher. Paradoxically, rather than increase bias this process may assist in reducing subjectivity and enabling further objectivity on the part of the researcher. The researcher's objective stance can be maintained by the use of reflective practice to bring into focus what may be influencing the data collection of a project. In this project without acknowledging the impact of mental illness on participants' involvement in the project, the research findings may not have been an accurate reflection of causal relationships. In this case the use of reflexivity has led to an objective stance that has decreased the potential bias of the study by acknowledging the impact of mental illness.

Conclusion

Reflexivity is a well known concept in the field of qualitative research where it is considered an essential component of qualitative studies. Reflexivity is largely unreported in quantitative research even though there is considerable discussion in the literature of the potential benefits of the inclusion of reflexivity in research. The use of reflexivity in this project enabled the researcher to utilise the skills of mental health nursing and researcher to enhance the data

collected, and decrease potential bias. While this paper presents, a novice researcher's experience of reflexivity demonstrating the potential benefits to the researcher and researched when a reflective approach is adopted, the implications for further quantitative research include refocusing of the researchers objective stance and protecting against bias by the use of reflexivity during data collection.

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6.6 Conclusion of the study

The program Passport 4 Life was developed due to the increasing body of evidence in the literature linking weight gain for people with serious mental illness to the prescription of second generation antipsychotics. Passport 4 Life included a healthy lifestyle booklet that consisted of weekly nutrition and exercise education, exercise sessions, support through nurse involvement, and motivational interviewing were the additional components of the intervention program that the intervention group participated in.

This study used a quantitative design to test the effects of a nurse led healthy lifestyle program on weight outcomes for people with serious mental illness prescribed and taking second generation antipsychotic medication. The study was a randomised control trial (RCT) and after ethical approval, 104 participants were recruited to the study from the local area. The study participants were randomly allocated to the control or intervention group.

There were seven outcome measures used during the study including self reported questionnaires, and body measurements. Body measurements included girth (cm), weight (kg), height (cm), and BMI (kg/m^2). Tools administered included the medication compliance questionnaire (MCQ), the Drug Attitude Inventory (DAI-10), the Liverpool University Neuroleptic Side Effect Rating Scale (LUNSERS), and the Medical Outcomes Study Short Form 36 (SF-36v2). Outcome measurements were collected from all participants in both the control and intervention group at baseline and at completion of the 12 week program. Statistical analysis was conducted to analyse the data collected.

The results of the study, while not statistically significant, have shown a positive outcome for participants in the intervention group, with weight measurements indicating

small losses. There was a mean weight change of - 0.74 kg (SD=3.78 kg, p=0.167) at 12 weeks for the intervention group (n=51), while the control group (n=50) had a mean weight change of - 0.17 kg (SD=3.36, p=0.729) at 12 weeks.

Recommendations from the study include conducting the program over a longer period of time. It is recommended a future study should implement the intervention over a period of 24 weeks or more. Researcher observations found a willingness to be engaged in the program and participant motivation to be involved in healthy lifestyle changes. Qualitative exploration of the experience of weight gain for people with a serious mental illness prescribed and taking second generation antipsychotic medication could offer deeper insight into the experience of weight gain, while also identifying individual stages of change.

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Appendices

Appendix A: Human Ethics Approval James Cook University

ADMINISTRATIVE DOCUMENTATION HAS BEEN REMOVED

Appendix B: Human Ethics Approval Townsville Health Service District

ADMINISTRATIVE DOCUMENTATION HAS BEEN REMOVED

Appendix C: Participant Information Form

INFORMATION SHEET

Prevention of weight gain with second generation antipsychotics: a nurse-led intervention

You are invited to take part in a research project that is being led by an experienced mental health nurse and is aimed to help you to maintain or lose weight that you have put on since commencing on second generation antipsychotic drugs. The project has a number of components and some people will be involved in all and others in only some aspects of the project. Taking part in the project will mean coming to weekly sessions for some participants but all participants will be required to read and use educational materials about healthy eating and increased activity and make use of a pedometer which will be supplied free of charge. You will also need to be prepared to have your measurements taken regularly, for example weight and waist measurements, and answer some questionnaires at 12 weekly intervals. The questionnaires will take about 30 minutes to complete and the registered nurse will be available to assist you if required. The study is being conducted by Professor Kim Usher, Dr Kim Foster, Dr Petra Buttner and Tanya Park, researchers from James Cook University. A registered nurse will also be employed to do all of the study measurements and provide support to participants should they need it. The project will contribute to the degree of PhD at James Cook University for Tanya Park.

Taking part in this study is completely voluntary and you can stop taking part in the study at any time without explanation or prejudice. You may also withdraw any unprocessed data from the study.

There are no known risks associated with the study, but as some people find taking part in research difficult and some find answering questions a problem, a registered nurse will be available to assist you. The registered nurse will also be available at all weekly sessions and will be introduced to you when you start the project. She will provide you with details of how to contact her at that time.

Your responses and contact details will be strictly confidential. The data from the study will be used in research publications, reports to the Queensland Nursing Council and in a PhD thesis. You will not be identified in any way in these or any other publications.

Appendix D: Participant Consent Form

JAMES COOK UNIVERSITY

TOWNSVILLE Queensland 4811 Australia Telephone: (07) 4781 4111

INFORMED CONSENT FORM

INVESTIGATOR	Tanya Park
PROJECT TITLE:	Prevention of weight gain with second generation antipsychotics: a nurse-led intervention
SCHOOL	Nursing, Midwifery & Nutrition

I understand the aim of this research study is to take part in a project aimed at maintaining or reducing weight gained since starting second generation antipsychotic drugs. I consent to participate in this project, the details of which have been explained to me, and I have been provided with a written plain language statement to keep.

I understand that my participation will involve attending weekly education and activity groups and using aids such as a pedometer, to help me track my activity level, for the next 12 months OR reading education and activity information and incorporating these into my activities of daily living, and using aids such as a pedometer, to help me track my activity level, over the next 12 months. I know that I will also have regular weight and body measurements taken and be asked to answer questionnaires at 12 weekly intervals, and I agree that the researcher may use the results as described in the plain language statement.

I acknowledge that:

- any risks and possible effects of participating in the education and activity groups have been explained to my satisfaction;

- taking part in this study is voluntary and I am aware that I can stop taking part in it at any time without explanation or prejudice and to withdraw any unprocessed data I have provided;

- that any information I give will be kept strictly confidential and that no names will be used to identify me with this study without my approval;

(Please tick to indicate consent)

I consent to being provided with educational and activity resources and incorporating them into my lifestyle over the next 12 months		**Yes**		**No**
I consent to having regular weight and body measurements taken by a registered nurse		**Yes**		**No**
I consent to complete the questionnaires and diet and activity booklets at 12 weekly intervals		**Yes**		**No**
I consent to being provided with a pedometer and use it to track my activity		**Yes**		**No**
I consent to take part in the weekly group sessions		**Yes**		**No**

Name: *(printed)*	
Signature:	**Date:**

Appendix E: Data collection Tools

E 1: Demographic data information

Demographic details

Name:

DOB:

Gender: Male □
Female □

Marital status: □ Single □ Married □ Divorced
□Separated □ living with partner □ Widowed

Cultural background: (include mother & fathers ethnicity)
_____
_____

Language spoken
_____

Address:
_____
_____

Phone:
_____

The best way to contact me is:
□ Phone
_____
□ Email _____
□ Letter sent to
_____
Or_____

Education

□ Completed High School (Year 12) □ TAFE course
□ University graduate □ University post graduate
□ Current student

Or_____

Employment

□ Currently in paid work
□ Full time □ part time

□ Volunteer
□ Full time □ part time

□ Not currently working

Or_____

Doctor: (include if you would like your doctor contacted with details of the program)
_____
_____
_____

Case manager: (include if you would like your case manager contacted with details of the program)
_____
_____
_____

Diagnosis :(including date of first diagnosis)
_____
_____
_____

Medication: (including, name, dose, date when medication was started and ceased/changed)
E.g. Olanzapine 10 mg at night started beginning of Dec 2008

_____
_____
_____
_____
_____

Medical / surgical problems:

_____
_____
_____

Emergency contact person:

_____
_____
_____

Why did you decide to participate in the program?

_____
_____
_____

Do you have a problem with weight gain? □ Yes □ No
If yes for how long?

_____

Have you tried to lose weight before? □ Yes □ No
If yes how?

_____

Is there anything else you think we should know?

_____
_____
_____

<u>NB</u>

If any of your details change during the next 12 weeks, <u>particularly if you change your medication</u> could you please let us know ASAP.

12 week program started: _____

Measurements collected.

Date/Time	Height (cms)	Weight (kgs)	Girth (cms)
Start			
3 months			

Assessment forms completed.

Date/Time	SF-36	DAI-10	LUNSERS	Medication compliance
Start				
3 months				

Appendix E: Data collection Tools

E 2: Medication compliance questionnaire (MCQ)

Medication Compliance Questionnaire.

Please tick the answer that best describes how you feel about taking your medication.

☐ Complete refusal

☐ Partial refusal--for example, refusing depot drugs or accepting only the minimum dose

☐ Reluctant acceptance--accepting only because treatment is compulsory or questioning the need for treatment often (every two days)

☐ Occasional reluctance about treatment--questioning the need for treatment once a week

☐ Moderate participation--some knowledge of and interest in treatment and no prompting needed to take the drugs

☐ Active participation, ready acceptance, and taking some responsibility for treatment

Appendix E: Data collection Tools

E 3: Drug Attitude Inventory (DAI-10)

Drug Attitude Inventory (DAI-10©)

Please read each statement below and decide whether it is true or false for you. Circle. If the statement is mostly true than circle T for True and if the statement is not usually true than circle F for False.

The medications referred to in the statements are psychiatric medications.

