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Effectiveness and cost-effectiveness of a health promotion intervention targeting physical activity and healthy eating in individuals with mental disorders

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“Anyone who has never made a mistake has never tried anything new”

(Albert Einstein)

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ABBREVIATIONS

BMI	Body Mass Index
BSI	Brief Symptom Inventory
CGI	Clinical Global Impressions
CGI-I	Clinical Global Impressions – Improvement
CGI-S	Clinical Global Impressions – Severity
CHD	Coronary heart disease
CVD	Cardiovascular disease
DSM	Diagnostic and Statistical Manual of Mental Disorders
EnRG	Environmental Research Framework for weight Gain prevention
GP	General practitioner
HDL	High-density lipoprotein
ICER	Incremental Cost-Effectiveness Ratio
IDF	International Diabetes Federation
ICC	Intraclass correlation coefficient
i.e.	id est
IPAQ	International Physical Activity Questionnaire
ITT	Intention to treat
MPD	Minimum Psychiatric Data
NHLBI	National Heart, Lung, and Blood Institute
NICE	National Institute for Health and Care Excellence
QALY	Quality Adjusted Life Year
Q-LES-Q-SF	Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form

QOL	Quality of life
RCT	Randomized controlled trial
RDA	Recommended Dietary Allowances
RIVM	Rijksinstituut voor Volksgezondheid en Milieu
RR	Relative risk
SGA	Second generation antipsychotics
SHO	Sheltered housing organization
SMI	Standardized mortality ratio
UK	United Kingdom
US	United States
YPLL	Years of potential life lost

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CHAPTER 1

General introduction

1. INTRODUCTION

The overall purpose of this thesis is to provide an overview of the evaluation of the effectiveness and cost-effectiveness of a health promotion intervention targeting physical activity and healthy eating in individuals with mental disorders living in sheltered housing in the Flanders region (Belgium).

There is growing evidence that individuals with mental disorders are at a greater risk of being overweight or obese than the general population. It is known that unhealthy lifestyle behavior including lack of regular physical activity, sedentary behavior and unhealthy eating habits are important determinants of the burden of excessive weight gain. In this sense, research is required to examine the effectiveness of health promotion interventions targeting physical activity and healthy eating in individuals with mental disorders.

The general introduction of the thesis will start with a description of some issues related to overweight and obesity including definition, classification, etiology and the global burden. This is followed by an overview of the prevalence, causes and consequences of these conditions in individuals with mental disorders. One possible pathway for weight gain management is the implementation of health promotion programs targeting physical activity and healthy eating. Issues of health promotion in individuals with mental disorders are described in a next part of the general introduction.

This is followed by a description of the relevance of health economic research in health care and more specifically in the field of health promotion. Health care budget holders have to make difficult choices about how to allocate scarce resources to mental health and other services. There is thus a growing need of health economic evaluations to obtain knowledge how to spend the available resources to those interventions which produce most health per invested amount of money. The general introduction ends with an overview of the aims and the outline of the research project.

2. OVERWEIGHT AND OBESITY IN INDIVIDUALS WITH MENTAL DISORDERS

2.1. Introduction

As described above, the research project starts from the observation that a high burden of overweight and obesity exist among individuals with mental disorders. For this reason, it is thought to be relevant to briefly describe how overweight and obesity are defined and classified, followed by a brief description of the etiology, and obesity as a global public health concern.

2.2. Overweight and obesity: definition, classification, etiology and global burden

Overweight and obesity are labels for ranges of body weight exceeding what is considered healthy for a given height. These conditions are usually determined by using the Body Mass Index (BMI) (Centers for Disease Control and Prevention 2012). The BMI is calculated by dividing the body weight in kilograms by the square of the height in meters (kg/m²). A commonly used classification is that one established by the World Health Organization (World Health Organization 2012). In table 1, an overview of the BMI categories is provided.

Table 1 Body Mass Index classification

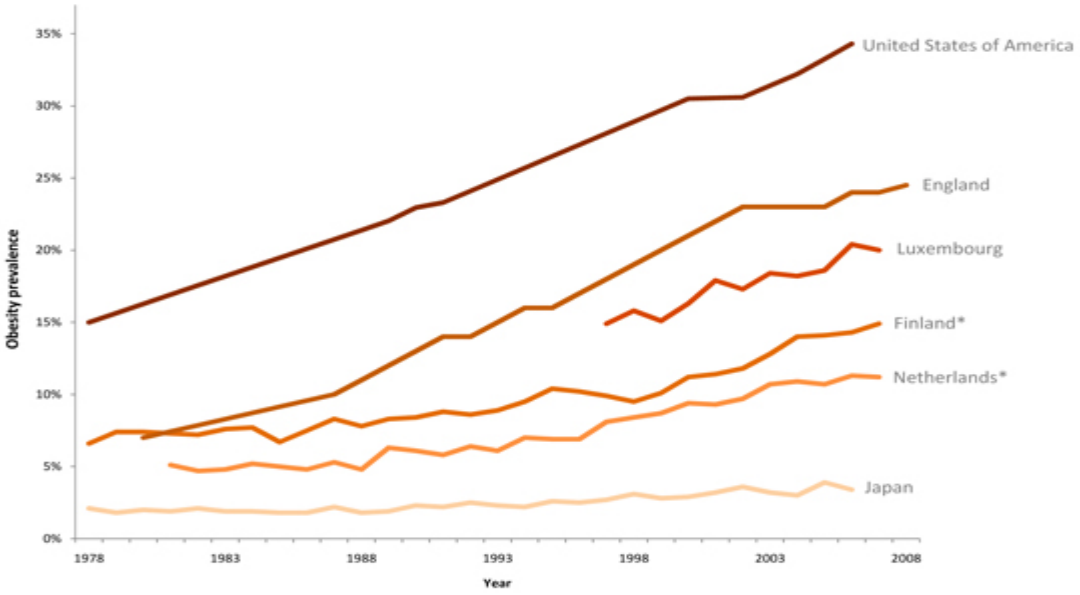
Classification	Body Mass Index (kg/m²)
Underweight	<18.50
Normal weight	18.50 – 24.99
Overweight	25.00 – 29.99
Obesity	
Obesity class I	30.00 – 34.99
Obesity class II	35.00 – 39.99
Obesity class III	≥40.00

There is however growing evidence that the measurement of the abdominal fat content is a stronger marker to evaluate the risk for the development of obesity-related diseases (Dalton *et al.* 2003, Janssen *et al.* 2004). The waist circumference and the waist-hip ratio are useful clinical measurements for assessing a patients' abdominal fat content. Different thresholds to define abdominal obesity exist. The International Diabetes Federation (IDF) defines abdominal obesity as a waist circumference of ≥94 cm in men and ≥80 cm in women (International Diabetes Federation

2012). According to the National Heart, Lung, and Blood Institute (NHLBI), a waist circumference of >102 cm in men and >88 cm in women is considered to increase the risk for the development of obesity-related diseases (Grundy *et al.* 2004).

It is beyond the scope of this research project to describe in detail the etiology of obesity. In brief, obesity is caused by an imbalance between energy intake and energy expenditure and is associated with a complex mixture of genetic, psychosocial, cultural, cognitive, environmental and behavior-related factors (Heitmann *et al.* 2012, Kremers *et al.* 2006, Liu *et al.* 2003, Schrauwen and Westerterp 2000). During the three most recent decades, overweight and obesity have become a serious global public health problem and the prevalence of obesity is rapidly increasing (World Health Organization 2004). In figure 1, an illustration of the increasing prevalence, based on BMI, in a selection of countries is provided.

Figure 1 Trends in adult prevalence of obesity (BMI ≥30 kg/m²) – percentage of the adult population assessed as obese in a selection of countries



Source: OECD http://www.ecosante.org/index2.php?base=OCDE&langs=ENG&langh=ENG - *self reported data (prevalence rates for the other countries are based on measured data)

The results of the National Health and Nutrition Examination Survey from 2009-2010 in the US (Flegal *et al.* 2012) indicated that 69.2% of a nationally representative sample of the US adult population was overweight. Almost 36% of them were classified as obese. In Europe, the obesity prevalence has increased by about 10-40% in the majority of countries during the last 10 years of the 20th century (World Health Organization 2004). Berghofer et al. (Berghofer *et al.* 2008) assessed the burden of

obesity in 30 European countries and concluded that this condition has reached epidemic proportions. In Belgium in 2008, 47% of the general population was classified as being overweight, and 13% was classified as obese (Van der Heyden *et al.* 2010).

The burden of overweight and obesity is not only rapidly increasing in the developed world, but also in low- and middle-income countries (Alwan *et al.* 2010). Where in the past obesity was mostly associated with the higher socioeconomic groups in these countries, it now tends to shift towards the groups with lower socioeconomic status (Caballero 2007, Monteiro *et al.* 2004). It is assumed that the two most important reasons for the obesity increase in low- and middle-income countries are urbanization and globalization of food production and marketing (Caballero 2007).

2.3. Overweight and obesity: prevalence

There is conclusive evidence that individuals with mental disorders are at an increased risk of being overweight or having obesity. Filik et al. (Filik *et al.* 2006) found a BMI of ≥30 kg/m² in almost 35% of a schizophrenia sample, compared with 19.4% in the UK general population. Significant differences in mean BMI between a group of schizophrenia patients and the general Canadian population were found by Coodin (Coodin 2001). The mean BMI in the male schizophrenia sample was 28.5 kg/m² compared with 26.3 kg/m² in the general population. In women, a mean BMI of 30 kg/m² was observed in the patient group compared with a mean BMI of 24.3 kg/m² in the control female group. Only 27% of the schizophrenia patients had a BMI within the normal range, compared with 48% in the general population.

Overweight and obesity are not only more common among schizophrenia patients. Mackin et al. (Mackin *et al.* 2007) found a mean BMI of 29.9 kg/m² in a sample of patients with a variety of disorders, such as bipolar disease, schizophrenia, depressive and anxiety disorders. This was significantly different from the mean BMI of 25.6 kg/m² in an age- and gender-matched control group. A BMI within the normal range was found in only 10% of the patient group, compared with 46% in the control group. Mean waist circumference was also found to be significantly higher in the patient group compared with the controls (96.6 vs. 84.1 cm, $p<0.001$). Significant differences in mean BMI were also found between a sample of schizophrenia and mood disorder patients and an age-, gender- and race- matched control group (Dickerson *et al.* 2006). After controlling for age, race and smoking status, the mean BMI in both the female and male psychiatric sample was significantly higher than in the control group (women: 32.3 vs. 27.2 kg/m², $p<0.0001$; men: 29.0 vs. 26.8 kg/m², $p<0.0001$). Fifty per cent of the female and 41% of the male patients had a BMI in the obese range,

compared with 27% and 20% in respectively the female and male control group. Significantly higher rates of overweight and obesity were also observed in female bipolar patients compared with a general population control group. In men, only obesity rates were greater in patients than in the control group (Elmslie *et al.* 2000). Chuang et al. (Chuang *et al.* 2008) found a obesity prevalence of 39% in a sample of schizophrenia, bipolar, anxiety, and depressive disorder patients. No significant differences in obesity rates were found according to the type of mental disorder.

It is noteworthy to report that data on waist circumference is rarely reported in studies assessing the prevalence of obesity between psychiatric patient populations and general populations. Nevertheless ,measuring the waist circumference is a useful tool to evaluate a patients' abdominal fat content (Janssen *et al.* 2004, Shields *et al.* 2012), as the presence of central obesity (assessed by measuring the waist circumference) may indicate the presence of the metabolic syndrome. The metabolic syndrome is defined as the appearance of at least three of the following risk factors in one individual : the presence of central obesity, raised triglyceride level, reduced HDL-cholesterol, raised blood pressure, and raised fasting plasma glucose (International Diabetes Federation 2012, National Heart Lung and Blood Institute 2012).

2.4. Overweight and obesity: causes

For the current research project we focus on two important behavioral determinants of overweight and obesity: physical activity and eating behavior. It is already established that weight gain is associated with a diet high in fat and low in fiber, frequent snacking and consumption of soft drinks containing sugar (World Health Organization and UN Food and Agriculture Organisation 2003) and sedentary lifestyles and lack of regular physical activity (Martinez-Gonzalez *et al.* 1999).

It is well known that many second generation antipsychotic drugs are associated with weight gain. The amount of weight gain appears to be determined by several factors including the type of antipsychotic drug used, the duration of the drug intake and the patients' age. Parsons et al. (Parsons *et al.* 2009) reviewed 21 studies examining weight changes in schizophrenia patients receiving the second generation drugs amilsupride, olanzapine, risperidone, or ziprasidone. In the short term (study duration between four and 12 weeks), weight gain was especially observed in patients taking amilsupride, olanzapine, and risperidone. In long-term follow up trials (study duration between six and 12 months), significantly greater weight change was associated with the use of risperidone and olanzapine. Beside these drugs, the use of clozapine has also been associated with significant weight gain (Henderson *et al.* 2000). According to the patients' age, a three- to four-fold greater weight gain

was found in young patients with shorter previous antipsychotic drug use compared with patients with chronic psychotic disorders (Alvarez-Jimenez *et al.* 2008a). The physiological and pharmacological mechanisms involved in antipsychotic drug use related weight gain are not fully clear. It is assumed that these drugs increase the appetite and cause abnormalities in the insulin and endocrine functions (Baptista 1999). No increased appetite was yet observed in schizophrenia patients in a recent study of the effects of olanzapine and risperidone on appetite during a five month period. The sample consisted of chronic patients who had been treated for many years with antipsychotic drugs which may have influenced the results of the study (Smith *et al.* 2012).