1. For me, the good things about medication outweigh the bad.	T	F
2. I feel weird, like a “zombie”, on medication.	T	F
3. I take medications of my own free choice.	T	F
4. Medications make me feel more relaxed.	T	F
5. Medication makes me feel tired and sluggish.	T	F
6. I take medication only when I am sick.	T	F
7. I feel normal on medication.	T	F
8. It is unnatural for my mind and body to be controlled by medications.	T	F
9. My thoughts are clearer on medications.	T	F
10. By staying on medications, I can prevent getting sick.	T	F

Appendix E: Data collection Tools

E 4: Liverpool University Neuroleptic Side Effect Rating Scale (LUNSERS)

Liverpool University Neuroleptic Side Effect Rating Scale (LUNSERS)

Please tick how much you have experienced the following symptoms over the last month.

SYMPTOM	NOT AT ALL	VERY LITTLE	A LITTLE	QUITE A LOT	VERY MUCH
1. Rash					
2. Difficulty staying awake during the day					
3. Runny nose					
4. Increased dreaming					
5. Headaches					
6. Dry mouth					
7. Swollen or tender chest					
8. Chilblains					
9. Difficulty in concentrating					
10. Constipation					
11. Hair loss					
12. Urine darker than usual					
13. Period pains					
14. Tension					
15. Dizziness					
16. Feeling sick					
17 Increased sex drive					
18. Tiredness					
19. Muscle stiffness					
20. Palpitations					
21. Difficulty in remembering things					
22. Losing weight					
23. Lack of emotions					
24. Difficulty in achieving orgasm/climax					
25. Weak fingernails					
26. Depression					
27. Increased sweating					
28. Mouth ulcers					
29. Slowing of movements					
30. Greasy skin					
31. Sleeping too much					
32. Difficulty passing water					
33. Flushing of face					

SYMPTOM	NOT AT ALL	VERY LITTLE	A LITTLE	QUITE A LOT	VERY MUCH
34. Muscle spasms					
35. Sensitivity of sun					
36. Diarrhoea					
37. Over-wet or drooling mouth					
38. Blurred vision					
39. Putting on weight					
40. Restlessness					
41. Difficulty getting to sleep					
42. Neck muscles aching					
43. Shakiness					
44. Pins and needles					
45. Painful joints					
46. Reduced sex drive					
47. New or unusual skin marks					
48. Parts of body moving of their own accord e.g. foot moving up and down					
49. Itchy skin					
50. Periods less frequent					
51. Passing a lot of water					

Appendix E: Data collection Tools

E 5: Medical Outcomes Study Short Form 36 (SF-36v2)

Your Health and Well-Being

This questionnaire asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. ***Thank you for completing this survey!***

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. <u>Compared to one year ago</u>, how would you rate your health in general <u>now</u>?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

3 The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐ 1	☐ 2	☐ 3
b Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
c Lifting or carrying groceries	☐ 1	☐ 2	☐ 3
d Climbing several flights of stairs	☐ 1	☐ 2	☐ 3
e Climbing one flight of stairs	☐ 1	☐ 2	☐ 3
f Bending, kneeling, or stooping	☐ 1	☐ 2	☐ 3
g Walking more than a kilometre	☐ 1	☐ 2	☐ 3
h Walking several hundred metres	☐ 1	☐ 2	☐ 3
i Walking one hundred metres	☐ 1	☐ 2	☐ 3
j Bathing or dressing yourself	☐ 1	☐ 2	☐ 3

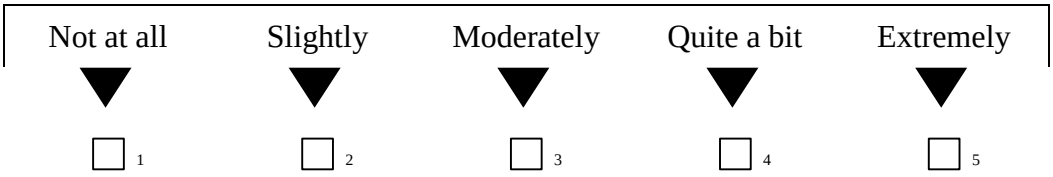
4. During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the <u>amount of time</u> you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Were limited in the <u>kind</u> of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Had <u>difficulty</u> performing the work or other activities (for example, it took extra effort)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

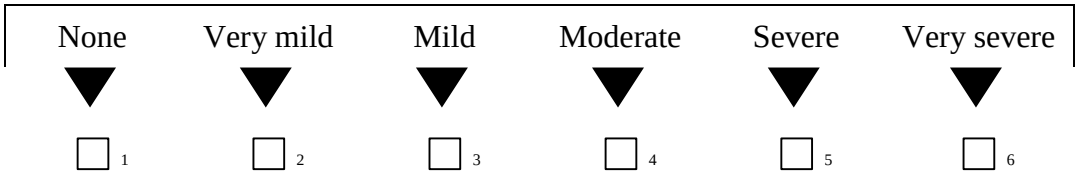
5. During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the <u>amount of time</u> you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Did work or other activities <u>less carefully than usual</u>	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

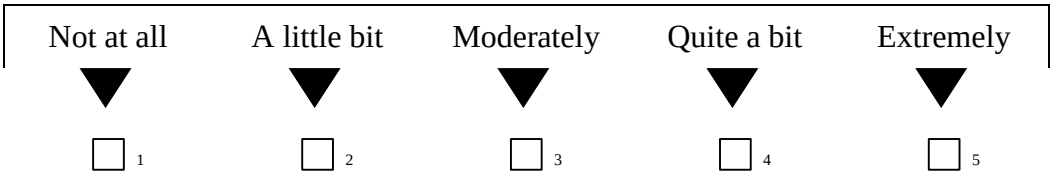
6. During the <u>past 4 weeks</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?



7. How much <u>bodily</u> pain have you had during the <u>past 4 weeks</u>?



8. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?



9. These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>…

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Did you feel full of life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Have you been very nervous?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Have you felt so down in the dumps that nothing could cheer you up?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f Have you felt downhearted and depressed?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
g Did you feel worn out?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
h Have you been happy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
i Did you feel tired?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11. How TRUE or FALSE is <u>each</u> of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a I seem to get sick a little easier than other people	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b I am as healthy as anybody I know	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c I expect my health to get worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d My health is excellent	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Thank you for completing these questions!

Appendix F: Study Protocols

F 1: Group allocation

Group Allocation Protocol

1. Ask participant to select a small envelope – inside is the participants ID number either **I** for intervention or **C** from control with a number next to the letter.

2. Cross off the ID number from the list at the front of the folder.

3. Add the ID number to the top of the questionnaires.

4. Add the participants name next to the ID number in the coding book.

5. Explain to the participant which group they have been allocated to – follow the protocol for either the control or intervention group.

6. The participant does not need to remember this number.

Appendix F: Study Protocols

F 2: Intervention group

Intervention Group Protocol

1. If the person has chosen an ID number that is I __ then need to explain as below

2. Explain to the participant - Your allocation for the study is for the group that is required to meet weekly.

3. Explain to the participant – You will be given information (show the folder, and pedometer) and asked to take this folder home and follow the weekly program for the next 12 weeks.

4. Spend 5 minutes briefly going through the 12 week program and the daily diary.

5. Explain to the participant that they are required to return each week for a group session that will involve light exercise.

6. Explain to the participant – you will need to come dressed to participate in light exercises like walking, give an example of what is appropriate to wear e.g. trainers or closed in easy to walk in shoes and loose clothing.

7. Explain to the participant - If you have any questions about the program in the next 12 weeks you will be able to ask questions at the group sessions, if you have questions before the groups please contact – Tanya Park – give them my card and show my work number – ask the person to leave a message and I will call back.

8. Ask the person if they require assistance with transport to the weekly sessions – if yes then provide with arrangements for travel.

9. Ask the participant to write the day and time for the weekly group sessions at the front of the folder.

Appendix F: Study Protocols

F 3: Control group

Control Group Protocol

1. If the person has chosen an ID number that is C _ then need to explain as below

2. Explain to the participant - Your allocation for the study is for the group that is given information (show the folder, and pedometer) and asked to take this folder home and follow the weekly program for the next 12 weeks.

3. Spend 5 minutes briefly going through the 12 week program and the daily diary.

4. Explain to the participant - If you have any questions about the program in the next 12 weeks please contact – give them my card and show my work number – ask the person to leave a message and I will call back.

5. Explain to the participant that they are required to return in 12 weeks for measurements and completing the questionnaires (same as they have today).