Beside the effects of second generation antipsychotic drugs, the burden of overweight and obesity in people with mental disorders is also associated with limited physical activity and unhealthy eating behavior, both to a larger extent than in the general population. Lack of regular physical activity and unhealthy eating habits in this population are associated with sedating effects of some drugs making it more difficult to engage in physical activities, lack of motivation due to the mental disorder , financial constraints (Robson and Gray 2007). Physical activity and exercise are often used reciprocally. So, it is necessary to provide a definition of those terms to avoid confusion. Physical activity can be defined as 'any bodily movement produced by skeletal muscles that results in energy expenditure' (Caspersen *et al.* 1985). Exercise is a subcategory of physical activity and can be defined as physical activity that is planned, structured, repetitive, purposive and aimed at improvement or maintenance of physical fitness (Caspersen *et al.* 1985). Sedentary time or inactivity can be considered as the time spent in sedentary behaviors (Dietz 1996).

Self-reported exercise levels were found to be lower in a schizophrenia sample than in the UK general population. Thirty-six per cent of the male and 32% of the female patients reported that they never took exercise (Brown *et al.* 1999). Significant differences in exercise levels between a group of individuals with mental disorders and a non-psychiatric comparison group were identified by Osborn et al. (Osborn *et al.* 2007b). The patient sample was less likely to engage in mild or vigorous forms of exercise compared with the control group. Similar results were reported by Davidson et al. (Davidson *et al.* 2001). Patients' self-reported light and vigorous exercise was respectively half and one-quarter as likely compared with the control group. Vancampfort et al.(Vancampfort *et al.* 2012) found a 40% longer overall sitting time in a sample of Belgian schizophrenia inpatients compared with age-, gender-, and BMI-matched healthy controls (overall sitting time: 8.5 vs. 6.2 hours/day, p=0.001). The patient group was also significantly less involved in physical activity.

The results of some studies indicate that individuals with mental disorders show more or less similar physical activity behavior compared with the general population or physical activity guidelines. Nevertheless, also in these studies it is concluded that more efforts to increase the amount of physical activity in this population are required (Jerome *et al.* 2009, McLeod *et al.* 2009). The evaluation of physical activity or exercise levels in individuals with mental disorders is frequently based on self-reported data (Brown *et al.* 1999, Davidson *et al.* 2001, McLeod *et al.* 2009). Self-report methods may however pose several problems such as recall bias resulting in underestimation or overestimation of physical activity or exercise levels (Prince *et al.* 2008). A valid alternative is the use of pedometers as a more objective tool to assess physical activity levels (Tudor-Locke *et al.* 2002). The results of a feasibility study suggested that pedometers are appropriate to record physical activity levels in schizophrenia patients (Kane *et al.* 2012).

Individuals with mental disorders also make poorer dietary choices than the general population. Research on eating behavior in mental health care primarily focused on schizophrenia patients. Roick et al. (Roick *et al.* 2007) assessed the eating and drinking habits of a schizophrenia sample compared with the general population in Germany. It was found that significantly fewer patients took breakfast on workdays compared with the control group. The patient sample also consumed less frequently fresh fruit, vegetables, wholegrain bread, and rice but ate more frequently instant meals. They consumed however significantly less alcoholic drinks than the controls. Almost 32% of the patients reported to drink no alcohol compared with 17% in the general population. This may be explained by the fact that alcohol drinking is avoided by patients because of the possible interaction with the drugs that they have to take. Poorer dietary habits including less consumption of fresh fruit, vegetables, milk, potatoes, pulses, pasta and rice were also found in a sample of schizophrenia patients compared with the general population in Scotland (McCreadie 2003). Ratliff et al. (Ratliff *et al.* 2012) compared the eating habits of 130 schizophrenia patients with a matched control group. The patient group consumed significantly more sugar, total and saturated fat. Higher fat intake in schizophrenia patients compared with a control group was also observed by Brown et al. (Brown *et al.* 1999).

2.5. Overweight and obesity: consequences

Obesity is together with a number of clinical and metabolic elements (known as the metabolic syndrome), a risk factor for the development of several non-communicable diseases including coronary artery disease, stroke, hypertension, diabetes, respiratory diseases, musculoskeletal

disorders, and certain cancers (Haslam and James 2005, International Diabetes Federation 2012, World Health Organization 2004).

It is beyond the scope of the research project to focus in detail on the burden of the metabolic syndrome in individuals with mental disorders. It is yet useful to report that there is a growing number of studies suggesting that metabolic syndrome rates in these individuals exceed the rates observed in general population samples. For example, Cohn et al. (Cohn *et al.* 2004) identified a metabolic syndrome prevalence of 43% and 49% in male and female schizophrenia patients respectively compared with 24% in men and 23% in women in an age-matched control group. High rates of the metabolic syndrome were also observed in a sample of 203 individuals with schizophrenia, bipolar disorder, depressive disorder and borderline personality disorder. The prevalence of the syndrome was almost twice as high compared with the general population in Australia. No significant differences in rates of the metabolic syndrome between the diagnostic categories were found (John *et al.* 2009). Krane –Gartiser et al. (Krane-Gartiser *et al.* 2011) found a significant higher prevalence of the metabolic syndrome in a psychiatric outpatient sample compared with the Danish general population. According to sex, rates of the syndrome were significantly higher among male than among female patients (56.0 vs. 39.2%, p=0.03).

People with mental disorders are at an increased risk of suffering from cardiovascular disease (CVD) and type 2 diabetes. It is estimated that the risk of CVD in individuals with mental disorders is almost two or three times as high as in the general population (De Hert M. *et al.* 2011, Hennekens *et al.* 2005, Hennekens *et al.* 2005). McCreadie (McCreadie 2003) found a significantly higher 10-year risk of coronary heart disease in both male and female schizophrenia patients compared with the general population. The mean 10-year risk for stroke was significantly higher in male patients, but not in female.

There is also conclusive evidence showing that type 2 diabetes is more common among people with mental disorders compared with the general population. A four to five times higher prevalence of diabetes was found in a sample of schizophrenia patients aged 15-65 years compared with the general population in Belgium. In those, aged 15-25 years, the diabetes prevalence was 0.4% and 2% in the general population and the schizophrenia sample respectively (absolute difference: 1.6%). In the individuals in the age-band 55-65 years, a diabetes prevalence of 5.8% and 25% was observed in the general population and schizophrenia sample respectively. This is equal to an absolute difference in diabetes prevalence of 19.2% between the two groups (De Hert M. *et al.* 2006). Bresee et al. (Bresee *et al.* 2010) reported an almost twofold diabetes prevalence in a sample of schizophrenia

patients compared with the Alberta (Canada) general population. Diabetes is not only found to be more common among schizophrenia patients, but also among those with schizoaffective, bipolar, and depressive disorders. The occurrence in people with the latter diagnosis was yet not significantly higher than in the US general population (Regenold *et al.* 2002). Conflicting evidence exists regarding the burden of cancer in individuals with mental disorders. According to the results of several studies, a higher (Hippisley-Cox *et al.* 2007), lower (Barak *et al.* 2005), or no difference (Osby *et al.* 2001) in cancer risk or mortality was observed in this population compared with the general population. Respiratory diseases and osteoporosis were also found to be more common among people with mental disorders (De Hert M. *et al.* 2006).

Individuals with mental disorders are at an increased risk of premature mortality. It is estimated that schizophrenia patients have approximately a 20% reduced life expectancy compared with the general population (Hennekens *et al.* 2005). Lower life expectancy rates ranging from 8 to 14.6 life years lost for men and 9.8 to 17.5 life years lost for women were found in a population with a variety of psychiatric diagnoses including schizophrenia, schizoaffective disorder, bipolar disorder, substance abuse, and depressive disorders compared with the general population (Chang *et al.* 2011). There is growing evidence that, beside suicide (Brown *et al.* 2000, Saha *et al.* 2007), CVD is an important cause of death in people with mental disorders. Osborn et al. (Osborn *et al.* 2007a) found a threefold increase in CVD mortality in schizophrenia, bipolar and delusional disorder patients aged 18 to 50 years and a twofold increase in patients aged 50 to 75 years compared with the UK general population. Similar results were observed in a sample of schizophrenia, schizoaffective and bipolar disorder patients in Denmark. Heart disease mortality was almost three times that of the Danish general population (Laursen *et al.* 2009).

Obesity results in reduced health-related quality of life, and increased health care costs (Padwal *et al.* 2012, Schmid *et al.* 2005, Tarride *et al.* 2012). For example, Tarride et al. (Tarride *et al.* 2012) found significantly higher annual combined physician, hospital and day procedure costs in a sample of obese individuals compared with a sample of normal-weight individuals in Ontario (Canada). Total annual cost was $708 and $884 in respectively normal-weight and obese individuals. Obese individuals were also more likely to have a significant lower health-related quality of life compared with the normal-weight sample (Health Utility Index, 0.83 vs. 0.89, $p<0.05$). The results of a recent meta-analysis of the association between BMI and health-related quality of life (assessed by using the SF-36 Health Survey) showed reduced quality of life in obese individuals (Ul-Haq *et al.* 2013). Hence, prevention of obesity and overweight is considered of very high societal value (Kumanyika *et al.* 2002, World Health Organization 2004).

3. HEALTH PROMOTION IN MENTAL HEALTH CARE

3.1. State-of-the art

In the general population, evaluation studies assessing the effectiveness of health promotion interventions targeting physical activity and healthy eating showed promising results (Eriksson *et al.* 2006, Lombard *et al.* 2010). The results of these studies demonstrated that important risk factors for the development of CVD and diabetes such as weight gain, abdominal obesity, raised blood pressure, and raised triglycerides can be reduced following such programs.

Strategies for managing weight gain including restricted daily caloric intake, and the implementation of both nutritional education and physical activity should be implemented into the treatment of individuals with mental disorders (Aquila 2002). According to the European Psychiatric Association, maintaining a healthy body weight and shape by healthy eating and regular physical activity is a key component in order to reduce the risk of some serious somatic diseases and to improve the overall health and well-being of patients (De Hert M. *et al.* 2009). Lowe and Lubos (Lowe and Lubos 2008) conducted a systematic review about the effectiveness of weight management interventions (calorie restriction) and interventions promoting healthy eating and regular exercise in mental health care. It was concluded that these studies only provide limited evidence on the effectiveness of either individually- or group-based psycho-educational programs (e.g. dietary counseling, lifestyle coaching) or interventions combining educational and exercise components. This review was limited to schizophrenia or schizoaffective disorder patients treated with atypical antipsychotic drugs. Given the substantial burden of weight gain in people with mental disorders independent from their psychiatric diagnosis and the fact that the impact of physical activity and healthy eating on the mental and physical health of this population received only recently attention by researchers (Richardson *et al.* 2005, Vreeland 2007), a systematic review evaluating the literature of the effectiveness of health promotion interventions targeting physical activity and healthy eating was required. We performed such a review and a detailed description of the methods and results of this review is provided in chapter 2.

3.2. Design issues

The design of evaluation studies of public health interventions including health promotion programs poses several problems and they require multiple and flexible strategies (Rychetnik *et al.* 2002). In most clinical trials, participants are randomized as individuals to intervention or control groups. When individual randomization is however not possible or desirable, groups of individuals can be randomized to intervention or control groups (Puffer *et al.* 2003). This kind of design is known as a cluster or group or community randomized trial (Christie *et al.* 2009). Cluster randomization may be appropriate when there is a risk of contamination, i.e. when individuals randomized to the intervention group may influence others within the group (Christie *et al.* 2009). Another concern in studies evaluating behavioral or psychosocial interventions is that the participants are typically informed about their experimental assignment soon after randomization. Being assigned to a non-preferred intervention condition could be disappointing or even demoralizing and reduce participants' interest to participate so that they may withdraw from the study (Howard and Thornicroft 2006, Macias *et al.* 2009). An alternative design is the preference design. This design is useful when strong preferences among potential participants threaten either the ability to recruit an adequate sample size of representative participants or when such preferences threaten participants' acceptance of treatment assignment, adherence or retention in the trial (TenHave *et al.* 2003).

In mental health care, there are two important gaps between the results of randomized controlled trials and the daily clinical practice. First, a gap exists between populations receiving psychiatric care and the highly selected study samples recruited for clinical trial research. Second, there is a gap between the complex individualized and sequential treatment for psychiatric disorders and the relatively fixed and simple interventions examined in clinical trials (TenHave *et al.* 2003). Prevention and health promotion activities for particular target populations such as people with mental disorders are complex interventions. This refers to the fact that these programs may be aimed at several outcomes such as physical activity, exercise, healthy eating, or smoking cessation. These interventions have to be adapted to and offered beside other treatment aspects including psychological therapy, medication treatment, or psychiatric rehabilitation. Moreover, underlying conditions, side effects of medication such as sedation (McDevitt *et al.* 2006), and the absence of support from others (Ussher *et al.* 2007) have to be taken into account in the study design and into the development and implementation of health promotion activities. Hence, participation in trials, compliance with programs, and interactions with other activities raise more issues than for example the assessment of a new drug in a well aligned disease area. Research examining the relationships and complexities of these factors will ameliorate the understanding and concerns of patients and

mental health professionals resulting in the development of health promotion programs that better meet the patients' and mental health professionals' needs. More research examining participants' perceptions on weight management programs is yet required in order to assist in designing interventions that are effective and satisfactory to those participants (Lowe and Lubos 2008). For this reason, a literature review examining the perceptions of patients and mental health nurses of health promotion targeting physical activity and healthy eating was to be performed. A detailed description of this part of the research project is elaborated in chapter 3.

As already mentioned, there is a lack of well designed health promotion interventions targeting physical activity and healthy eating in mental health care. Important limitations of studies evaluating the effectiveness of such programs consist of methodological considerations such as relatively small power, reducing the validity of the results, short intervention duration, and lack of standardized outcome measures including percentage of weight loss and waist circumference (Lowe and Lubos 2008). Moreover, as shown in our review (see chapter 2) no attempts were thus far made to assess the cost-effectiveness of such interventions. There is thus a need of well designed trials assessing both the effectiveness and cost-effectiveness of health promotion interventions in mental health care (Alvarez-Jimenez *et al.* 2008b). Hence we developed a health promotion program targeted to people with mental disorders.

3.3. Content issues

Mental health care can be delivered in a broad spectrum of facilities including residential settings (psychiatric hospital, psychiatric nursing home), outpatient ambulatory services, sheltered housing facilities (Eyssen *et al.* 2010). The health promotion intervention in the research project was aimed at individuals with mental disorders living in sheltered housing. This may have some implications on the design of the program as the context of sheltered housing is likely to be different from for example the context of a psychiatric hospital facility. In inpatient settings patients usually do not have to cook or shop for themselves, and exercise may probably be integrated into the treatment program. The main goal of sheltered housing is the psychiatric rehabilitation of the patients (often called 'residents') maximizing the personal autonomy of the patient. Patients are encouraged to do as much as possible for him/herself including shopping, cooking, participate in leisure time activities (for example: go to the gym) with the support of the mental health nurse. Insight into the factors influencing the integration of healthy lifestyle behavior targeting physical activity and healthy eating into the daily care of people with mental disorders in the specific context of sheltered housing was thought to be relevant for the current research project. For this reason, individual interviews with

patients and focus groups with mental health nurses were conducted to increase the understanding of health promotion in sheltered housing (this part of the research project is elaborated in chapter 4).

A useful tool to assist in the development of interventions is the intervention mapping protocol. This is a problem- and theory driven protocol to guide the design of evidence-based intervention programs (Bartholomew *et al.* 2006). The use of the intervention mapping protocol is yet complex and requires scientific staff, budget and time (Verbestel *et al.* 2011). It was not the purpose of the research project to develop a new health promotion intervention, but to evaluate if an adapted version of an existing health promotion program designed for the general population was effective in a population of individuals with mental disorders. Nevertheless, the use of the intervention mapping protocol was useful as a background information tool.

The "Health promotion on well-balanced eating and healthy physical activity" program (Flemish Institute of Health Promotion and Disease Prevention 2007) served as basis for the health promotion program used for the research project. Some adjustments to the program of the Flemish Institute of Health Promotion and Disease Prevention were made to better meet the needs and interests of the study population of individuals with mental disorders. The health promotion program did not include individualized energy restriction or energy expenditure goals such as low fat or low calorie diets. It was assumed that such an intervention would be too demanding for both the patients and the mental health nurses. The results of previous research showed that individuals with mental disorders strongly valued the support from the mental health nurse if they were willing to change unhealthy lifestyle behavior (Shiner *et al.* 2008, Ussher *et al.* 2007). For this reason and due to practical considerations, the group-based health promotion program was led and supervised by the mental health nurses working in the participating sheltered housing organizations. A detailed description of the design and results of the health promotion intervention is provided in chapter 5 and in chapter 6.

4. HEALTH ECONOMIC RESEARCH IN HEALTH CARE

At the start of this part, it is important to briefly focus on the difference between the evaluation of the 'effectiveness' and the 'efficiency' of for example a health promotion program. An intervention is 'effective' if it can be demonstrated that the intervention works in real life situations. If there is evidence that the intervention is effective and it can be demonstrated that the money spent on this intervention is money spent well, then the intervention is 'efficient' (Annemans 2008).

The purpose of the health care sector is to produce health. Health care budgets are yet limited resulting in the fact that health systems are facing the problem how to set priorities in the allocation of health care resources to medical or public health interventions (Littlejohns *et al.* 2012). To produce more health with the available (financial) resources, the budget must be allocated to those interventions, programs and therapies which produce most health per invested amount of money (Annemans 2008). Knowledge on this can be obtained by performing economic evaluations of health care interventions providing payers and governments with better insights how to spend the available resources in the most efficient way.

Economic evaluation of a health care intervention can be defined as the comparative analysis of alternative courses of action (health care interventions) in terms of both their costs and health consequences (Drummond *et al.* 2005). In general, the difference in costs between alternative health care interventions are compared with the difference in health consequences of those interventions. The most frequently applied method for a health economic evaluation is the so called cost-utility analysis. Cost-utility analyses are a type of health economic evaluation that focus particular attention on the quality of the health outcome produced or forgone by health care interventions and whereby the health effects are expressed in quality adjusted life years (QALYs). QALYs are calculated by multiplying the quality of life of a certain health state with the number of years a person is in that health state. Health-related quality of life of an individual on a certain moment, also referred to as "utility", is ranging from 0 until 1 with 1 stands for perfect health and 0 is equal to dead.

There is growing need on health economic research in health care. Evidence on the effectiveness of a new drug, medical device or intervention alone is insufficient for policy making. In addition to knowing what works and in what context, information on ratio between the costs and health consequences of an intervention is needed (Annemans 2008). Traditionally, most attention of health economic research is going to economic evaluations of medicines and medical devices. Recently, more emphasis is given to such evaluations of preventive health care. Prevention and health promotion have an economic cost, but in certain cases can also save money because diseases and complications can be avoided or controlled. In the general population, health economic evaluations of health promotion interventions targeting physical activity (Muller-Riemenschneider *et al.* 2009) and healthy eating (Brunner *et al.* 2001) yield no conclusive evidence, which is probably explained by wide difference in program contents. In mental health care, there is even a lack of trials examining the cost-effectiveness of such health promotion interventions. For this reason, a health economic evaluation of the health promotion intervention was performed (a detailed description of this part of the research project is elaborated in chapter 7).

CONCLUSION

Overweight and obesity have become a serious global problem and these conditions contribute to the development of major non-communicable diseases including CVD, type 2 diabetes, musculoskeletal disorders, and certain cancers. In individuals with mental disorders the prevalence of overweight and obesity is even higher than in the general population. The higher prevalence of excessive weight is, at least partially, related to unhealthy lifestyle behavior including lack of regular physical activity, sedentary behavior, and unhealthy eating habits. This contributes to the high burden of CVD and diabetes and associated premature mortality in this population. Lifestyle modification is likely to be a substantial pathway to reduce the risk factors for the development and burden of these somatic diseases. This provides the rationale for the development and implementation of health promotion interventions targeting physical activity and healthy eating into the daily care of psychiatric patients.

AIMS AND OUTLINE OF THE RESEARCH PROJECT

The research reported in this thesis is based on four papers published in international scientific peer-reviewed journals, on one paper under review for publication and on one paper submitted to such a journal.

A first aim of the research project was to summarize the evidence on the effectiveness and cost-effectiveness of health promotion interventions targeting physical activity and healthy eating in individuals with mental disorders (chapter 2). This was reflected in a systematic review (published as: Verhaeghe N, De Maeseneer J, Maes L, Van Heeringen C, Annemans L. Effectiveness and cost-effectiveness of lifestyle interventions on physical activity and eating habits in persons with severe mental disorders: a systematic review. International Journal of Behavioral Nutrition and Physical Activity, 2011, 8:28).

A second aim of the research project was to evaluate the perceptions of patients and mental health nurses of health promotion targeting physical activity and healthy eating in mental health care (chapter 3). This objective was also achieved by means of a literature review (published as: Verhaeghe N, De Maeseneer J, Maes L, Van Heeringen C, Annemans L. Perceptions of mental health nurses and patients about health promotion in mental health care: a literature review. Journal of Psychiatric and Mental Health Nursing, 2011, 18:487-492).

A third aim was to gain insight into the factors influencing the integration of healthy lifestyle behavior targeting physical activity and healthy eating into the daily care of people with mental disorders living in sheltered housing and to increase the understanding of the relationships between and complexities of these factors. This was done by means of a qualitative study using individual interviews and focus groups. This part of the research project is reported in chapter 4 (published as: Verhaeghe N, De Maeseneer J, Maes L, Van Heeringen C, Annemans L. Health promotion in mental health care: Perceptions from patients and mental health nurses. Journal of Clinical Nursing, 2013, 22:1569-78).

A fourth objective was to examine the effectiveness of a health promotion intervention targeting physical activity and healthy eating in individuals with mental disorders living in sheltered housing. A detailed overview of the study design together with the baseline characteristics of the study population is described in chapter 5 (published as: Verhaeghe N, De Maeseneer J, Maes L, Van Heeringen C, Bogaert V, Clays E, De Bacquer D, Annemans L. Health promotion intervention in

mental health care: Design and baseline findings of a cluster preference randomized controlled trial. BMC Public Health, 2012, 12:431). This is followed by a chapter (chapter 6) reporting the results of the effectiveness study (manuscript in second round of revision: Verhaeghe N, Clays E, Vereecken C, De Maeseneer J, Maes L, Van Heeringen C, De Bacquer D, Annemans L. Health promotion in individuals with mental disorders: a cluster preference randomized controlled trial. BMC Public Health).

The last aim of the research project was to examine if the health promotion intervention was cost-effective (chapter 7). In this chapter, the methodology and findings of the health economic evaluation are described (manuscript submitted for publication: Verhaeghe N, De Maeseneer J, Maes L, Van Heeringen C, Annemans L. Health economic evaluation of a health promotion intervention in mental health care. International Journal of Behavioral Nutrition and Physical Activity).

The thesis ends with a general discussion of some methodological considerations, strengths and limitations of the research project and by a discussion on the relevance of the study to public health and directions for future research.

Each chapter is presented as an independent paper which has been published or submitted for publication in peer-reviewed journals. For this reason, some overlap between the chapters is inevitable.

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CHAPTER 2

Effectiveness and cost-effectiveness of lifestyle interventions on physical activity and eating habits in persons with severe mental disorders: a systematic review

Verhaeghe N, De Maeseneer J, Maes L, Van Heeringen C, Annemans L.
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ABSTRACT

Background: There is a high prevalence of overweight and obesity in persons with severe mental disorders and this has serious implications on the short and long term health outcomes of these patients. The aim of this review was to evaluate the effectiveness of lifestyle interventions targeting physical activity and eating habits in persons with severe mental disorders. Special attention was given if any of the included studies in the review also examined the cost-effectiveness of these health promotion interventions.

Methods: A systematic search through the electronic databases Medline, Web of Science, CINAHL and Cochrane Library was conducted, and by hand-searching the reference lists of the retrieved articles from the electronic databases. Studies were included if they examined effectiveness and/or cost-effectiveness of lifestyle interventions targeting physical activity and eating habits in persons with severe mental disorders, with primary outcome changes in Body Mass Index and body weight.

Results: Fourteen studies met the inclusion criteria. Weight loss and Body Mass Index decrease were observed in intervention groups in 11 studies. The difference in weight change between intervention and control groups was statistically significant in nine studies. Differences in mean Body Mass Index between intervention and control groups were statistically significant in eight studies. Five studies reported improvements in quality of life and general health. In none of the studies cost-effectiveness of lifestyle interventions was examined.

Conclusion: Further research on both effectiveness and cost-effectiveness of lifestyle interventions targeting physical activity and eating habits in persons with severe mental disorders is required to assist in the development of new health promotion interventions in this population.

INTRODUCTION

Overweight (Body Mass Index 25-29 kg/m²) and obesity (Body Mass Index >30 kg/m²) have become a serious global public health problem, and the prevalence of obesity is rapidly increasing (World Health Organization 2004b). Obesity is associated with lifestyle factors such as sedentary lifestyles and poor dietary choices (Cameron *et al.* 2003, Sanchez *et al.* 2008) which contribute to major non communicable diseases, including cardiovascular disease (CVD), type 2 diabetes and certain types of cancer (World Health Organization 2004a). The burden of overweight and obesity is also increasing in low- and middle-income countries (Alwan *et al.* 2010). Where in the past obesity was mostly associated with the higher socioeconomic groups, now tends to shift towards the groups with lower socioeconomic status. In developing countries, the underprivileged people living in urban areas are especially affected by overweight and obesity (Monteiro *et al.* 2004).

Growing attention is given to the effects of 'healthy living interventions' targeting physical activity and eating habits. In the general population, the effectiveness of such interventions is already well established (Clark *et al.* 2004, Eriksson *et al.* 2006, Woo *et al.* 2007). However, research on cost-effectiveness of 'healthy living interventions' does not provide clear evidence. The results of some studies suggest that specific lifestyle interventions for specific target groups are cost-effective (Annemans *et al.* 2007, Jacobs-van der Bruggen MA *et al.* 2007, Roux *et al.* 2008). Contrary, based on a systematic review, the authors concluded that there is currently no sufficient evidence to reliably compare cost-effectiveness results of individual studies and that the generalization of presented findings is restricted considerably (Muller-Riemenschneider *et al.* 2009).