6. Organise a return date and time, for 12 weeks time.

Appendix F: Study Protocols

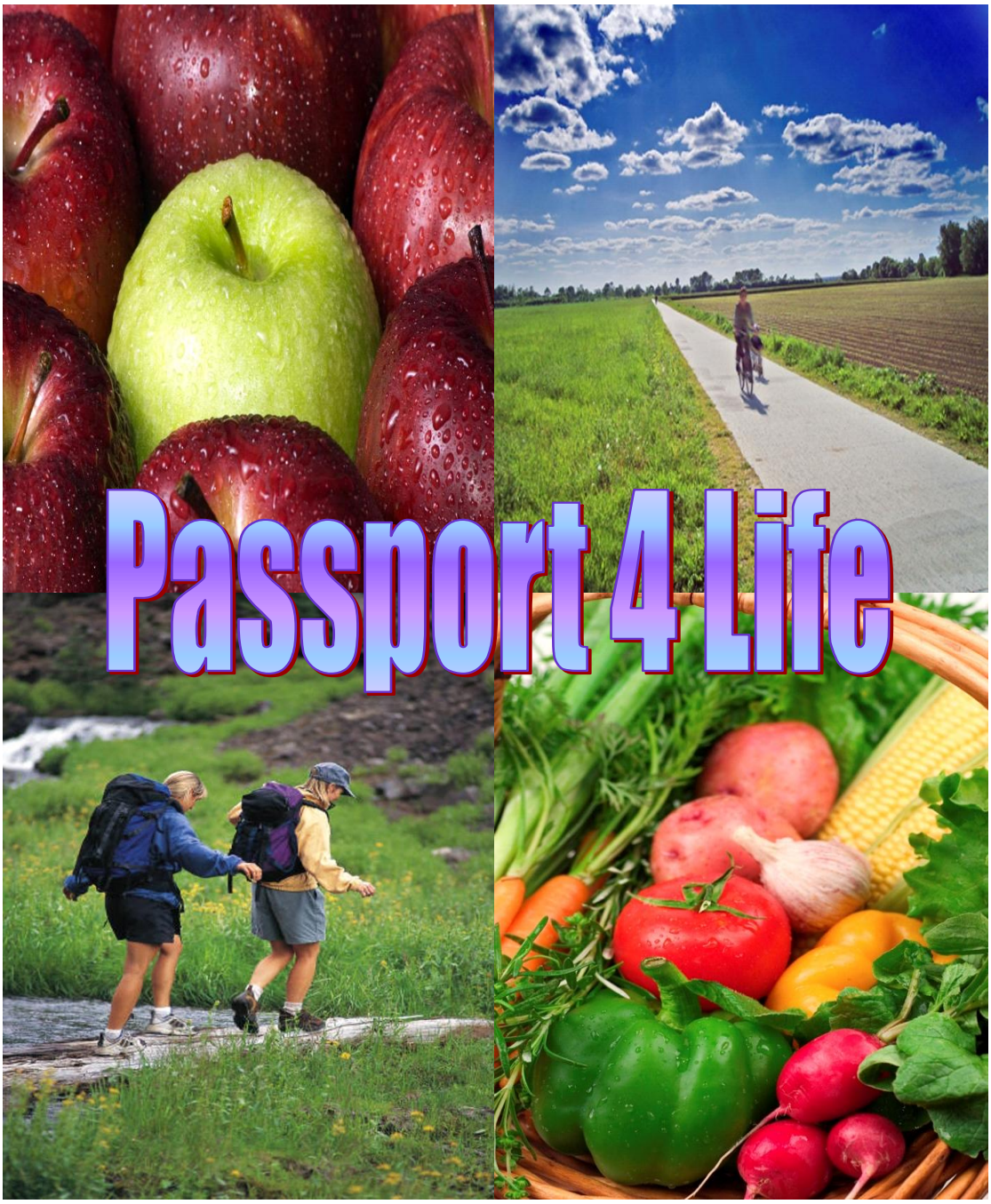
F 4: Consent and Data collection

RA = Research Assistant
RP = Research Participant

- RA introduces themself and invites the RP into the interview room
- RA reads through the consent form with the RP and asks for questions
- RP signs consent form
- RP then selects envelope which will identify which group the RP will join i.e. control group or intervention group
- RA then explains procedure for the assessment:

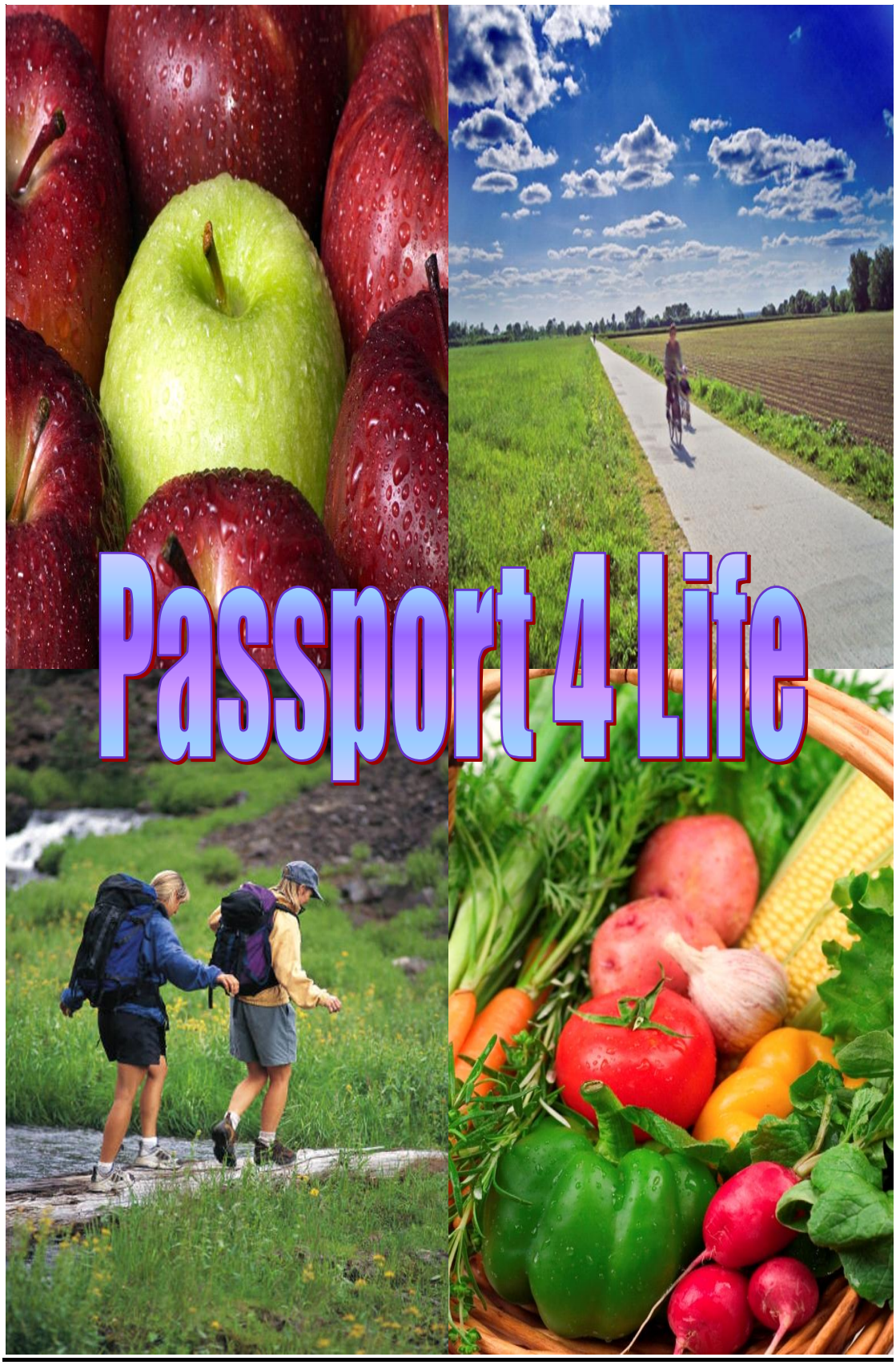
1. RP empty's bladder in preparation for weighing
2. RP removes shoes in preparation for weighing
3. RP stands on scales
4. RA then measures RP's girth
5. RA then invites RP to complete demographic details form
6. RA then invites RP to complete questionnaires
7. RP then receives folder
8. If RP is in intervention group they are directed to group room
9. If RP is in the control group they are asked to return in 12 weeks for further measurements and to complete the surveys
10. RA then provides contact details if questions arise before next week

Appendix G: Advertising poster for program



Great New Program
Are you taking one of the new antipsychotics?
Are you interested in being a part of a project to help you with diet and exercise in a friendly group atmosphere?
Please call: Tanya Park
47815319

Appendix H: Education Program “Passport 4 Life”



Passport 4 Life Includes:

- **12 Week Program**
- **My Daily Record**
- **Menu Planning**
- **My Personal Passport**

12 Week Program

12 Week Outline

1. Let's get started
    - Welcome
    - How to use the booklet
    - Outline of 12 weeks
    - How to use the pedometer
    - Recording your success
2. Healthy eating choices
    - 2+5 fruit & vegetables
    - Healthy plate
3. Healthy snacks
    - How to choose healthy snacks
    - What's healthy?
    - Making a healthy snack
    - Suggestions
4. Recording and rewarding your success
    - Healthy celebrations – movies, clothes
    - Recording success
    - Sharing your success
5. Exercise
    - When to
    - How to
    - Variety
6. Exercise choices
    - Making exercise fun
7. Healthy eating review
    - Reminders
    - Review what works
    - Review what doesn't work
8. Feelings, exercise & eating – Part 1
    - What is the relationship?
9. Feelings, exercise & eating – Part 2
    - Who's in control?
10. Evaluating your success
    - Comparing to others – positive & negative
11. How to keep motivated with the program
    - Setting achievable goals
    - Keep moving forward
12. Healthy celebrations
    - Review
    - Reward
    - Remind
    - Evaluation
    - Bon voyage!

Let's Get Started

Introduction

Welcome

Welcome to this exciting program! The overall aim of this program is to improve your lifestyle to become a healthier you. Over the next 12 weeks as you read through the books and practise the many tips you will start to make small changes to your life. These changes will help improve your physical health which, as you know, affects your mental health. I am really looking forward to working with you throughout the next 12 weeks and most of all I am looking forward to celebrating your successes during the program!

Outline of 12 week program

During the next 12 weeks we will look at a variety of topics including: healthy eating choices, healthy snacks, healthy celebrations, exercise & exercise choices, feelings, exercise & eating and motivation. As we move through each week you will find a variety of activities that you can do to learn more about making healthy choices and how those choices will lead to a healthier you.

How to use the booklets

There are 2 booklets in this package, the first is the "12 Week program booklet" and the second is "My daily record" booklet.

The 12 week program booklet is designed to provide you with the information and activities you need to get healthier in an easy to read week to week format with a different theme for each week.

The "My daily record" booklet is designed for you to record your daily activities, food intake and personal notes each day. This record will become more important to you as we move through the weeks as you reflect on where you started, and what is working for your healthy lifestyle choices.

The way to successfully use this program is to set some time aside each Sunday to spend in preparation for the week ahead. During this preparation time you might want to reflect on the previous week and make a note of how you felt it went, and then move on to the next week.

Spend some time reading what the theme of the week is; think about what you might already know about the weekly theme and what has already worked for you. Then you need to plan what you will do to be healthier in the coming week. Plan your exercise, plan your menus and don't forget to plan a reward for yourself for all the work you are doing towards a healthier you.

How to use the pedometer

As part of this program you have been provided with a pedometer. The pedometer is an easy to use tool to monitor the number of steps you take each day. Here's how to use it.

1. As soon as you wake up clip your pedometer onto the waist band of your trousers, shorts or skirt.
2. Make sure the number is zero.
3. Now all you need to do is move, your pedometer will record the number of steps you take each day.
4. At the end of the day, write down in your daily record, the number of steps the pedometer has recorded.
5. Remember to follow this plan every day.

Week 1
Planning for success!

Welcome to the first week of the program, during this week I would like you to spend some time planning for your success.

Use the "My daily record" booklet and record what you eat, when you exercise, how many steps you take each day (pedometer) and any notes you would like to write about your day.

In the notes section you might want to write down what you did for the day, for example; maybe you visited a friend or went to work or watched a movie.

Writing notes for yourself will help you to identify what activities might lead you to healthy or unhealthy behaviours. For example I often find when I go to the movies it is very hard to resist having popcorn and a big soft drink. Now that I am thinking about being healthier I might change the soft drink to water as this is a healthier choice and still leaves me with a treat – the yummy popcorn!

Now that you have thought about your plans for the week, have you thought about how you might add some exercise to those plans?

Research tells us that being active for 30 minutes a day will lead us to having a healthier heart, a decreased risk of diabetes and feeling a lot better about ourselves (National Physical Activity Guidelines for Adults, 2005)

In the coming weeks we will look at many ways to increase our activity/exercise and we will also look at how exercise can be fun.

For this first week I want you to try out your pedometer. Put it on when you get up in the morning and check it when you go to bed at night. Now write down how many steps you took today and reset the pedometer for tomorrow.

In this first week, try to increase your steps by 100 each day. This might mean walking to the corner shop to get the paper or walking around the block.

The eventual aim is to take 10,000 steps per day as this is the number of steps that National Heart Foundation Australia suggests for a healthy heart. If you are not yet taking 10,000 steps each day that is OK, remember this program is about improving your lifestyle. (10,000 Steps, Qld Health, 2006)

Recording your success

Each day take some time to record what you are eating, in your "My daily record" booklet.

Remember to be honest with yourself so that you will know for sure what works for you and what doesn't.

Healthy Eating Hint

To be healthy we need to eat each day:

2 serves of fruit

&

5 serves of vegetables

1 serve of fruit = 1 medium apple or 1 cup of chopped/canned fruit

1 serve of vegetables = ½ cup of cooked vegetables or 1 cup of salad

(www.gofor2and5.com.au)

It is also important to know that being healthier does not happen in 1 day, it will take a few weeks or even months. This program is 12 weeks long so that we can slowly build to success and not try to make it happen all in the first week.

Tip

Don't think you have failed if you forget to exercise or you eat something that is not the healthiest choice, this program is about slowly building to success. Start your next day with a healthier plan in place!

Goal for the week

Each week you will see this heading with a few blank lines underneath. Each week I would like you to choose your own goal in keeping with the theme of the week.

For example this week is about "Getting started and planning for Success".

Remember everyone's goal will be different - maybe you want to increase the amount of vegetables you eat or eat an apple each day.

One of the most important things to remember when setting your goal is to make sure it is achievable. There is no point in setting a goal like 'I want to run a marathon this week' if you've never tried running before. You will find over the coming weeks when you meet each goal you will start to feel better about yourself and when you reach each goal you will also know you are on the way to a healthier you.

Tips for Goal setting

- ✓ Achievable "I will eat one piece of fruit each day"
- ✓ Practical "I will eat an apple each day"
- ✓ Accessible "I will eat a piece of fruit that I can buy at the corner store each day instead of a can of coke"

Another important part of goal setting is rewarding yourself when you achieve your goal. This is very important as it reminds you that you have been successful.

Try to think of some healthy rewards that you can use over the coming weeks. Here are a few suggestions. We will add to this list as the weeks go by.

Suggestions for Rewards

Tell a friend about your success
Buy a favourite magazine or book
Go the movies
Listen to your favourite music
Do something that you don't usually have the time for!

Goal for Week 1

_____
_____
_____
_____
_____

Reward for Week 1

_____
_____
_____
_____

Week 1 Summary

- Plan ahead for your success
- Remember to write each day in your "My daily record"
- Remember to put your pedometer on each day and record your steps each night
- Set an achievable goal for the week
- Try to have 2 serves of fruit and 5 serves of vegetables each day

Week 2
Healthy Eating Choices

Welcome to the second week of the program. This week spend some time planning healthy eating choices for yourself.

What are healthy eating choices? There is a lot of advice available about what is healthy and what isn't. The information we will use for this program comes from the Australian government Dietary guidelines for Australian Adults. These guidelines were developed to help people choose foods that are healthy and fit in with their lifestyle. Let's look at the guidelines.

There are five food groups

- Bread, cereals, rice, pasta and noodles
- Vegetables and legumes
- Fruit
- Milk, yoghurt and cheese
- Meat, fish, poultry, eggs, nuts and legumes

Choosing from these food groups will provide you with a variety of healthy food choices each day. At the end of this week, we are going to plan a menu for the week using the Dietary guidelines for Australian Adults. To be able to do this you need to know what is in each food group and how much of each food group you need to eat each day.

The next decision to make is how much of each food group should we eat each day. The Australian Dietary Guidelines (1998) tell us the following number of serves per day for each food group.

FOOD GROUP	WOMEN 19–60 YEARS SERVES PER DAY	MEN 19-60 YEARS SERVES PER DAY
Bread, cereals, rice, pasta and noodles	4-9	6-12
Vegetables and legumes	5	5
Fruit	2	2
Milk, yoghurt and cheese	2	2
Meat, fish, poultry, eggs, nuts and legumes	1	1

What is a serve for each food group?

FOOD GROUP	1 SERVE =
Bread, cereals, rice, pasta and noodles	2 slices of bread or 1 cup of cooked rice or pasta or 1 cup of breakfast cereal
Vegetables and legumes	1 med potato or ½ cup of cabbage, broccoli, cauliflower or 1 cup of lettuce or salad vegetables or ½ cup of peas, beans, zucchini, tomatoes, cucumber, celery
Fruit	1 piece of medium fruit e.g. apple, orange, mango, banana or 8 strawberries or 4 dried apricots or 1 ½ tablespoons of sultanas or 1 cup of canned fruit
Milk, yoghurt and cheese	250 mls of milk or 40 g of cheese or 200 g of yoghurt
Meat, fish, poultry, eggs, nuts and legumes	65-100 g of cooked meat/chicken or 80-120 g of cooked fish or 2 small eggs

There is one food group that we haven't mentioned yet – the "Extras". These are the foods that we can **occasionally** include in our diet because they are higher in fat and sugar than most foods.

Extras include:

1 medium piece of cake, 1 bun, 3-4 sweet biscuits, 30 g potato crisps, 2 scoops of ice-cream, half a chocolate bar, 1 slice of pizza, 1 can of soft drink, 1 tablespoon of butter.

FOOD GROUP	**WOMEN 19–60 YEARS**	**MEN 19-60 YEARS**
Extras	0-2 1/2	0-3

Menu Planning for healthy eating

Now that we know what a serve is and how much of each food group to eat, we can start making a menu plan for the week.

Let's start by looking at breakfast choices.

- Cereal, milk and a piece of fruit
- Toast with eggs, tomato or baked beans
- Cereal, milk and a tub of yoghurt
- Toast with cheese and a piece of fruit

Now let's look at lunch choices.
Here are some suggestions from Nutrition Australia (2002) for healthy lunch choices:

- Mini Pizza – split an English muffin, spread with tomato paste, top with chopped capsicum, mushroom, pineapple, ham and grated cheese - and grill
- Pita bread with hummus, grated cheese, carrot, lettuce, apple, pineapple and a banana muffin.

- Wholemeal bread sandwich with beef, lettuce, mustard, cheese, cherry tomatoes and a yoghurt tub.
- Wholegrain bread roll with a tin of tuna, sliced tomato, cucumber, lettuce and an apple.
- Wholegrain bread roll with lean ham, sliced tomato, mayonnaise and an orange.

Now let's look at your evening meal.

- 100 g of fish with salad, a piece of fruit and yoghurt
- 100 g of chicken stir fried with vegetables, a piece of fruit and yoghurt
- 100 g steak or lamb with vegetables, a piece of fruit and yoghurt
- 100 g of grilled fish with a baked potato and salad

Now that you have started to think about your healthy eating choices for the week let's make a menu plan to get you started using the Dietary Guidelines for Australian Adults.

REMEMBER THE HEALTHY EATING HINT TO BE HEALTHY WE NEED TO EAT EACH DAY FROM THE FIVE FOOD GROUPS:
▪ BREAD, CEREALS, RICE, PASTA AND NOODLES ▪ VEGETABLES AND LEGUMES ▪ FRUIT ▪ MILK, YOGHURT AND CHEESE ▪ MEAT, FISH, POULTRY, EGGS, NUTS AND LEGUMES

Here's a sample menu plan for 1 day.

	MONDAY	SERVES
BREAKFAST	1 cup of Cereal , 250 mls of milk and a piece of fruit	1 cereal 1 milk 1 fruit
LUNCH	Wholegrain bread roll with lean ham, sliced tomato, lettuce, grated carrot, mayonnaise.	2 cereal 2 veg 1 extra
EVENING MEAL	100 g grilled fish with a baked potato and 3 cups of salad	1 meat 1 cereal 3 veg
SNACKS	Carrot sticks, yoghurt, apple, Vegemite sandwich	1 fruit 1 milk 1 veg 1 cereal
	TOTAL SERVES for DAY	Milk = 2 Cereal=5 Fruit= 2 Veg=5 Meat=1 Extra=1

In your "My daily record" booklet you will find an area to record your planned menu for the week. Take some time now to think about and plan your menu for the week. Remember to include foods that you enjoy and foods that are in season. There is no point in planning to eat a banana each day and finding out they are the most expensive fruit at the shop or it isn't banana season. Remember to allow some flexibility when you first start to plan your menus, as what is available and what you can afford when you go shopping, will affect what you eat.