In people with severe mental disorders the prevalence of obesity is higher than in the general population (Filik *et al.* 2006, Paton *et al.* 2004). Moreover, some studies provide evidence of differences in rates of overweight and obesity when gender is considered. In a study of the prevalence of overweight and obesity in bipolar patients, the results indicated that, in women with bipolar disorders, overweight and obesity were significantly more frequent, compared to reference women. In men, only rates of obesity were greater in patients than in reference subjects but rates of overweight were not (Elmslie *et al.* 2000). In a study of 169 patients with schizophrenia or major mood disorder, 17.0% of women had Body Mass Index (BMI) in the obese III range (BMI >40 kg/m²), compared with only 4.0% in the general population. Among the male patients, 5.0% had BMI in the obese III range, compared with 2.0% in the general population (Dickerson *et al.* 2006).

In people with severe mental disorders, it is important to note that some atypical antipsychotics also have been associated with weight gain. The degree of weight gain can vary according to the type of antipsychotic medication (Parsons *et al.* 2009).

Beside the higher prevalence of overweight and obesity, people with severe mental disorders also have more sedentary lifestyles, including less moderate to vigorous physical activity (Brown *et al.* 1999, Osborn *et al.* 2007), and make poorer dietary choices, compared with the general population. Poor dietary choices include eating less frequently food recommended for large consumption (e.g. fresh fruit, vegetables, wholegrain bread, rice) and more instant meals (Henderson *et al.* 2006, McCreadie 2003, Roick *et al.* 2007) and fat (Brown *et al.* 1999) and having less variety of food in their diet (Chuang *et al.* 2008, Strassnig *et al.* 2003).

Despite these negative conditions, patients suffering from severe mental disorders are less likely having their physical illnesses diagnosed and managed effectively. Barriers to effective physical healthcare include patient-related elements (poor treatment compliance, treatment refusal), the nature of the illness (social isolation and suspicion, physical symptoms unreported or masked because of high pain tolerance in some patients associated with the use of antipsychotics), physicians' attention principally focused on patients' psychiatric problems and physical complaints regarded as psychosomatic symptoms (Brown *et al.* 2000, Fleischhacker *et al.* 2008, Lambert *et al.* 2003, Phelan *et al.* 2001). There is limited evidence describing that the presence of a mental disorder does not affect the quality of physical health care. For example, no differences in quality of diabetes care were found between patients with schizophrenia or bipolar disorder and patients with diabetes without mental disorders (Whyte *et al.* 2007).

This raises even more concern given an increased risk of premature death in this population in comparison with the general population (Brown *et al.* 2000, Harris and Barraclough 1998). Premature mortality can be expressed by measuring the "years of potential life lost" (YPLL). The YPLL is based on the current mean survival age for a living cohort by age and by gender (Dembling *et al.* 1999). YPLL among persons with mental disorders are described in several studies. In a study among 608 patients with mental disorders, the mean YPLL for all causes was 32 years (Miller *et al.* 2006). The results of a recent study identified a mean YPLL of 14.5 years in persons with mental disorders compared with 10.3 years for the general population (Piatt *et al.* 2010). The risk of premature death can also be assessed by calculating the standardized mortality ratio (SMI). For example, in a retrospective cohort study, a SMI of 3.7 for patients with mental disorders was found compared with the general population (Daumit *et al.* 2010). Respiratory disease, CVD and cancer are important causes of this premature mortality in addition to suicide (Auquier *et al.* 2007, Brown 1997, Lawrence *et al.* 2003). As mentioned above, sedentary lifestyles and poor dietary choices are important risk factors for these non communicable diseases.

Therefore, people with severe mental disorders require careful baseline assessment and ongoing monitoring of physical health parameters (Beebe 2008). The treatment and prevention strategies should include encouraging healthy lifestyles, smoking cessation, appropriate diets and levels of activity, with contribution of both mental health professionals and primary care providers (Casey *et al.* 2004, Filik *et al.* 2006, MacHaffie 2002). The European Psychiatric Association stated that maintaining a healthy body weight and shape by healthy eating and regular physical activity is a key component in order to reduce the risk of some important somatic diseases such as CVD and to improve the overall health and well-being of patients (De *et al.* 2009).

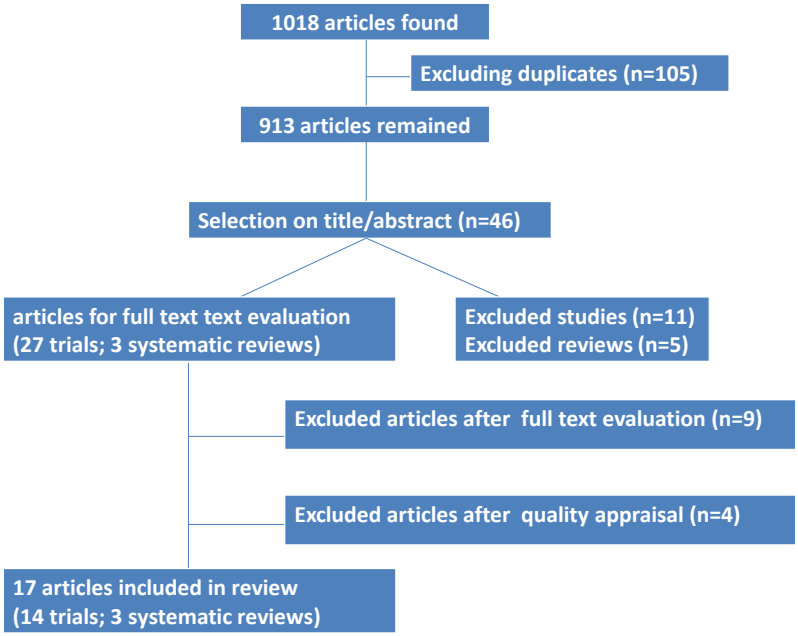
The aim of this review was to evaluate the effects on weight, BMI and quality of life (QOL) of lifestyle interventions targeting physical activity and eating habits in persons with severe mental disorders. Special attention was given if any of the included studies in the review also examined the cost-effectiveness of these health promotion interventions.

METHODS

Initially, the following electronic databases were searched for the period 01-03-1990 until 01-03-2010: Medline, Web of Science, CINAHL and Cochrane Library using the search string '(Mental Disorders [MeSH] OR Severe Mental Illness OR Antipsychotic Agents [MeSH]) AND (Obesity [MeSH] OR Weight Gain [MeSH] OR Weight) AND (Lifestyle OR Intervention Studies [MeSH] OR Food Habits [MeSH] OR Physical Activity OR Fruit [MeSH] OR Vegetables [MeSH])'. The search was limited to randomized controlled trials, clinical trials, reviews and meta-analysis in English.

One thousand and eighteen records were found (Figure 1). After excluding the duplicate records (n=105) 913 references remained.

Figure 1 Search strategy



One reviewer (the first author) assessed the relevance of the references. First, a selection was made on title and/or abstract. Studies were included if they examined effectiveness and/or cost-effectiveness of lifestyle interventions targeting physical activity and eating habits in persons with severe mental disorders. Studies were also included if participants were adults aged 18 and over with a DSM-IV diagnosis of schizophrenia, schizoaffective, depressive or bipolar disorder or 'severe mental disorder' in general. Furthermore, studies were included if the focus was on changes in weight and BMI through the application of psycho educational and/or behavioral interventions on physical activity and/or eating habits.

Studies were excluded if they examined the effect on weight and BMI of lifestyle interventions targeting physical activity and eating habits in general populations. Studies were also excluded if the primary outcome was not a mean change in weight and BMI by the end of the intervention. Studies examining the effect of a pharmacological intervention on body weight and BMI without lifestyle intervention were also excluded.

The selection based on title and/or abstract resulted in 34 references. Twelve additional references were found by hand-searching the reference lists of the retrieved articles from the electronic databases. Next, all non-systematic reviews (n=5) were excluded, whereby 38 primary studies and three systematic reviews remained. As we were only interested in randomized and non-randomized controlled trials, all non-comparative trials (n=11) were excluded. Full text of the remaining 27

primary studies was then evaluated in detail on the above mentioned in- and exclusion criteria. Nine trials were excluded. In two trials, participants were aged 15-44 years (Alvarez-Jimenez *et al.* 2006) and 16-50 years (Alvarez-Jimenez *et al.* 2010). In three studies (Beebe *et al.* 2005, Jean-Baptiste *et al.* 2007, McCreadie *et al.* 2005) changes in body weight and BMI were not considered as an outcome. In another study (Khazaal *et al.* 2007), changes in body weight and BMI were secondary outcomes. Two trials (Aquila and Emanuel 2000, Melamed *et al.* 2008) reported no detailed data on changes in body weight or BMI. Finally, in one trial (Skouroliakou *et al.* 2009) changes in weight loss between persons with severe mental disorders and persons without psychiatric problems were compared.

After this selection, 18 primary studies remained for evaluation on quality. Study quality was assessed using a checklist developed by the Cochrane Centre (Dutch version) (Dutch Cochrane Centre 2009) and a checklist for the assessment of the methodological quality of both randomized and non-randomized studies of health care interventions (Downs and Black 1998).

Finally, 14 primary studies and three systematic reviews were appropriate for this review.

RESULTS

Three previous systematic reviews were identified (Faulkner *et al.* 2003, Faulkner *et al.* 2007, Lowe and Lubos 2008). The review by Faulkner et al. (Faulkner *et al.* 2003) systematically reviewed the literature of the effectiveness of interventions designed to control weight gain in schizophrenia. Sixteen studies met the inclusion criteria. Eight studies consisted of pharmacological interventions, which was an exclusion criterion for our review. The eight remaining trials consisted of behavioral/dietary interventions. Of these, two studies were also found by our electronic search. One (Aquila and Emanuel 2000) was excluded (no data on changes in BMI) and one (Ball *et al.* 2001) was included in our review. Six references were not found by our search. Four of these were conducted in the period before 1990 and consisted of dietary restriction treatment. Another study of the period after 1990 also consisted of a dietary intervention without behavioral intervention and one reference consisted of a letter to the editor.

In another systematic review of Faulkner et al. (Faulkner *et al.* 2007) 23 randomized controlled trials were included. Eighteen consisted of a pharmacological intervention, while the five remaining studies consisted of a cognitive/behavioral intervention. These five studies were also found in our search. The study by Lowe & Lubos (Lowe and Lubos 2008) systematically searched major databases for references about the effectiveness of weight management interventions for people with severe mental disorders receiving treatment with atypical antipsychotics. All studies (n=8) included in this review were also found in our search. Six were included in our review.

Primary studies – Participants

The total number of participants in the selected studies included 669 individuals (321 males, 328 females, 20 not specified). Mean age of the participants was 39.7 years. One study (Weber and Wyne 2006) provided no information about the mean age of participants. The target group of eight studies consisted of patients with schizophrenia or schizoaffective disorder, in three trials of patients with schizophrenia, in one study a combination of patients with schizophrenia, schizoaffective disorder, bipolar disorder or depression and in one study the target group were patients with bipolar disorder, schizoaffective disorder or depression. One study provided no detailed information on DSM-IV diagnosis of participants. The study population was defined as 'patients with mood or psychotic disorder'. In all studies, patients were treated with atypical antipsychotics such as olanzapine, clozapine, risperidone.

The total number of 669 participants consisted of 361 individuals in the intervention groups and 308 in the control groups. Mean drop out rates were 20.6% (range 0.0 – 47.6%) in the intervention groups and 11.5% (range 0.0 – 33.3%) in the control groups. In three studies (Littrell *et al.* 2003, Weber and Wyne 2006, Wu *et al.* 2007), no drop outs were observed in the intervention groups.

Nine studies recruited from outpatient settings, three from inpatient settings and two from a combination of both. Eight studies were conducted in the US, while the remaining were from Italy (n=2), Australia (n=1), China (n=1), Taiwan (n=1), and South Korea (n=1).

Primary studies – Design

Among the 14 included studies, 11 were randomized controlled trials, while three were non-randomized controlled trials (table 1). In eight trials, assessment of the outcomes was made at baseline and endpoint, while in six studies multi evaluation points were used. In eight studies, assessment of the outcomes was based only on participants who completed the intervention period (per protocol). In the other six studies, outcome assessment was based on data of all participants (intention to treat).