Tips for Menu Planning

Affordability e.g. healthy food does not have to mean expensive, if something is not on your menu plan but is on special, change your menu plan for the week.

Accessible e.g. if you catch the bus to the shops, then it might not be easy to buy in bulk, you might have to shop 2 times a week.

Seasonal e.g. choose fruit and vegetables when they are in season they are usually cheaper e.g. bananas

Bulk buying e.g. buy food when it is on special and freeze in portions.

Tasty e.g. add some fresh herbs to your shopping- parsley & lemon go well with grilled fish!

Now that you've planned your menu for the week it is a good time to write a shopping list and think about when you are going to go shopping. A good idea is to go shopping straight after you have eaten so that you won't be tempted to buy something unhealthy.

Recording your success

Each day take some time to record what you are eating. In your "My daily record" booklet you can use your menu plan to tick off what you have eaten each day.

Remember to be honest with yourself so that you will know for sure what works for you and what doesn't.

Remember you will not become healthier overnight; it will take a few weeks or even months. That's why this program is 12 weeks long so that we can slowly build to success and not try to make it happen all in the first few weeks.

Tip

Don’t think you have failed if you don’t follow your menu plan or eat an “extra” one day; this program is about slowly building to success. Start your next day with a healthier plan in place!

Goal for the week

Remember each week we will be setting a goal for the week. Take some time now to look back at your goal from last week, and ask yourself the following questions:

- How did you achieve your goal?
- How challenging was it for you?
- Is there anything about the goal that now you have finished the week you would change?

Another important part of goal setting is rewarding yourself when you achieve your goal. Remember this is very important as it reminds you that you have been successful.

- What was your reward last week?
- Did you enjoy that reward?
- What will your reward be for this week?

Each week, choose your own goal in keeping with the theme of the week. This week is about making healthy food choices.

One of the most important things to remember when setting your goal is to make sure it is achievable. You will find over the coming weeks when you meet each goal you will start to feel better about yourself and when you reach each goal you will also know that you are on the way to a healthier you.

Try to think of some healthy rewards that you can use over the coming weeks. Here are a few suggestions to start with. We will add to this list as the weeks go by.

Suggestions for Rewards

Go for a walk on the beach and eat a small ice cream
Buy a favourite CD
Go the movies
And…….

Goal for Week 2

_____
_____
_____
_____
_____
_____

Reward for Week 2

_____
_____
_____
_____
_____

Week 2 Summary

- Plan your menu for success with healthy eating
- Remember to write each day in your "My daily record"
- Remember to put your pedometer on each day and record your steps each night
- Set an achievable goal for the week and don't forget to reward yourself!

Week 3
Healthy snacks

Welcome to the third week of the program. This week spend some time planning healthy snacks. We will look at what a healthy snack is and come up with a list of healthy snacks that you can choose from when you are feeling hungry between meals.

Firstly, let's remind ourselves of what a serve for each food group is and how much of each food group to have each day to maintain a healthy diet according to the recommended guidelines.

FOOD GROUP	**WOMEN 19 – 60 YEARS SERVES PER DAY**	**MEN 19-60 YEARS SERVES PER DAY**
Bread, cereals, rice, pasta and noodles	4-9	6-12
Vegetables and legumes	5	5
Fruit	2	2
Milk, yoghurt and cheese	2	2
Meat, fish, poultry, eggs, nuts and legumes	1	1

What is a serve?

One serve of **fruit** is 150 grams of fruit which is 1 medium apple or 1 cup of chopped or canned fruit.
One serve of **vegetable** is 75 grams of vegetables which is ½ cup of cooked vegetables or 1 medium potato or 1 cup of salad.
One serve of **bread/cereals** is 2 slices of bread or 1 cup of cooked rice or pasta.
One serve of **milk** is 250 mls of milk or 200 grams of yoghurt.
One serve of **meat** is 65-100 grams of cooked meat or chicken or 80-120 grams of cooked fish.

When planning your menu for the day it is important to plan for 2-3 snacks per day. This way you will already have some ideas to choose from when you are feeling hungry.

Take some time now to look back at last week's menu plans. Did you write down the snacks that you had throughout the week in your "My daily record"? If so, you should have a few snacks to choose from to add to the following list.

SNACKS	SERVES
1 cup of carrot sticks	1 vegetable
200 gram tub of yoghurt	1 milk
1 cup of celery sticks	1 vegetable
1 medium apple	1 fruit
8 strawberries	1 fruit
1 piece of toast with vegemite	1 bread
Banana smoothie	1 milk & 1 fruit

Now that you have some ideas for healthy snacks, take some time to think of a few healthy snacks that you can incorporate into your menu plan for the week ahead.

Remember

- **choose foods that you like**
- **use a variety of foods so you don't get bored**

Snack ideas for the week ahead……..

SNACKS……	SERVES…….

Recording your success
Each day take some time to record what you are eating in your "My daily record" booklet. You can use your menu plan to tick off what you have eaten each day.

Remember to be honest with yourself so that you will know for sure what works for you and what doesn't.

Remember you will not become healthier overnight; it will take a few weeks or even months. That's why this program is 12 weeks long so that we can slowly build to success and not try to make it happen all in the first few weeks.

Tip
Don't think you have failed if you don't follow your menu plan or eat an "extra" one day; this program is about slowly building to success. Start your next day with a healthier plan in place!

Goal for the week

Remember each week we will be setting a goal for the week. I want you to take some time now to look back at your goal from last week, and ask yourself the following questions:

- How did you achieve your goal?
- How challenging was it for you?
- Is there anything about the goal that now you have finished the week you would change?

What if you didn't achieve your goal from last week?

Sometimes you won't achieve your goals and it is important to remind yourself that this is OK. Sometimes we set goals that are too high. Maybe your goal was to follow your menu plan and not have any take away food, but then you found you didn't feel like cooking one night and had take away: - that is ok. It is important to remember that the journey to a healthier you will take more than one week. It is also important to remember that your life is not the same every day and from time to time you won't want to cook.

One of the most important things to remember when setting your goal is to make sure it is achievable. You will find over the coming weeks when you meet each goal you will start to feel better about yourself and when you reach each goal you will also know that you are on the way to a healthier you.

This week is about making healthy snack choices; maybe you want to set a goal to include healthy snacks in your menu planning for each day.

Tips for Goal setting

Achievable
Practical
Accessible

Remember it is important to reward yourself when you achieve your goal for the week. What was your reward for last week? Have you added any healthy rewards to the list that you can use over the coming weeks? You could ask a friend for some suggestions and add them to your list here.

Suggestions for Rewards

_____

_____

_____

Goal for Week 3

_____

_____

_____

_____

_____

_____

Reward for Week 3

_____

_____

_____

_____

_____

Week 3 Summary

- Plan your healthy snacks for the week
- Remember to write each day in your "My daily record"
- Remember to put your pedometer on each day and record your steps each night
- Set an achievable goal for the week and don't forget to reward yourself!

Week 4
Recording and rewarding your success

Welcome to the fourth week of the program. This week we will look at recording and rewarding your success. It will be important to spend some time this week looking back through your daily record and asking yourself the following questions and writing your answers in the spaces provided.

- When was my healthiest day so far?
  - _____
    _____
- Why did you choose that day as your healthiest?
  - _____
    _____
- Did recording what you ate and the exercise you did help you to choose your healthiest day?
  - _____
    _____

What are the benefits of recording your diet and exercise choices?

There are a range of benefits that you have already hopefully experienced by recording your diet and exercise choices. One of the most important benefits is that you can look back and see the healthy changes you have made in your life. You can also look back and see what worked for you and what didn't work. Spend some time now looking back through your daily record and choose the change that you have enjoyed making the most.

Maybe you have noticed that by increasing your exercise and activity you now have more energy, or maybe you have noticed that by eating more fruit and vegetables you are feeling healthier. In the space below write down the favourite change that you have made in the last 3 weeks of the program.

My favourite change has been……

_____
_____
_____
_____

Recording your success

Remember you will not become healthier overnight. It will take a few weeks or even months. That's why this program is 12 weeks long so that we can slowly build to success and not try to make it happen all in the first few weeks.

Recording what you eat and the exercise you do each day is important:- it will help when you are having a bad day or feel that you have made no improvement, as you can look back and see all the changes you have made in your daily record.

HEALTHY EATING HINT

TO BE HEALTHY WE NEED TO EAT EACH DAY:
2 SERVES OF FRUIT
&
5 SERVES OF VEGETABLES

1 SERVE OF FRUIT = 1 MEDIUM APPLE OR 1 CUP OF CHOPPED/CANNED FRUIT

1 SERVE OF VEGETABLES = ½ CUP OF COOKED VEGETABLES OR 1 CUP OF SALAD

(WWW.GOFOR2AND5.COM.AU)

Tip

Remember to be honest with yourself when you are writing in your daily diary so that you will know for sure what works for you and what doesn't.

Goal for the week

Remember each week we have been setting goals. This week we have talked about the importance of recording your success. Your goal could be to remember to record your eating and exercise each day. While you may have been doing, this it is important at this time to remind yourself to continue to record your success.

Another important part of goal setting is rewarding yourself when you achieve your goal. Remember this is very important as it reminds you that you have been successful.

- What was your reward last week?
- Did you enjoy that reward?
- What will your reward be for this week?

One of the most important things to remember when setting your goal is to make sure it is achievable. Ask yourself after you have written your goal "how am I going to do this?" Here's an example.

Goal - To write in my daily diary each day
How - I will keep a pen in my folder and at the end of each meal I will write what I ate. After my shower at the end of the day I will record my activity for the day and write how I felt about the day.