Table 1 Design of the studies included in the review

author	design	intervention	study period	intervention period	individually/group-based
Scocco et al.	randomized controlled trial	intervention on providing information and assessment of dietary topics compared to a control group not receiving intervention	24 weeks	8 weeks	individually-based
Evans et al.	randomized controlled trial	intervention on education and setting specific goals on healthy eating and lifestyle compared to a control group not receiving intervention	6 months	3 months	individually-based
Littrell et al.	randomized controlled trial	intervention on providing information and prompting self-monitoring of behavior on nutrition and exercise compared to a control group not receiving intervention	6 months	16 weeks	combination
Vreeland et al.	non-randomized controlled trial	intervention on providing information and teaching on nutrition and healthy living compared to a control group not receiving intervention	12 weeks	12 weeks	combination
Weber & Wyne	randomized controlled trial	intervention providing information and prompting self-monitoring of behavior on nutrition and exercise compared to a control group not receiving intervention	16 weeks	16 weeks	group-based
McKibbin et al.	randomized controlled trial	intervention on exercise and providing information and prompting self-monitoring of behavior on nutrition and exercise compared to a control group not receiving intervention	24 weeks	24 weeks	group-based
Wu et al.	randomized controlled trial	intervention on exercise and on providing information and prompting self-monitoring of behavior compared to a control group not receiving intervention	12 weeks	12 weeks	combination

Table 1 Design of the studies included in the review (continued)

author	Design	intervention	study period	intervention period	individually/group-based
Mauri et al.	randomized controlled trial	intervention on providing information and teaching on nutrition compared to a control group receiving intervention in second study phase	24 weeks	12 weeks	combination
Wu et al.	randomized controlled trial	intervention on exercise and assessment of food and caloric intake compared to a control group not receiving intervention	6 months	6 months	combination
Ball et al.	non-randomized controlled trial	intervention on exercise and on prompting self-monitoring of food choices behaviour compared to a control group not receiving intervention	10 weeks	10 weeks	combination
Skrinar et al.	randomized controlled trial	intervention on exercise and providing information and prompting self-monitoring of behavior on nutrition and wellness compared to a control group not receiving intervention	12 weeks	12 weeks	group-based
Kwon et al.	randomized controlled trial	intervention on nutritional education and prompting self-monitoring of dietary behavior and exercise compared to a control group not receiving intervention	12 weeks	12 weeks	individually-based
Menza et al.	non-randomized controlled trial	intervention on exercise and prompting self-monitoring of behavior on nutrition and exercise compared to a control group not receiving intervention	12 months	12 months	combination
Brar et al.	randomized controlled trial	intervention on teaching various behavioral techniques on nutrition and exercise for weight loss compared to a control group not receiving intervention	14 weeks	14 weeks	group-based

Primary studies – Weighing process

An analysis was performed to what extent information about the weighing process (time of weighing, the use of a weighing scale, clothing) was reported in the studies included in the review. In eight studies, no details about issues of the weighing process were described. Details about the time of weighing were described in only four studies (Littrell *et al.* 2003, McKibbin *et al.* 2006, Scocco *et al.* 2006, Wu *et al.* 2007). In all of these four studies, participants were weighed in the morning. In only one study, details on the scale used for the weighing was described (Mauri *et al.* 2008). Two other studies reported that "the same scale" (without any details) was used. Details on the person(s) who performed the measurement of weight and height was described in three studies (Mauri *et al.* 2008, Scocco *et al.* 2006, Weber and Wyne 2006). Information about the clothing was reported in four studies: "without shoes" (Littrell *et al.* 2003, Mauri *et al.* 2008), "in light clothing" (McKibbin *et al.* 2006), "wearing underwear" (Scocco *et al.* 2006).

Primary studies – Interventions

We were interested in studies on psycho educational and/or behavioral interventions on physical activity and/or eating habits in persons with severe mental disorders. Seven studies consisted of a psycho educational and/or behavioral intervention on physical activity and/or dietary management. In the remaining seven trials, the focus was not only on these kinds of interventions, but also included supervised exercise (walking or jogging). Topics on dietary management included education and discussion on eating habits with emphasis on energy intake/ energy expenditure, and healthy eating. Topics on physical activity management focused on assessment of physical activity levels and discussion on changing activity levels and adequate amounts of exercise. Intervention were group-based (n=4), individual (n=3) or a combination of both (n=7).

The mean duration of the interventions was 20±10.8 weeks (range 10-52 weeks). The study period was equal to the duration of the health promotion intervention in 12 studies. In one study (Evans *et al.* 2005) the intervention period was 12 weeks, while the study period lasted 24 weeks. In another study (Littrell *et al.* 2003) the intervention and study period lasted respectively 16 and 24 weeks.

In two trials the control group also received the intervention in a second phase of the study (cross-over design). In one study (Scocco *et al.* 2006), the control group received no intervention from baseline until week nine. Afterwards, a cross over was made, whereby the controls also received the intervention between week nine and week 24. The study by Mauri et al. (Mauri *et al.* 2008) had a similar design, as the control group also received the intervention between week 12 and week 24.

Primary studies – Results of the interventions

First, changes in body weight and BMI were analyzed in intervention and control groups separately (table 2 & 3). In the intervention groups, weight loss was observed in 11 studies. This was statistically significant in five studies and not statistically significant in one study. For five trials, no information on the level of significance of weight loss was provided. Weight increase was observed in three studies. In two studies (Littrell *et al.* 2003, Scocco *et al.* 2006), the increase was not statistically significant. The study by Evans et al.(Evans *et al.* 2005) provided no information on the level of significance of weight increase in the intervention group.

In the control groups, a decrease in mean body weight was reported in only four studies. This decrease was statistically significant in one study, not significant in another and two trials provided no information on significance of weight decline. In the other ten studies, mean endpoint weight in controls increased (in three a significant change, in one no significant change, and six reported no information on significance).

Table 2 Mean weight and BMI change from baseline to endpoint in intervention groups

author	number	baseline weight (kg)	endpoint weight (kg)	baseline BMI (kg/m²)	endpoint BMI (kg/m²)	changes in weight (kg)	changes in BMI (kg/m²)
Scocco et al. [1]	10	75,33	76,32	27,53		0,99 [NS]	
Evans et al.	29	82,80	84,80	28,80	29,50	2,00 [NI]	0,70 [NI]
Littrell et al.	35	81,12	81,49	26,26	26,39	0,37 [NS]	0,13 [NS]
Vreeland et al.	31	100,20	97,48	34,32	33,34	-2,72 [NI]	-0,98 [NI]
Weber & Wyne	8	86,64	84,20	33,00	32,05	-2,44 [NS]	-0,95 [NS]
McKibbin et al.	32	100,83	98,52	33,60	32,90	-2,31 [NI]	-0,70 [NI]
Wu et al.	32	64,70	63,40	24,60	23,10	-1,30 [**]	-1,50 [**]
Mauri et al.[2]	22	83,90	80,30	30,00	28,70	-3,60 [**]	-1,30 [**]
Wu et al.	28	78,40	74,20	30,43	28,84	-4,20 [*]	-1,59 [*]
Ball et al.	21	107,91	105,60	36,90	36,20	-2,31 [NI]	-0,70 [NI]
Skrinar et al.	15	97,10	94,90	32,90	32,30	-2,20 [NI]	-0,60 [NI]
Kwon et al.[3]	33			26,81	25,31	-3,94 [NI]	-1,50 [NI]
Menza et al.	31	100,20	97,20	34,30	32,60	-3,00 [**]	-1,70 [**]
Brar et al.[4]	34	101,30	99,30			-2,00 [**]	-0,90 [**]

[1] Scocco et al.: controls received intervention from week 9-24; results presented are the results after 8 weeks

[2] Mauri et al.: controls received intervention from week 12-24; results presented are the results after 12 weeks

[3] Kwon et al.: no information on baseline and endpoint weight, only on changes in weight

[4] Brar et al.: no information on baseline and endpoint BMI, only on changes in BMI

* significant difference in weight or BMI change from baseline to endpoint in intervention groups (p<.001)

** significant difference in weight or BMI change from baseline to endpoint in intervention groups (p<.05)

Abbreviations: kg= kilogramme; BMI= Body Mass Index; NS= not significant; NI= no information on significance

In the intervention groups, a decrease in the mean BMI was observed in 11 studies. The decrease was statistically significant in five of these trials. In one study the decrease was not significant, while for five trials no information on the level of significance was provided. Endpoint BMI was increased in two studies. In one trial, this increase was not statistically significant, while the other study reported no information on significance of BMI increase. One study (Scocco *et al.* 2006) provided no information on mean endpoint BMI or changes in BMI neither in intervention nor in control groups.

In the control groups, the mean BMI decreased in only four studies (significant in one study, not significant in another study and no information in the other two). Mean BMI increased in nine trials. This increase was significant in two studies, and not significant in one study. No information on the level of significance was available for the remaining six studies. Only one study (Wu *et al.* 2008) reported confidence intervals around the changes in weight or BMI.

Table 3 Mean weight and BMI change from baseline to endpoint in control groups

author	number	baseline weight (kg)	endpoint weight (kg)	baseline BMI (kg/m²)	endpoint BMI (kg/m²)	changes in weight (kg)	changes in BMI (kg/m²)
Scocco et al.[1]	10	80,36	82,32	27,05		2,96 **	
Evans et al.	22	80,20	86,20	27,20	29,20	6,00 NI	2,00 NI
Littrell et al.	35	81,93	85,18	27,17	28,18	3,25 *	1,01 *
Vreeland et al.	15	93,62	96,52	33,40	34,60	2,90 NI	1,20 NI
Weber & Wyne	9	91,08	90,49	33,00	32,76	-0,59 NS	-0,24 NS
McKibbin et al.	32	96,21	99,29	32,90	33,90	3,08 NI	1,00 NI
Wu et al.	32	64,60	67,20	24,50	25,40	2,60 **	0,90 **
Mauri et al.[2]	27	86,20	86,40	31,10	31,10	0,20 NS	0,00 NS
Wu et al.	28	77,80	78,80	30,27	30,62	1,00 NI	0,35 NI
Ball et al.	11	87,41	87,18	29,00	28,90	-0,23 NI	-0,10 NI
Skrinar et al.	15	90,90	92,10	31,80	32,30	1,20 NI	0,50 NI
Kwon et al.[3]	15			27,99	27,40	-1,48 NI	-0,59 NI
Menza et al.	20	87,45	90,63	32,20	34,80	3,18 NI	2,60 NI
Brar et al.[4]	37	98,90	97,80			-1,10 **	-0,50 **

[1] Scocco et al.: controls received intervention from week 9-24; results presented are the results after 8 weeks

[2] Mauri et al.: controls received intervention from week 12-24; results presented are the results after 12 weeks

[3] Kwon et al.: no information on baseline and endpoint weight, only on changes in weight

[4] Brar et al.: no information on baseline and endpoint BMI, only on changes in BMI

* significant difference in weight or BMI change from baseline to endpoint in intervention groups (p<.001)

** significant difference in weight or BMI change from baseline to endpoint in intervention groups (p<.05)

Abbreviations: kg= kilogramme; BMI= Body Mass Index; NS= not significant; NI= no information on significance

Secondly, differences in changes in body weight and BMI between the intervention and control groups were analyzed (table 4). The difference in weight change between intervention and control groups was statistically significant in nine studies and not statistically significant in five studies. Weighted average weight change based on sample size in the intervention groups was -1.96±1.84 kg (-1.74%) versus +1.77±2.12 kg (+2.28%) in the control groups. Differences in mean endpoint BMI between intervention and control groups were statistically significant in eight studies and not significant in three studies. In three trials, no information on significant changes in BMI was reported. Weighted average BMI change based on sample size in the intervention groups was -0.87±0.69 kg/m² versus +0.64±0.96 kg/m² in the control groups.

Table 4 Changes in weight and BMI between intervention and control groups

author	changes in weight (kg)	changes in BMI (kg/m²)
Scocco et al.	-1,97 ^{NS}	NI
Evans et al.	-4,00 **	-1,30 **
Littrell et al.	-2,88 **	-0,88 ^{NI}
Vreeland et al.	-5,62 **	-2,18 **
Weber & Wyne	-1,85 ^{NS}	-0,71 ^{NS}
McKibbin et al.	-5,39 *	-1,70 *
Wu et al.	-3,90 *	-2,40 *
Mauri et al.	-3,80 **	-1,30 **
Wu et al.	-5,20 *	-1,94 *
Ball et al.	-2,08 ^{NS}	-0,60 ^{NS}
Skrinar et al.	-3,40 ^{NS}	-1,10 ^{NS}
Kwon et al.	-2,46 **	-0,91 **
Menza et al.	-6,18 **	-4,30 **
Brar et al.	-0,90 ^{NS}	-0,40 ^{NI}

* significant difference in weight or BMI change from baseline to endpoint in intervention groups (p<.001)

** significant difference in weight or BMI change from baseline to endpoint in intervention groups (p<.05)

Abbreviations: kg= kilogramme; BMI= Body Mass Index; NS= not significant; NI= no information on significance

In four studies, the intervention period was followed by a follow up period during which the outcomes 'weight' and 'BMI' were also assessed. In the intervention group, a significant increase in weight (+3.16 kg, p<.03) during the follow up period of 12 weeks occurred in the study of Scocco et al. (Scocco *et al.* 2006). In the study of Evans et al. (Evans *et al.* 2005) the intervention group had not gained any further weight during the follow up period of three months. A similar stable mean body weight (follow up period of two months) was reported by Littrell et al.(Littrell *et al.* 2003). In the trial of Mauri et al. (Mauri *et al.* 2008), weight loss occurred during the intervention period (-3.6 kg), with a further weight loss during the 16-week follow up period (-4.5 kg between baseline and endpoint).

Finally, differences in changes in body weight and BMI between intervention and control groups were studied in relation to the design of the intervention (individually, group-based or a combination of both) and to the duration of the interventions.

Seven studies consisted of a combination of an individual and a group-based intervention. In six of these studies significant changes in weight between intervention and control groups were found. Furthermore, two of three individual and one of four group-based interventions produced statistically significant weight changes between intervention and control groups. Similar results were found for changes in BMI between intervention and control groups. Changes in BMI were statistically significant in five of seven studies consisting of a combination of an individual and group intervention.