By incorporating writing in the daily diary into your normal daily activities you will find that you will no longer need to remind yourself to do this, it will become part of your life – a healthier life for you!

Tips for Goal setting

Ask yourself after you have written your goal "how am I going to do this?"

Goal for Week 4

_____
_____
_____
_____
_____

Reward for Week 4

_____
_____
_____
_____

Week 4 Summary

- Planning for success means remembering to:-
- Write each day in your "My daily record"
- Put your pedometer on each day
- Record the number of steps you have taken each day
- Choose a healthy reward for each week
- Write a reward for yourself each week
- Plan your menu each week

Week 5
Exercise!

Welcome to week five of the program. The focus for this week is exercise and getting active. Throughout the last four weeks we have been creating a healthier you by making healthy food choices. For the next few weeks it is important to continue making healthy food choices but the focus will change to getting active.

Spend this week focusing on your activities:-

- What do you do each day?
- How can you increase your activity level to the recommended 30 minutes each day?

You already have two things that will help you to know the answers to these questions. One is the "My daily record" booklet and the other is your pedometer. Take some time to read back through your "My daily record", have you noticed a change in your activity level since starting the program? Are you remembering to write how many steps you take each day? Maybe you already have some ideas on how to increase your activity levels.

"Everyone should try to do at least 30 minutes of moderate intensity physical activity on most days of the week"
(Australian Government Physical Activity Guidelines + yr)

In the coming weeks we will look at many ways to increase our activity/exercise and we will also look at how exercise can be fun.

Pedometer

Remember during the first week you received a pedometer with the program. Have you been using your pedometer? Have you

been recording the number of steps you take each day? Have you been increasing your steps each day?

The National Heart Foundation of Australia tells us that it is good for our heart to take 10,000 steps per day (10,000 Steps, Qld Health, 2006).

Recording your success
Each day take some time to record what activities you have been doing, in your "My daily record" booklet.

Remember to be honest with yourself so that you will know for sure what works for you and what doesn't.

Hints for increasing your daily activities

Use reminders – place a note on the fridge to remind you to go for a walk.
Place your walking shoes near the door.
Plan your activity.
Make an activity planner and place in a prominent place to remind you to be active.
Involve a friend in your activities.
(National Physical Activity Guidelines for Adults, 2005)

Remember that being healthier does not happen in 1 day, it will take a few weeks or even months, that's why this program is 12 weeks long so that we can slowly build to success and not try to make it happen in the first few weeks.

Tip

Slowly increase your exercise each day by increasing the steps you take by 100 each day, and try some of the hints in the box above.

Goal for the week

The focus for this week is on getting active, therefore your goal for the week should include a plan to be active during the week, here are some suggestions from the National Physical Activity Guidelines for Adults(2005) :-

"I will walk every day for 10 minutes after meals"
"I will walk to the shop each day to get the paper or milk"
"I will go dancing this week"
"I will go swimming this week"

Before writing your goals for the week remember to make your goal achievable, practical and accessible.

Tips for Goal setting

"Think of movement as an opportunity, not an inconvenience" (National Physical Activity Guidelines for Australians, 1999)

Another important part of goal-setting is rewarding yourself when you achieve your goal. This is very important as it reminds you that you have been successful.

Goal for Week 5

_____
_____
_____
_____

Reward for Week 5

_____
_____
_____
_____

Week 5 Summary

- Plan ahead for your success
- Remember to write each day in your “My daily record”
- Remember to put your pedometer on each day and record your steps each night
- Set an achievable goal for the week
- Try to increase your daily activity to 30 minutes each day.

Week 6
Exercise choices

Welcome to the sixth week of the program. This week spend some time looking at how you can incorporate exercise into your daily life and how to make exercise fun!

First, let's revise Week 5 by asking the following questions:

- Did you increase your activity level for the week?
- Which activities did you enjoy?
- Which activities didn't you enjoy?
- Are there any activities that you would like to do each day?

Remember - when answering the questions be honest with yourself so that you will know for sure what works for you and what doesn't.

The National Physical Activity Guidelines for Adults 2005 have the following suggestions.

1. Think of movement as an opportunity, not an inconvenience.
2. Be active every day in as many ways as you can
3. Put together at least 30 minutes of moderate intensity physical activity on most, preferably all, days.

Why is it important to increase your activity levels?

- Exercise makes you look and feel better
- Exercise gives you more energy
- Exercise can help you to sleep better
- Exercise can help you to feel relaxed
- Exercise tones your body
- Exercise helps you to control your weight
- Exercise helps reduce your risk of heart disease, diabetes, and some cancers

Making exercise fun!

Making exercise fun will increase the amount of time you will want to spend exercising, rather than exercise being something you have to do; exercise can be something that you look forward to each day.

Here some ideas for different types of exercise that you might find are fun.

- Dancing
- Bowls
- Yoga
- Tai chi
- Aerobics
- Golf
- Washing the car
- Water aerobics
- Walking the dog
- Tennis

Tips for Goal setting

- You can accumulate your 30 minutes of exercise throughout the day by combining a few shorter sessions of activity like 3 x 10 minute walks
- "Think of movement as an opportunity, not an inconvenience" (National Physical Activity Guidelines for Australians, 1999)

An important part of goal setting is rewarding yourself when you achieve your goal. Giving yourself a reward reminds you that you have been successful.

Take some time to review the rewards you have used in the past few weeks, have you thought of any new rewards?

Suggestions for Rewards

Listen to your favourite music
Go dancing
Join a yoga class
Try water aerobics

Goal for Week 6

_____
_____
_____
_____

Reward for Week 6

_____
_____
_____
_____

Week 6 Summary

- Try to be active for 30 minutes each day
- Remember to write each day in your "My daily record"
- Remember to put your pedometer on each day and record your steps each night
- Set an achievable goal for the week
- Try a new activity this week

Week 7
Healthy eating review

Welcome to Week 7 of the program. This week we are going to review healthy eating choices. I would like you to take some time to look back at the food choices you have been making.

Use your daily record to look at what you have been eating. Are there any patterns to your eating that you notice? Maybe you have takeaway on the weekends or eat ice cream every time you visit family, or is there a food choice that you have been making that you are not recording in your daily diary?

Let's spend some time revising what we know about healthy food choices.

In Week 2 of the program we looked at the five food groups and the number of serves we needed to eat each day to maintain a healthy diet.

FOOD GROUP	**WOMEN 19–60 YEARS**	**MEN 19-60 YEARS**
Bread, cereals, rice, pasta and noodles	4-9	6-12
Vegetables and legumes	5	5
Fruit	2	2
Milk, yoghurt and cheese	2	2
Meat, fish, poultry, eggs, nuts and legumes	1	1

The Australian dietary guidelines for adults also tell us how much of each food group a serve is.

FOOD GROUP	1 SERVE =
Bread, cereals, rice, pasta and noodles	2 slices of bread or 1 cup of cooked rice or pasta or 1 cup of breakfast cereal
Vegetables and legumes	1 med potato or ½ cup of cabbage, broccoli, cauliflower or 1 cup of lettuce or salad vegetables or ½ cup of peas, beans, zucchini, tomatoes, cucumber, celery
Fruit	1 piece of medium fruit e.g. apple, orange, mango, banana or 8 strawberries or 4 dried apricots or 1 ½ tablespoons of sultanas or 1 cup of canned fruit
Milk, yoghurt and cheese	250 mls of milk or 40 g of cheese or 200 g of yoghurt
Meat, fish, poultry, eggs, nuts and legumes	65-100 g of cooked meat/chicken or 80-120 g of cooked fish or 2 small eggs

There is also the "Extra's". These are the foods that we can occasionally include in our diet because they are higher in fat and sugar than most foods.

Extra's or occasional food choices include:

1 med piece of cake, 1 bun, 3-4 sweet biscuits, 30 g potato crisps, 2 scoops of ice-cream, half a chocolate bar, 1 slice of pizza, 1 can of soft drink, 1 table spoon of butter.

FOOD GROUP	WOMEN 19–60 YEARS	MEN 19-60 YEARS
Extra's	0-2 ½	0-3

Now that we have reminded ourselves of what healthy food choices are, write in the table below your favourite healthy choice menu for a day.

MEAL	**DAY**	**SERVES**
BREAKFAST		
LUNCH		
EVENING MEAL		
SNACKS		
	TOTAL SERVES for DAY	

Now you have written you favourite healthy choice menu, spend some time thinking about the not- so-healthy choices that you make. Write a list of the not so healthy choices you make below.

Not so healthy choices.

_____
_____
_____
_____
_____
_____
_____
_____
_____

Now that you have written this list I want you to spend some time thinking about when it is that you are making the not so healthy food choice. Is it when you are feeling sad? Or maybe bored? Or maybe you felt like rewarding yourself? Or did you feel too tired to make a salad for lunch?

Now write a list of things you were feeling or doing when you made the not so healthy food choices.

What I was doing or feeling when I made the not so healthy food choice.

_____
_____
_____
_____
_____
_____
_____
_____
_____

The next list to write is the foods that you can replace the not-so-healthy food choices list with, e.g. when I am feeling like a chocolate or lollies I will have a sweet juicy orange instead.

Once you have finished this list you will need to make sure you add these foods to your weekly shopping list so that they are available when you want to make a healthy choice.

Healthy choice foods to replace the not-so-healthy food choices

_____
_____
_____
_____
_____
_____
_____
_____
_____

Remember

……you will not become healthier overnight, it will take a few weeks or even months, that's why this program is 12 weeks long so that we can slowly build to success and not try to make it happen all in the first few weeks.

Goal for the week

This week is about reminding you about healthy food choices, an example goal is:

Goal - I will follow my menu plan each day and choose healthy snacks

How – I will keep a copy of my menu plan on the fridge and when I do the shopping I will make sure to buy some healthy snacks for when I want a treat.

Healthy eating hint

To be healthy we need to eat each day:

2 serves of fruit

&

5 serves of vegetables

1 serve of fruit = 1 medium apple or 1 cup of chopped/canned fruit

1 serve of vegetables = ½ cup of cooked vegetables or 1 cup of salad

(www.gofor2and5.com.au)

Goal for Week 7

_____

_____

_____

_____

_____

_____

Reward for Week 7

_____

_____

_____

_____

_____

Week 7 Summary

- Plan your menu for success with healthy eating
- Add healthy snack choices to your shopping list
- Remember to choose food from the five food groups each day
- Remember to write each day in your "My daily record"
- Remember to put your pedometer on each day and record your steps each night
- Set an achievable goal for the week and don't forget to reward yourself!

Week 8
Feelings, Exercise & Eating – Part 1

Welcome to Week 8 of the program. During this week I would like you to spend some time thinking about how the way you are feeling impacts on the exercise that you do and the healthy eating choices that you make. Feelings, either positive or negative, are known to have a strong effect on our eating. For example some people might not feel like eating when they are feeling sad, and for others eating when they are feeling sad might make them feel happy for a short time.

First, I would like you to spend some time finishing the following sentences.

When I feel happy I…

_____
_____
_____
_____
_____

When I feel sad I …

_____
_____
_____
_____
_____

When I feel angry I…

_____
_____
_____

_____
_____

Now let's look at what your sentences say. Do you see a pattern? Do you always have a chocolate when you are feeling sad? Or maybe you reward yourself by not exercising when you are feeling happy.

Remember

……becoming a healthier you will not happen overnight and recognising your patterns of behaviour is just the first step in the journey to making healthy food choice, that's why this program is 12 weeks long so that we can slowly build to success.

Let's take some time now to choose some healthy choices for when you are feeling sad, happy and angry.

Examples

…When I feel angry I will walk down the street for 10 minutes until I feel calm again.

…When I feel happy I will go to the pool for a swim.

…When I feel sad I will sit outside in the sunshine for 15 minutes and think about the goals I have achieved in the last few weeks.

When I feel angry I will…

_____
_____
_____

_____
_____

When I feel sad I will…

_____
_____
_____
_____
_____

When I feel happy I will…

_____
_____
_____
_____
_____

Now that you have a list of healthy choices for when you are feeling happy, sad and angry, you might like to put this list on your wall to remind you of your choices.

Recording your feelings

In your daily diary there is a section for writing down what you do each day. Use this section now to note how you are feeling.

In the notes section you might also want to write down what you did for the day, perhaps you visited a friend or went to work or watched a movie. Next week we will be discussing what you have recorded.

Goal for the week

This week is about reminding you about recognising the link between how you feel and what you do. An example goal is:

Goal - I will write how I feel in my daily diary each day.

How – I will keep my daily diary next to my bed and write in it each night before I go to sleep.

Remember recognising your pattern of behaviour is just the first step in the journey to making healthy food choice. It is important to remember that some of the choices we make when we are feeling happy, sad or angry we have been making for a very long time and changing the unhealthy behaviours will not happen overnight and, that's why this program is 12 weeks long so that we can slowly build to success.

Goal for Week 8

_____
_____
_____
_____
_____
_____

Reward for Week 8

_____
_____
_____
_____
_____

Week 8 Summary

- Plan your menu for success with healthy eating
- Add healthy choices to your shopping list
- Remember to choose food from the five food groups each day
- Remember to write how you are feeling each day in your "My daily record"
- Remember to put your pedometer on each day and record your steps each night
- Set an achievable goal for the week and don't forget to reward yourself!

Week 9
Feelings, Exercise & Eating – Part 2

Welcome to Week 9 of the program. During this week I would like you to spend some time thinking about how healthy living can balance your feelings. Last week we looked at how different emotions can sometimes lead to unhealthy activities. Spend some time reviewing how last week was for you, using your "My Daily Record" to discover the feelings you experienced during the past week. We will also see if we can change the way you think by making healthy choices.

First, summarise how you feel about Week 8 of the program.

When I think about last week I feel…

_____
_____
_____
_____
_____

Did you see a pattern in your recording in your daily diary? Where you able to change that pattern to include healthy choices?

To help us maintain a balance between feelings, eating and exercise the National Health and Medical Research Council (1998) has developed twelve guidelines that can help to maintain vitality, energy and health.

Guidelines for Vitality, Energy and Health.
(Adapted from the National Health and Medical Research Council, 1998)

After each of the guidelines is a space, take some time now to write in how you do this or how you could incorporate these guidelines into your healthy life style.

- Enjoy a wide variety of nutritious foods
  -
- Keep active each day
  -
- Eat at least three meals every day
  -
- Care for your food
  -
- Eat plenty of vegetables and fruit
  -
- Eat plenty of cereals, breads and pasta
  -
- Include foods that are high in calcium
  -
- Choose activities that develop strength, & flexibility
  -
- Drink adequate amounts of water each day
  -
- Choose healthy rewards
  -
- Choose food low in salt and saturated fat
  -
- Limit alcohol intake

Now that you have done that you can choose one of the suggestions as your goal for the week, here's an example.

Goal - I will keep active each day.
How – I will call a friend and make plans to meet for a walk each afternoon this week. I will use the stairs when I go to a building where there is lift. I will walk to the shop on the weekend and buy the paper.

Remember to keep your goals

- Achievable
- Practical
- Accessible
    - By asking yourself "how can I do this?"

Goal for Week 9

_____
_____
_____
_____
_____
_____

Reward for Week 9

_____
_____
_____
_____
_____

Week 9 Summary

- Plan for healthy choices that lead to vitality, energy and health in your life
- Remember to write each day in your "My daily record" how you are feeling.
- Remember to put your pedometer on each day and record your steps each night
- Set an achievable goal for the week and don't forget to reward yourself

Week 10
Evaluating your success

Welcome to Week Ten of the program. During this week we are going to spend some time evaluating how you are going.
First, let's look at different ways to evaluate your success.

There are many ways that you can evaluate your success, you could compare yourself to others who are following the same or a similar program….but, STOP!

Comparing yourself to others does not work. There are many reasons why, including we are all different and our bodies work differently. Your metabolic rate might be faster than your friends and that means you burn the fuel you give your body faster, which can lead to faster weight loss. Or, you might do more exercise than your friend but eat a higher fat diet, which can lead to slower weight loss.

The best ways to evaluate your success include looking at the following:

- What do the scales say?
- How do your clothes feel?
- When you are exercising do you find yourself less breathless?
- Do you have more energy?
- Do you eat more fruit?
- Do you eat more vegetables?
- Do you make healthy reward choices?
- Do you know more about healthy living?

Take some time to answer all of the questions in the spaces below. Remember to be honest with yourself and remember that healthy living doesn't happen overnight it can take a while to incorporate all that you have learnt.

What do the scales say?

_____
_____
_____

How do your clothes feel?

_____
_____
_____

When you are exercising do you find yourself less breathless?

_____
_____
_____

Do you have more energy?

_____
_____
_____

Do you eat more fruit?

_____
_____
_____

Do you eat more vegetables?

_____
_____
_____

Do you make healthy reward choices?

_____
_____
_____

Do you know more about healthy living?

_____
_____
_____

From your answers to the questions above list the five things you are doing really well and the five things you would like to improve.

Things I am doing really well

1.

2.

3.

4.

5.

Things I need to improve on

1.

2.

3.

4.

5.

Recording your success

Don't forget to take some time to record what you are eating, what activity you are doing and how you are feeling in your "My daily record" booklet. This record will be very helpful for you to use when you are evaluating your successes, and evaluating how you are going.

Tip for Recording your Success

Be honest with yourself so that you will know for sure what works for you and what doesn't.

Goal for the week

Since this week is all about evaluation, I want you to spend some time evaluating your goals. Take some time now to look

back at your goals from the last week few weeks, and ask yourself the following questions:

- How did you achieve your goal?
- How challenging was it for your?
- Is there anything about the goal/s that now you have finished the week you would change?

Another important part of goal setting is rewarding yourself when you achieve your goal, remember this is very important as it reminders you that you have been successful.

- What rewards have you're used in the last few week?
- Did you enjoy that reward/s?
- What will your reward be for this week?

This week is about evaluating your success. Perhaps your goal could be to improve on something from the list you have made earlier, maybe you want to increase the amount of vegetables you eat or to eat a piece of fruit each day or to increase your activity to 30 minutes per day.

Rewards

Try to think of some healthy rewards that you have used in the past few weeks. Which one was your favourite reward? Perhaps you want to use that reward again or maybe you have thought of something else you would like to use as a reward.

My favourite Rewards

1.
2.
3.
4.

Goal for Week 10

_____
_____
_____
_____
_____
_____

Reward for Week 10

_____
_____
_____
_____
_____

Week 10 Summary

- DON'T compare your success to others
- Plan your menu for success with healthy eating
- Remember to write each day in your "My daily record"
- Remember to put your pedometer on each day and record your steps each night
- Set an achievable goal for the week and don't forget to reward yourself!

Week 11
How to keep motivated with the program

Welcome to Week 11 of the program. During this week I would like you to spend some time planning for your continued success with healthy living choices.

What works for you?
Following is a list of skills you have learnt over the past ten weeks. I want you to spend some time reviewing this list and looking at what has worked for you.

Ask yourself - Did I do this activity? If so did it help? If you didn't, then ask yourself why not.

Menu planning

_____
_____
_____

Writing in your daily diary

_____
_____
_____

Setting a goal each week

_____
_____
_____
_____

Using the pedometer

_____
_____
_____

Shopping list

_____

_____

_____

Reminders of healthy rewards

_____

_____

_____

Planning healthy snacks

_____

_____

_____

Planning your day to include exercise

_____

_____

_____

Five food groups and recommended serving sizes

_____

_____

_____

Using your daily record

_____

_____

_____

Now that you have reviewed each of the skills you have learnt in the past ten weeks, let's spend some time thinking back to when you first started the program. Answer the following questions:

Why did I start the program?