A significant difference in changes in body weight and BMI between intervention and control groups was found in five of six trials with an intervention period of 12 weeks. In the two trials with an intervention period of 24 weeks and one trial with an intervention period of 52 weeks, a significant difference in changes in body weight and BMI was found.

Among the eight studies in which assessment of the outcomes was based only on participants who completed the intervention period (per protocol), the differences in body weight and BMI between intervention and control groups were statistically significant in only four studies. In respectively five (body weight) and four (BMI) of six studies, in which outcome assessment was based on data of all participants (intention to treat), differences between intervention and control groups were statistically significant.

Primary studies – Effects on quality of life

Effects on QOL of psycho educational and behavioral interventions targeting physical activity and eating habits were examined in five studies. Evans et al. (Evans *et al.* 2005) found a statistically significant difference between intervention and control group in subjective improvement of QOL ($p=.047$) and in overall health ($p=.023$) as measured by the Clinical Global Impressions (CGI). In the study by Mauri et al.(Mauri *et al.* 2008) the results of the Clinical Global Impressions Severity (CGI-S) in the total population showed a significant improvement from baseline to endpoint ($p<.05$), while no significant changes were shown for the Clinical Global Impressions Improvement (CGI-I). No statistically significant differences on the CGI-S and CGI-I were observed between the intervention and control groups. Furthermore, scores on the Quality of Life Enjoyment and Satisfaction Questionnaire-Short Form (Q-LES-Q-SF) significantly improved only in the control group ($p<.05$).

The CGI-scale was also used in the study by Ball et al. (Ball *et al.* 2001). No statistically significant differences in CGI were observed between baseline and endpoint of the intervention. In the study by

Skrinar et al. (Skrinar *et al.* 2005) only subjective ratings of general health ($p<.05$) and empowerment ($p<.01$) were significantly more improved in the intervention group than in the control group. There was a statistically non-significant improvement in health and well-being from the Health Survey SF-36 and subscales from the Lehman Quality of Life Questionnaire.

Finally, scores on psychological well-being, social relationship, and environmental domains did not show a significant difference between the intervention and control group in the study by Kwon et al. (Kwon *et al.* 2006). There was only a trend toward statistical difference in the physical health score changes between the intervention and control group.

Primary studies – Cost-effectiveness of interventions

The cost-effectiveness of psycho educational, behavioral and/or exercise interventions targeting physical activity and eating habits in persons with severe mental disorders was examined in none of the studies included in this review. Only in four studies, there was a reference to topics of cost-effectiveness. In their conclusion Vreeland et al. (Vreeland *et al.* 2003) and Menza et al. (Menza *et al.* 2004) stated that cost-effectiveness of these kinds of interventions must be examined in further studies. Evans et al.(Evans *et al.* 2005) concluded that further research is necessary to investigate the most cost-effective 'dose' of intervention required. Scocco et al. (Scocco *et al.* 2006) emphasize the need for further research in order to develop an efficacious approach with an advantageous cost-benefit ratio.

DISCUSSION

The results of this review demonstrate that small improvements in body weight, BMI and QOL are possible through psycho educational and/or behavioral interventions targeting physical activity and/or eating habits in persons with severe mental disorders.

In the intervention groups, weight loss and a decrease of BMI is observed in 11 studies. In the control groups, a decrease in mean body weight and BMI is reported in only four studies. The difference in weight change between intervention and control groups is statistically significant in nine studies. Differences in mean endpoint BMI between intervention and control groups are statistically significant in eight studies.

Beside the significance of results it is also important to give attention to the clinical relevance of these results. According to the UK Department of Health (Department of Health 2006) reductions in body weight of 5.0% or more are considered to greatly reduce the risks of physical health problems. In the included trials in our review, no study achieved this target. Moreover, only in a limited number

of studies the weight loss resulted in changes of BMI classification (e.g. from obesity to overweight or from overweight to normal weight). In this sense, participants in the studies included in the review may lose weight following a lifestyle intervention but still remain in the overweight or obesity class. It can thus be questioned to what extent the BMI is useful to identify the risk for developing CVD. It appears that, according to the results of several studies, the measurement of the waist circumference and the waist-hip ratio is more appropriate than measuring the BMI to estimate the risk for future cardiovascular events (Dalton *et al.* 2003, Janssen *et al.* 2004). It is important to note that in all 14 trials participants were taking atypical antipsychotics. It is well known that these drugs cause weight gain (Parsons *et al.* 2009). Furthermore, there is conclusive evidence that persons with severe mental disorders are more likely having sedentary lifestyles, making poor dietary choices and are more likely to smoke (Henderson *et al.* 2006).

In eight studies included in the review, no information was provided about the weighing process (time of weighing, scale, clothing). The remaining six studies provided, however not always detailed, information about the weighing process. To minimize weighing errors, patients should be weighed at the same time of day using the same scale and in light clothing without shoes (Collins and Friedrich L 2009). Including this information in the methods section of studies is important to enable an appropriate assessment of the results. According to the results of a study of weight measurement protocols no advantage was found about measurement of weight on two separate days compared with measurement on a single day (Maruthur *et al.* 2010). However, as far as we know, literature on this topic is scarce and further studies evaluating weight measurement procedures are required.

There are some limitations to acknowledge. For this review, only references from the period 01/03/1990 until 01/03/2010 were included. In this way, it is possible that we miss relevant papers from the period before 1990.

The trials included in this review are frequently limited in terms of small sample sizes, short intervention periods and absence of long-term follow up. This raises questions about the generalization of the results to wider populations with mental disorders. In their review, Lowe & Lubos (Lowe and Lubos 2008) concluded that the current literature on weight reduction interventions appears to provide limited evidence on the effectiveness either of psycho educational or of programs including educational and exercise components. They also concluded that more research is needed, with larger sample sizes as well as standardized outcome measures to determine and compare the effectiveness of these kinds of interventions.

The focus of the review considered ‘healthy living interventions’ in persons with severe mental disorders. This created a broad spectrum of ‘healthy living interventions’ topics and approaches.

From a research perspective it may have been more appropriate only investigating one type of intervention. However, people with severe mental disorders share many risk factors, so it appears that general interventions will be more beneficial (Brown and Chan 2006). Weight management programs through healthy eating, exercise and tobacco cessation should be integrated into mental health care (Robson and Gray 2007). In this sense, it was decided to include randomized and non-randomized controlled trials with focus on health promotion interventions targeting physical activity and eating habits with primary outcomes changes in weight and BMI. Beside 'healthy living interventions' also pharmacological interventions to control weight gain in persons with mental disorders have been evaluated. In a review of pharmacological and non-pharmacological interventions to control weight in persons with schizophrenia, the authors concluded that non-pharmacological interventions are preferable . The promising results in the non-pharmacological studies must however be tempered by weaker designs and small sample sizes used in these studies (Faulkner *et al.* 2003). According to the results of a review on the mechanisms and management of antipsychotic weight gain in schizophrenia, it was concluded that pharmacological agents like orlistat and sibutramine have not been sufficiently evaluated in antipsychotic weight gain (Rege 2008).

Despite the limitations, it is promising that small decreases of body weight and BMI in this population are possible. It appears that health promotion interventions targeting physical activity and eating habits in persons with severe mental disorders may be useful for prevention of weight gain. It is yet important to note that there may be some patients (outliers) that may derive tremendous benefit, but that the mean changes observed in the group are modest. Categorical outcomes would enable the calculation of the number needed to treat for the observation of a clinically significant benefit for the intervention. Only one study (Wu *et al.* 2008) reported confidence intervals around the changes in weight or BMI. Data on confidence intervals could however give insight in the ranges and thus in the solidness of weight changes.

Furthermore, persons with mental health problems usually want to learn more about healthy lifestyles and background theories of lifestyle interventions (Crone and Guy 2008, Schmutte *et al.* 2009). In a study of perceptions of barriers to and benefits of physical activity among patients with severe mental disorders, participants saw exercise as positive and desirable, with benefits for both physical and mental health (McDevitt *et al.* 2006). This suggests that persons with severe mental disorders are prepared to participate in health promotion interventions.

Such findings support the integration of health promotion interventions targeting physical activity and eating habits into mental health care, whereby patients should be motivated to follow these kinds of interventions. When health promotion becomes a part of daily care, mental health

professionals could play an important role in motivating their patients to participate. According to patients' perceptions mental health professionals can provide support, motivation, and structure and they feel comfortable with this support (Shiner *et al.* 2008).

Elements of QOL were only investigated in five studies, providing no homogeneity of the effectiveness of 'healthy living interventions' on QOL and general health. Yet, improvements in QOL were, although not always statistically significant, observed. This is important because weight gain is associated with perceptions of poorer QOL and general health (Allison *et al.* 2003).

As far as known to the authors, this is the first systematic review of 'healthy living interventions' targeting physical activity and eating habits in persons with severe mental disorders, in which special attention was given if any of the included studies also examined the cost-effectiveness of these interventions. There is a growing need on health economic research in health care and health policy. Especially, attention is given to health economic evaluations of medicines and technologies. Recently, more attention is given to health economic evaluations of preventive health care. In general populations, research on cost-effectiveness of 'healthy living interventions' produces no conclusive evidence (Muller-Riemenschneider *et al.* 2009, Roux *et al.* 2008), which is likely explained by wide differences in program contents. In persons with severe mental disorders, no studies examining the cost-effectiveness of 'healthy living interventions' targeting physical activity and eating habits were found. Yet, such research has a great social value. Prevention has an economic cost, but it can also save money because diseases and complications can be avoided. Finally, prevention can produce healthy life expectation.

Eight of 14 studies included in this review were conducted in the US. Because of differences in e.g. the management of health care, health insurance systems, and access to hospital care further studies, especially in European countries examining both effectiveness and cost-effectiveness of lifestyle interventions targeting physical activity and eating habits in persons with severe mental disorders are required to assist in the development of new health promotion interventions in this population. Concerning cost-effectiveness of interventions the viewpoint for the analysis (e.g. point of view of society, the Ministry of Health, the patient) should be carefully considered. Emphasis should also be put on long-term effects of these kinds of interventions.

CONCLUSIONS

This review demonstrated that, however not always statistically significant, small improvements in body weight, BMI and QOL in persons with severe mental disorders are possible through health promotion interventions targeting physical activity and eating habits. In this sense, it appears to be relevant to integrate these kinds of interventions into the daily care of this population. Further research on both effectiveness and cost-effectiveness of lifestyle interventions on physical activity and eating habits in this population is required to assist in the development of new health promotion interventions. Additional qualitative research on perceptions of health promotion of both mental health professionals and patients appears to be relevant. This information can be useful when editing and implementing lifestyle interventions on physical activity and eating habits in mental health care.

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CHAPTER 3

Perceptions of mental health nurses and patients about health promotion in mental health care: a literature review

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ABSTRACT

The aim of this review was to examine the perceptions of patients with mental disorders and mental health nurses of health promotion targeting physical activity and eating habits in mental health care. An electronic search strategy was conducted. Furthermore, references were searched by hand-searching the reference lists of the retrieved articles from the electronic databases. The literature on perceptions of health promotion and lifestyle interventions in mental health care principally consist of qualitative studies using interviews and focus groups. Positive perceptions of both mental health nurses and patients towards health promotion targeting physical activity and eating habits in mental health care were identified. Contrary, several barriers for integrating healthy lifestyles into the daily life of patients were described. Patients usually want to learn more about healthy lifestyles, but see the ability to change their physical health as beyond their control. In this sense, support from mental health nurses is considered as important. Despite the awareness of the importance of health promotion in mental health care, it appears that visions and attitudes towards the potential of health promotion are in need of change.

INTRODUCTION

A healthy lifestyle, including physical activity and good eating habits contributes to a better health. Furthermore, this diminishes the risk of some of the most common diseases, such as coronary heart disease (CHD), cerebrovascular disease, hypertension, diabetes, and osteoporosis (Vuori 2001). In addition, such a lifestyle appears to decrease contributing factors like overweight and obesity (Chaput *et al.* 2007).

People with mental disorders are at increased risk of being overweight or having obesity (Coodin 2001, Filik *et al.* 2006). Moreover, the prevalence of related diseases such as CHD, respiratory diseases and diabetes mellitus is even higher among these people than among those in the general population (Mackin *et al.* 2007, Osborn *et al.* 2006). The higher prevalence of these conditions appears to be, at least partially, the consequence of lifestyle factors. There is conclusive evidence showing that people with mental disorders have more sedentary lifestyles, which include having less mild or strenuous forms of physical activity (Brown *et al.* 1999, Osborn *et al.* 2007), and make poorer dietary choices, compared with the general population (Roick *et al.* 2007, Strassnig *et al.* 2003).

This raises even more concern given the increased risk of premature death in persons with mental disorders in comparison with the general population (Harris and Barraclough 1998, Mortensen and Juel 1993). Important causes of this premature mortality are, besides suicide, natural causes such as CHD, respiratory diseases, and cancer (Lawrence *et al.* 2003, Osby *et al.* 2001).

In this sense, there is conclusive 'medical evidence' of implementing lifestyle interventions on physical activity and eating habits in mental health care. However, besides this medical evidence other factors could support the applicability of health promotion interventions in daily practice. These additional factors could be defined as the 'contextual evidence' (De Maeseneer *et al.* 2003). Important questions in health services concern the organization and culture of those who provide health care, such as why the findings of randomized controlled trials are often difficult to apply in day-to-day clinical practice. Therefore, qualitative research can be complementary to quantitative methods by developing concepts, which help to understand social phenomena in health care settings. So, emphasis can be given to the meanings, experiences, and views of participants (Pope and Mays 1995).

The aim of this review is to examine the perceptions of patients with mental disorders and mental health nurses of health promotion targeting physical activity and eating habits in mental health care.

METHODS

The electronic database Medline was searched using the search string '(Mental Health Nursing OR Mental Health Professionals) AND (Health Promotion [MeSH])'. This search produced 694 references. First, a selection was made based on title and/or abstract. References were included if they referred to qualitative studies of perceptions of mental health nurses or patients of health promotion targeting physical activity and eating habits in mental health care. Patients were defined as persons aged 18 year and older with mental disorders irrespective of a specific diagnosis and living in inpatient or outpatient settings. For this review, mental health nurses comprised nurses caring for these patients in in- and outpatient mental health care. Health promotion was considered as a broad spectrum of interventions targeting the (unhealthy) lifestyles of patients with mental disorders, whereby special attention was given to studies focusing on perceptions of mental health nurses and patients regarding the effects of physical activity and eating habits. This selection on title and/or abstract produced 11 references. In addition, nine references were found by hand-searching the references of the retrieved articles of the initial search.

The full text of these 20 articles was then evaluated on the above mentioned inclusion criteria. After the full text evaluation, four papers were excluded. The quality of the remaining 16 studies was then assessed using the 'Critical appraisal checklist Programme' for qualitative research (Critical Appraisal Skills Programme Collaboration 2006). After this selection, 14 articles were considered appropriate for this review.

RESULTS

Design and target groups

The design and target groups of the studies included in the review are listed in table 1. The participants of eight trials consisted of patients receiving outpatient or community-based mental health care. The target group of only one study (Svedberg *et al.* 2004) comprised inpatients, while in two other studies both in- and outpatients were included. The target population of only one study (Fogarty and Happell 2005) included patients with a specific diagnosis (schizophrenia). In the other trials (n=10) targeting persons with mental disorders, patients could be included irrespective of their psychiatric diagnosis. Six of these studies provided no information of the diagnoses of participants. In only one study (Sorensen 2006), the motivation for the inclusion of participants independent from their specific diagnosis was reported.

Table 1 Target groups and design of included studies

author	target group	number	design
(Svedberg *et al.* 2003)	patients	12	individual interviews
(Faulkner and Biddle 2002)	mental health nurses	12	individual interviews
(Jormfeldt *et al.* 2003)	mental health nurses	12	individual interviews
(MacHaffie 2002)	patients	41	questionnaire and individual interviews
(Pitkanen *et al.* 2008)	patients	35	individual interviews
(McDevitt *et al.* 2006)	patients	34	focus groups
(Sorensen 2006)	patients	109	questionnaires
(Svedberg *et al.* 2004)	patients	12	individual interviews
(Ussher *et al.* 2007)	patients	120	individual interviews
(Crone and Guy 2008)	patients	11	focus groups
(Jormfeldt *et al.* 2007)	mental health nurses	12	individual interviews
(Shiner *et al.* 2008)	patients	8	individual interviews
(Carless and Douglas 2008)	patients	11	individual interviews
Fogarty & Happell (2005)	patients	6	focus groups
	mental health nurses	6	focus groups

Benefits of healthy living

In two studies of the benefits of an exercise program for people with mental disorders, participants described themselves as becoming more active and experiencing considerable improvement in their physical capacity and fitness (Crone and Guy 2008, Fogarty and Happell 2005). Beside these somatic benefits, physical activity can also influence the psychological health of people with mental disorders. In a study of the effects of health promotion, mental health nurses stated that exercise could reduce a number of negative mood states experienced by patients, such as frustration, aggression, anger, anxiety, stress, and tension. Participants were also aware that physical activity could improve health-related quality of life (Faulkner and Biddle 2002). In another study, participating patients reported that, by gaining control over aspects of their health through diet and exercise, they gained self-confidence through developing new social skills and healthy behaviors and an enhanced sense of self-efficacy (Ussher *et al.* 2007) (table 2).

Table 2 Benefits and barriers of health promotion in mental health care

Benefits	Barriers
improvement in physical capacity	**Reported by patients**
improvement in fitness	mental illness itself
decrease of negative mood states	side effects of medication
improvement of health-related quality of life	absence of support
self-confidence and self-efficacy	financial barriers
development of social skills	stigma
	Reported by MH nurses
	poor motivation
	unwillingness to participate

MH nurses= mental health nurses

Barriers to participate in lifestyle interventions

Barriers identified by both mental health nurses and patients in the studies included in the review are listed in table 2. Especially, barriers related to the mental disorder itself were reported: lack of initiative, which is a defining symptom of psychotic and affective disorders and side effects of medication like sedation (McDevitt *et al.* 2006, Shiner *et al.* 2008, Ussher *et al.* 2007).

Health promotion: perceptions of mental health nurses

In a study of perceptions of mental health nurses of the promotion of physical activity, all participants were extremely positive regarding the potential role of exercise within inpatient settings. Furthermore, they believed that there should be greater promotion of physical activity (Faulkner and Biddle 2002). However, in a study about mental health nurses' conceptions of health promotion in mental health care, half of the respondents stated that they felt more secure focusing on disease, because of the association with the traditional nursing role (Jormfeldt *et al.* 2003). In acute mental health care settings, physical activity is sometimes considered as a lifestyle choice and not as 'treatment', because treatment would not be seen as a lifestyle choice (Faulkner and Biddle 2002). Subsequently, the question as to who is responsible for the patient's health and his lifestyle choices can be raised. According to the results of a study on health promotion in mental health nursing, respondents considered it to be important to follow the patients in their process of defining their own needs and desires, even if a conflict with their treatment may arise. The aim is to strengthen the patient's ability to trust himself or herself through making their own decisions and taking the consequences of these decisions with support from the mental health nurse (Jormfeldt *et al.* 2003).

Health promotion: perceptions of people with mental disorders

The results of a study of experiences with sports therapy among persons with mental disorders indicated that participants usually want to learn more about healthy lifestyles and background theories of lifestyle interventions (Crone and Guy 2008). They feel themselves able to identify ways in which they think they could be healthier (MacHaffie 2002).

In a study of perceptions of barriers and benefits of physical activity among outpatients in psychiatric rehabilitation, participants considered physical activity as positive and desirable, with benefits for both physical and mental health (McDevitt *et al.* 2006). However, in another study more nuanced perceptions were described by patients (Sorensen 2006). Thirty percent of the participants experienced no change in their illness symptoms during physical activity and another 11% reported an increase in illness symptoms. The main reason for this was that exercise made them think more about their problems.

It appears that patients feel comfortable with the support of mental health nurses. In a cross-sectional survey among 120 patients, a majority agreed or strongly agreed that they would exercise more if they talked with an instructor or were advised by their physician to do so (Ussher *et al.* 2007). Similar results were found in a qualitative evaluation of a health promotion program in mental health care (Shiner *et al.* 2008). Participants described that the health mentor provided direction, structure and motivation. For example, membership by itself was not enough to ensure that participants actually went to the gym.

Finally, patients find it important to be treated with dignity and respect. If not seen as individuals, their ability to develop health processes will be negatively affected. Mutuality in the relationship with the mental health nurse is described as an important factor for the promotion of health processes (Svedberg *et al.* 2003).

DISCUSSION

As far as known to the authors, this is the first review of the literature on perceptions of mental health nurses and patients of health promotion targeting physical activity and eating habits in mental health care.

The findings indicate that, according to the perceptions of mental health nurses and patients, healthy lifestyles including physical activity and eating habits contribute to a better physical and mental health. However, several barriers to integrate physical activity and healthy eating habits into daily life are reported. In general, both mental health nurses and patients are positive towards the potential

of integrating health promotion targeting physical activity and eating habits into daily care. Nevertheless, beliefs and attitudes specifically towards the promotion of this lifestyle issues for patients in mental health care appear to be in need of change.

The target population of only one study (Fogarty and Happell 2005) consisted of patients with a specific diagnosis. In the other studies on perceptions of patients, participants could be included irrespective of their psychiatric diagnosis. However, the results of this review indicate that barriers to participate in lifestyle interventions may vary according to the mental disorder itself. In their review, Richardson et al. (Richardson *et al.* 2005) argued that health promotion interventions in mental health care targeting specific groups or tailored to the individual are more effective in increasing levels of physical activity.

Growing attention is given to the effects of 'healthy living interventions' targeting physical activity and eating habits. In the general population, the effectiveness of such interventions is already well established (Clark *et al.* 2004, Eriksson *et al.* 2006). Furthermore, several guidelines already emphasized the importance of physical activity and healthy eating as contributing to a better physical and mental health (NICE 2006, U.S.Department of Health and Human Services 2008, World Health Organization 2004). The relevance of health promotion in mental health care is also acknowledged by the European Psychiatric Association declaring that maintaining a healthy body weight and shape by healthy eating and regular physical activity is a key component in order to reduce the risk of some important somatic diseases and to improve the overall health and well-being of persons with mental disorders (De Hert M. *et al.* 2009). According to the results of several studies of weight management programs including exercise and healthy eating in mental health care, significant weight reduction in this population is possible (Mauri *et al.* 2008, McKibbin *et al.* 2006). The results of these trials must however be cautiously interpreted because they are limited by small sample sizes and short intervention periods. Nevertheless, it is promising that small weight reduction in this population is possible.

Health promotion targeting physical activity and healthy eating should be integrated into the daily care of persons with mental disorders (Robson and Gray 2007). According to the findings of some of the qualitative studies included in this review, it appears that mental health nurses feel more secure about focusing on the mental health problems of patients rather than addressing issues of health promotion. Nurse educational programs must therefore teach mental health nurses how to recognize the potential for health promotion opportunities, as well as how to develop and plan for health promotion so that it becomes a recognized part of planned practice (Casey 2007).

Several barriers to integrate physical activity and healthy eating habits in the daily routine of this population were reported by both mental health nurses and patients. Yet, the findings of this review demonstrate that persons with mental disorders usually want to learn more about healthy lifestyles. This is congruent with the results of a study of knowledge of nutrition and healthy lifestyles among inpatients with schizophrenia. Knowledge of these issues improved significantly following a single 30 minutes education program (Wirshing *et al.* 2006).

According to the findings of the current review, support from mental health nurses appears to be an element of concern for people with mental disorders. The results of two studies (Shiner *et al.* 2008, Ussher *et al.* 2007) included in this review reported that patients feel comfortable with support in changing their lifestyle to more physical activity and better eating habits. Support provides direction, structure and motivation. This is important because self-efficacy or confidence in one's ability to overcome barriers to regular physical activity is a strong predictor of physical activity (Trost *et al.* 2002). This is also congruent with the results of a study on the nurse-client relationship in which participating mental health nurses stated that being present for their patients was probably the most important factor in this relationship (O'Brien 2000). Still, mental health nurses are working alongside other professionals like psychiatrists, psychologists, psychotherapists, occupational therapists… whereby all are having their role in supporting the patients in making healthy lifestyle choices. According to Robson and Gray (Robson and Gray 2007) an active collaboration between mental health nurses and other professionals is required to design health promotion programs.

It can be questioned to what extent the unhealthy lifestyles of persons with mental disorders can be exclusively associated with the mental health problem. Also in the general population the diet is characterized by eating more fat and sugars and decreased levels of physical activity (Kennedy 2005). Nevertheless, it is disturbing that persons with mental disorders are having even more unhealthy lifestyles, compared to the general population (Osborn *et al.* 2007, Roick *et al.* 2007).

The literature on perceptions of mental health nurses and patients of health promotion and lifestyle interventions in mental health care principally consist of qualitative studies using interviews and focus groups. A common limitation in this kind of research is the impracticality of using large, representative samples in order to collect data. As a consequence, it is questionable whether results can be generalized to a wider population (Horberg *et al.* 2004). However, the goal in qualitative research is not to generalize to larger populations but to gain insight and understanding by hearing from people in depth whereby meanings, experiences, and visions of participants can be emphasized (Morgan 1998, Pope and Mays 1995).

The inclusion of only qualitative studies of health promotion regarding physical activity and eating habits is another limitation of this review. Other lifestyle issues such as smoking habits and alcohol use were not included. In addition, no distinction was made between inpatient and outpatient settings in the analysis of the findings. We are aware that eating habits and levels of physical activity between in- and outpatients may vary. For example, in inpatient settings patients do not have to cook for themselves, and exercise may probably be integrated into their program. In the studies included in the review, no references towards these potential differences were provided. Analysis of qualitative research of perceptions of health promotion targeting physical activity and eating habits in inpatient and outpatient settings may probably lead to different results.

For this review, studies targeting patients irrespective of their psychiatric diagnosis were eligible for inclusion. Although this can be interpreted as a limitation, health promotion targeting physical activity and healthy eating, given the significant burden of overweight and obesity in this population, is important for all patients with mental disorders independent from the diagnosis.

In conclusion, the results of this review provide 'contextual evidence' of different aspects of perceptions of both mental health nurses and patients of health promotion in mental health care. First, positive perceptions of both mental health nurses and patients towards the potential of health promotion targeting physical activity and eating habits in mental health care could be identified. This is an important conclusion given the extent of overweight and obesity in this population. Secondly, several barriers hampering the integration of health promotion into the daily care of this population were described. Despite the awareness of the importance of health promotion in mental health care, it appears that visions and attitudes towards the potential of health promotion are in need of change.