_____

_____

_____

Why do I want to continue the program?

_____

_____

_____

When you are answering these questions remember to be honest with yourself so that you will know for sure why you are making healthy lifestyle choices.

Remember, being healthier does not happen in 1 day, it will take a few weeks or even months of making healthy choices.

Healthy Hints

Plan your menu for the week
Plan for healthy snacks
Plan exercise/activities that you enjoy each day
Remember the 2 and 5 rule; to be healthy we need to eat each day:
2 serves of fruit
&
5 serves of vegetables
1 serve of fruit = 1 medium apple or 1 cup of chopped/canned fruit
1 serve of vegetables = ½ cup of cooked vegetables or 1 cup of salad
(www.gofor2and5.com.au)

Tip

Don't think you have failed if you forget to exercise or you eat something that is not the healthiest choice, this program is about slowly building to success. Start your next day with a healthier plan in place!

Goal for the week

Each week of the program you have been choosing a goal in keeping with the focus of the week. As this week is about motivation I want you to choose one of the skills we have learnt in the past weeks and focus on improving that skill.

Remember to ask yourself the following questions when setting a goal –

- How will I achieve this goal?
- How challenging will this goal be for me?

Asking yourself these questions when you are setting your goal will help you to make your goal practical and achievable.

Goal for Week 11

_____
_____
_____
_____
_____
_____

Reward for Week 11

_____
_____
_____
_____
_____

Week 11 Summary

- Using the skills you have learnt to stay motivated
- Plan your menu for success with healthy eating
- Remember to write each day in your "My daily record"
- Remember to put your pedometer on each day and record your steps each night
- Set an achievable goal for the week and don't forget to reward yourself!

Week 12
Healthy Celebrations!!

Welcome to the Week 12 of the program – Congratulations! You have made it through the twelve week healthy living program – Well done!

If you have followed the tips and suggestions from the past twelve weeks, today you are healthier than when you first started.

Let's spend some time reviewing what you have learnt. First, we'll review the healthy eating guidelines.

What are healthy eating choices?

There is a lot of advice available about what is healthy and what isn't. The information we will used for this program comes from the Dietary Guidelines for Australian Adults (1998). These guidelines where developed to help people choose foods that are healthy and fit in with your lifestyle. Let's look at the guidelines.

There are five food groups

- Bread, cereals, rice, pasta and noodles
- Vegetables and legumes
- Fruit
- Milk, yoghurt and cheese
- Meat, fish, poultry, eggs, nuts and legumes

Choosing from these food groups will provide you with a variety of healthy food choices each day. During the past weeks you have learnt how to plan a healthy menu and hopefully you have a few different menus that you can alternate each week

An important part of menu planning is choosing the right amount of healthy food.

To be able to do this you need to know what is in each food group and how much of each food group you need to eat each day.

FOOD GROUP	WOMEN 19 – 60 YEARS	MEN 19-60 YEARS
Bread, cereals, rice, pasta and noodles	4-9	6-12
Vegetables and legumes	5	5
Fruit	2	2
Milk, yoghurt and cheese	2	2
Meat, fish, poultry, eggs, nuts and legumes	1	1

What is a serve for each food group?

FOOD GROUP	1 SERVE =
Bread, cereals, rice, pasta and noodles	2 slices of bread or 1 cup of cooked rice or pasta or 1 cup of breakfast cereal
Vegetables and legumes	1 med potato or ½ cup of cabbage, broccoli, cauliflower or 1 cup of lettuce or salad vegetables or ½ cup of peas, beans, zucchini, tomatoes, cucumber, celery
Fruit	1 piece of medium fruit e.g. apple, orange, mango, banana or 8 strawberries or 4 dried apricots or 1 ½ tablespoons of sultanas or 1 cup of canned fruit
Milk, yoghurt and cheese	250 mls of milk or 40 g of cheese or 200 g of yoghurt
Meat, fish, poultry, eggs, nuts and legumes	65-100 g of cooked meat/chicken or 80-120 g of cooked fish or 2 small eggs

Then there are the “Extras”. These are the foods that we can occasionally include in our diet because they are higher in fat and sugar than most foods.

Extras include:

1 medium piece of cake, 1 bun, 3-4 sweet biscuits, 30 g potato crisps, 2 scoops of ice-cream, half a chocolate bar, 1 slice of pizza, 1 can of soft drink, 1 table spoon of butter.

FOOD GROUP	**WOMEN 19–60 YEARS**	**MEN 19-60 YEARS**
Extra’s	0-2 ½	0-3

Now that we have reviewed healthy food choices I want you to write in the table your favourite healthy choice menu for a day.

MEAL	DAY	SERVES
BREAKFAST		
LUNCH		
EVENING MEAL		
SNACKS		
	TOTAL SERVES for DAY	

Now that we have revised healthy eating choices let's look at exercise.

"Everyone should try to do at least 30 minutes of moderate intensity physical activity on most days of the week"
(National Physical Activity Guidelines for Adults, 2005)

Hints for increasing your daily activities

Use reminders – place a note on the fridge to remind you to go for a walk.
Place your walking shoes near the door.
Plan your activity.
Make an activity planner and place in a prominent place to remind you to be active.
Involve a friend in your activities.
(Australian Government Physical Activity Guidelines)

Getting active

Suggestions for increasing your exercise from the National Physical Activity Guidelines for Adults 2005: –

"I will walk every day for 10 minutes after meals"
"I will walk to the shop each day to get the paper or milk"
"I will go dancing this week"
"I will go swimming this week"

Tips for increasing your exercise

"Think of movement as an opportunity, not an inconvenience"
(National Physical Activity Guidelines for Adults, 2005)

During the past 12 weeks you have set yourself goals and rewards each week. Now I would like you to take some time to choose your favourite rewards from the past 12 weeks and write them in the box below.

My Favourite Rewards

1.
2.
3.
4.
5.

Now I would like you to think of a reward to give yourself for completing the program.

My Reward for completing the 12 week program….

Congratulations on completing the 12 week program!

Remember that being healthy is a life long journey. This program is designed to help you develop healthy living strategies and it is important to continue to make healthy living choices now that the program is over.

To continue making healthy choices I would like you now to think of a goal for week 12 that will help to keep you motivated with your healthy living choices.

Goal for Week 12

_____
_____
_____
_____

Reward for Week 12

_____
_____
_____
_____

Week 12 Summary

- Reward your successful completion of the 12 Week program
- Plan ahead for your continued success
- Remember to write each day in your "My daily record"
- Remember to put your pedometer on each day and record your steps each night
- Set an achievable goal for the week
- Try to maintain your daily activity at 30 minutes of exercise each day.

Congratulations and Best Wishes!

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Your Passport to a Healthy You

My Daily Record

*** Please note for the purpose of the thesis this section contains a one week example. All participants were given 12 weeks.

Monday

Breakfast

Lunch

Dinner

Snacks

Fruit □□

Vegetables □□□□□

Daily Activity Record

Activity

Pedometer steps

Today I felt.....

Tuesday

Breakfast

Lunch

Dinner

Snacks

Fruit □□

Vegetables □□□□□

Daily Activity Record

Activity

Pedometer steps

Today I felt.....

Wednesday

Breakfast

Lunch

Dinner

Snacks

Fruit □□

Vegetables □□□□□

Daily Activity Record

Activity

Pedometer steps

Today I felt.....

Thursday

Breakfast

Lunch

Dinner

Snacks

Fruit □□

Vegetables □□□□□

Daily Activity Record

Activity

Pedometer steps

Today I felt.....

Friday

Breakfast

Lunch

Dinner

Snacks

Fruit □□

Vegetables □□□□□

Daily Activity Record

Activity

Pedometer steps

Today I felt.....

Saturday

Breakfast

Lunch

Dinner

Snacks

Fruit □□

Vegetables □□□□□

Daily Activity Record

Activity

Pedometer steps

Today I felt.....

Sunday

Breakfast

Lunch

Dinner

Snacks

Fruit □□

Vegetables □□□□□

Daily Activity Record

Activity

Pedometer steps

Today I felt.....

Your Passport to a Healthy You

Menu Planning

*** Please note for the purpose of the thesis this section contains a one week example. All participants were given 12 weeks.

Menu Plan for _____

MEAL	FOOD	SERVES
BREAKFAST		
LUNCH		
EVENING MEAL		
SNACKS		
	TOTAL SERVES for DAY	

Menu Plan for _____

MEAL	FOOD	SERVES
BREAKFAST		
LUNCH		
EVENING MEAL		
SNACKS		
	TOTAL SERVES for DAY	

Menu Plan for _____

MEAL	FOOD	SERVES
BREAKFAST		
LUNCH		
EVENING MEAL		
SNACKS		
	TOTAL SERVES for DAY	

Menu Plan for _____

MEAL	FOOD	SERVES
BREAKFAST		
LUNCH		
EVENING MEAL		
SNACKS		
	TOTAL SERVES for DAY	

Menu Plan for _____

MEAL	FOOD	SERVES
BREAKFAST		
LUNCH		
EVENING MEAL		
SNACKS		
	TOTAL SERVES for DAY	

Menu Plan for _____

MEAL	FOOD	SERVES
BREAKFAST		
LUNCH		
EVENING MEAL		
SNACKS		
	TOTAL SERVES for DAY	

Menu Plan for _____

MEAL	FOOD	SERVES
BREAKFAST		
LUNCH		
EVENING MEAL		
SNACKS		
	TOTAL SERVES for DAY	

Your Passport to a Healthy You

My Personal Record

Name:_____

Address:_____

_____

_____

Phone:_____

Doctor:_____

_____

_____

Casemanager:_____

_____

_____

Medication:_____

_____

_____

Height:_____

Weight:_____

Medicalproblems:_____

_____

_____

Emergency contact person:_____

_____

12 week program started:_____

Program contact person:_____

Notes