Consequently, further qualitative research how to overcome the reported barriers is required. This can provide significant information when editing lifestyle interventions in mental health care. Some of the reported barriers are associated with the mental disorder itself. Therefore, special attention towards the perceptions of health promotion of patients with different diagnoses is required.

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CHAPTER 4

Health promotion in mental health care: perceptions from patients and mental health nurses

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ABSTRACT

Aims and objectives. To gain insight into the factors influencing the integration of physical activity and healthy eating into the daily care of individuals with mental disorders living in sheltered housing and to increase the understanding of the relationships between and complexities of these factors.

Background. Growing attention is given to the implementation of health promotion activities in mental health care. By improving the understanding of perceptions of patients and mental health nurses, health promotion programs targeting physical activity and healthy eating can be developed that better meet the patients' needs.

Design. A descriptive qualitative study.

Methods. Based on a purposive sampling strategy, three focus groups including 17 mental health nurses and individual interviews with 15 patients were conducted.

Results. Although physical and mental health benefits of physical activity and healthy eating were identified, several barriers to integrate healthy lifestyles into the daily life of patients were reported. Important barriers identified by the patients consisted of lack of energy and motivation as a result of the mental disorder, side effects of psychotropic drug use, and hospitalization. Lack of time and personal views and attitudes towards health promotion were reported by the mental health nurses as important elements influencing the way in which they integrate health promotion in the care provided. Support from the mental health nurse was considered important by the patients in changing their unhealthy lifestyle behavior.

Conclusions. The results of the study provide insight into important factors influencing the integration of health promotion activities targeting physical activity and healthy eating in individuals with mental disorder living in sheltered housing.

Relevance to clinical practice. The information derived from this study is useful and relevant in the design and implementation of health promotion interventions targeting physical activity and healthy eating in people with mental disorders living in sheltered housing.

INTRODUCTION

People with mental disorders are at increased risk of being overweight or obese (Filik *et al.* 2006a, Saarni *et al.* 2009). The higher prevalence of these conditions appears to be, at least partially, the consequence of more sedentary lifestyle behavior (Brown *et al.* 1999a, Osborn *et al.* 2007a) and more unhealthy eating habits (Roick *et al.* 2007a, Strassnig *et al.* 2003a), compared with the general population. Growing attention is given to the implementation of health promotion activities in mental health care, but a limited understanding of health promotion is a significant barrier to effective nursing-related health promotion in mental health care (Whitehead 2009). Despite previous research on benefits and barriers to integrate healthy lifestyle behavior into the daily life of people with mental disorders more research is needed to increase the understanding of the relationships and complexities of these factors.

BACKGROUND

Individuals with mental disorders including schizophrenia, schizoaffective disorders, bipolar and depressive disorders are at increased risk of being overweight or obese. For example, Filik et al. (Filik *et al.* 2006b) found a body mass index (BMI) of ≥30 kg/m² in 34.9% of a group of schizophrenia patients, compared with 19.4% in the general population. In another study, a mean BMI of 29.9 kg/m² was found in a sample of individuals with mental disorders. Mean BMI in the controls without mental disorder was 25.6 (Mackin *et al.* 2007). The high prevalence of these conditions contributes to the substantial burden of coronary heart disease (CHD), respiratory diseases and diabetes mellitus in this population (Hennekens *et al.* 2005, Mackin *et al.* 2007, Osborn *et al.* 2006).

The high prevalence of overweight and obesity in individuals with mental disorders is associated with both treatment-related and lifestyle behavior elements. It is well established that especially second generation antipsychotics (SGAs) cause weight gain. The degree of weight gain can vary according to the type of antipsychotic drug used (Allison and Casey 2001, Parsons *et al.* 2009).People with mental disorders also make poorer dietary choices such as eating less frequently food recommended for large consumption (e.g. fresh fruit, vegetables, wholegrain bread, rice) and more instant meals (Henderson *et al.* 2006, McCreadie 2003, Roick *et al.* 2007b) and fat (Brown *et al.* 1999b), and having less variety of food in their diet compared with the general population (Strassnig *et al.* 2003b). These dietary behaviors are associated with weight gain, overweight and obesity (World Health Organisation and UN Food and Agriculture Organisation 2003). Conflicting evidence exists regarding the physical activity levels of this population. The results of some studies indicate that people with mental disorders have a more sedentary lifestyle including less moderate or vigorous physical activity

(Brown *et al.* 1999c, Osborn *et al.* 2007b), while other studies conclude that this population show more or less similar physical activity levels compared with the general population or physical activity guidelines. Nevertheless, also the latter studies conclude that efforts to increase physical activity levels in this population are required (Jerome *et al.* 2009, McLeod *et al.* 2009).

There is growing recognition that weight management programs through healthy eating and physical activity should be integrated into the daily care of people with mental disorders (Robson and Gray 2007). Integration of such interventions in mental health care may have some important advantages: frequent contact with and support of the mental health nurse can play a critical role in behavior change, and barriers related to the mental disorder can be more appropriately addressed (Richardson *et al.* 2005a). However, several factors influence the integration of health promotion interventions into daily practice. Important questions in health services concern the organization and culture of those who provide health care. These factors could be defined as the 'contextual evidence' (De Maeseneer *et al.* 2003).

Previous principally qualitative research already identified a number of benefits of and barriers to integrate regular physical activity and healthy eating into the daily life of individuals with mental disorders. For example, both physical and mental benefits of regular physical activity and healthy eating were reported by patients (Crone and Guy 2008, Shiner *et al.* 2008) and by mental health nurses (Faulkner and Biddle 2002a). Barriers to healthy lifestyles consist of barriers related to the mental disorder itself such as the absence of motivation (avolition), which is a defining symptom of psychotic and affective disorders, side effects of medication such as sedation (McDevitt *et al.* 2006), absence of support from others (Ussher *et al.* 2007), and feeling vulnerable and unsafe out in public and fear of being identified as a person with mental disorders (McDevitt *et al.* 2006).

The findings of some studies also indicate that visions and attitudes towards the potential of health promotion in mental health care are in need of change (Jerden *et al.* 2006, Jormfeldt *et al.* 2003a). For example, in the study of Jerden et al. (Jerden *et al.* 2006), the mental health nurses described a discrepancy between their own personal attitude towards health promotion and the actual conduct of health promotion as secondary to more disease-oriented work. It can be questioned to what extent lifestyle choices are the responsibility of the patient or the mental health nurse. Mental health nurses considered it important to follow the patients in their process of defining their own needs and desires, even if it sometimes conflicts with the treatment. They described their role as to strengthen the patients' ability to trust themselves through making their own decisions and taking the consequences of these decisions with support from the staff (Jormfeldt *et al.* 2003a). According to patients' perceptions, mental health nurses can provide support, motivation, and structure and they feel comfortable with it (Shiner *et al.* 2008).

A number of factors influencing the integration of health promotion activities targeting physical activity and healthy eating in mental health care have thus yet been identified. Little research however exists concerning the relationships and complexities of these factors influencing the physical activity levels and eating habits of individuals with mental disorders. It is also not clear if the identified factors are congruent with those that will be identified by individuals with mental disorders and mental health nurses in the specific context of sheltered housing. By improving the understanding of concerns of patients and mental health nurses health promotion programs targeting physical activity and healthy eating can be developed that better meet the patients' and nurses' needs.

The aim of the study was to examine the factors influencing the integration of physical activity and healthy eating into the daily care of individuals with mental disorders living in sheltered housing and to gain insight into the relationships and complexities of these factors. Subsequently, the information derived from this study was to be used in the development of a health promotion intervention targeting physical activity and healthy eating in sheltered housing in the Flanders region (Belgium).

METHODS AND DESIGN

Design

The study had a descriptive qualitative design using focus groups (mental health nurses) and individual interviews (patients), based on a purposive sampling strategy. This kind of sampling chooses the participants according to the projects' goals to gain insight and understanding by hearing from respondents in depth (Morgan DL 1998). By using focus groups and interviews it was possible to get more insight into the perceptions of patients and mental health nurses about health promotion targeting physical activity and eating habits in mental health care.

Setting and recruitment of participants

The study population comprised patients with mental disorders living in sheltered housing and mental health nurses working in these settings in the Flanders region (Belgium). In Belgium, sheltered housing arose as a result of the shift from the traditional inpatient care to more outpatient care facilities. It is aimed at individuals with a wide variety of mental disorders (e.g. schizophrenia, mood disorders, personality disorders, substance abuse) aged 18 years and older who do not need to stay in a mental health care inpatient facility on permanent basis. The main goal is the psychiatric rehabilitation of the patient (often called 'resident'). In the rehabilitation process, patients receive support to develop the emotional, social and intellectual skills needed to live, learn and work in the community with the least amount of support (Anthony *et al.* 2002).The residents are encouraged to

do as much possible for themselves such as self-care, shopping, cooking, domestic chores… with support of the mental health nurse. People can live alone or together with other residents in 'community houses'. The specific context of sheltered housing strongly influences the resident – mental health nurse relationship. The relationship is different from that in inpatient facilities in a sense that the nurse enters into the private living environment of the patient. Also, the institutional background of the psychiatric inpatient facility is absent which provides a certain authority to the mental health nurse (Sheltered Housing Federation 2004).

The managers of three sheltered housing organizations (SHOs) were informed, both orally and in writing about the study. They were asked to inform their team of mental health nurses and ask whether they were prepared to participate in the focus groups. The nurses of all three SHOs agreed to participate. To ensure that not only patients already being interested and living a more or less healthy lifestyle should be included, the mental health nurses of the three participating SHOs were asked to recruit preferably five patients per SHO. They were asked to recruit patients accounting for an adequate representation of both genders, different age, psychiatric diagnosis (as sheltered housing is aimed at individuals with a wide variety of diagnoses) and lifestyle behavior (i.e. physical activity and eating habits). The aim was to recruit individuals relevant to the study purpose and to collect a wide variety of information on perceptions of patients about health promotion in mental health care. The nurses were also asked to only recruit residents who were cognitively able (assessed by the mental health nurses) to understand and participate in the interview. Finally, all practical issues were discussed with the managers (date, duration of the focus groups and interviews, informed consent).

The sample of mental health nurses consisted of 17 participants (13 females, 4 males) with a mean age of 34.8±8.9 years. Average working years in sheltered housing was 9.7±6.4 years. Fifteen patients (6 females, 9 males) agreed to participate in the study. Mean age was 43.0±13.4 years. Mean length of stay in sheltered housing was 5.6±5.2 years.

Data collection

A semi structured guideline (separately for the patients and nurses) including questions about health promotion targeting physical activity and eating habits was developed. The topics of the questionnaire were based on the items addressed in the background section (i.e. benefits and barriers, the integration of regular physical activity and healthy eating into the daily care of patients, and the role of the mental health nurse) and on the results of a previous literature review performed by the research team on perceptions of mental health nurses and patients about health promotion in mental health care (Verhaeghe *et al.* 2011). The purpose of the guideline was to achieve an open

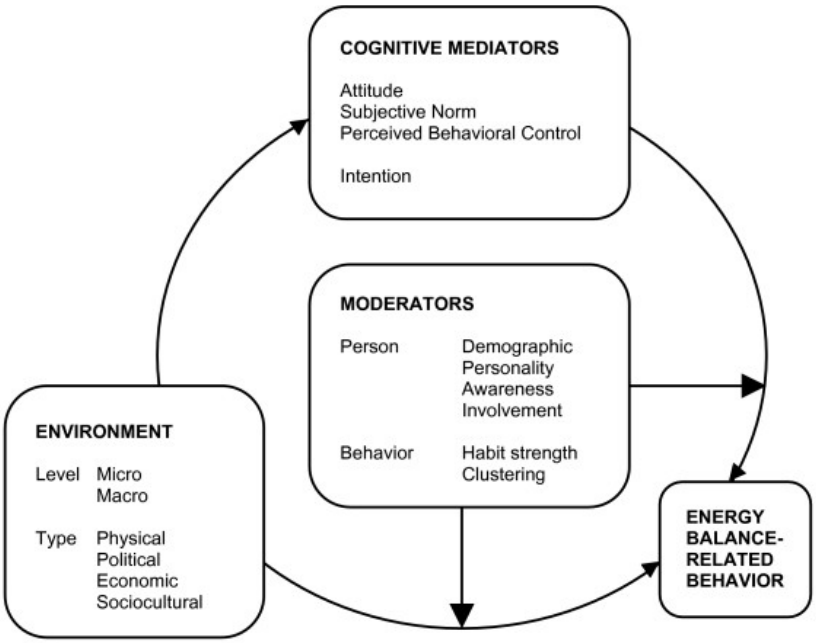
discussion to increase the understanding of the perceptions of the participants and to ensure consistency in questions asked across the focus groups and interviews. The discussion guide used in the focus groups with the mental health nurses included the following topics: knowledge and importance of regular physical activity and healthy eating for patients, the integration of health promotion targeting physical activity and healthy eating into the daily care, and the role of the mental health nurse in this process. The questionnaire used in the interviews with the patients comprised the following topics: knowledge and importance of a healthy lifestyle, perceived support from the mental health nurses, benefits and barriers to a healthy lifestyle, and the integration of health promotion activities targeting physical activity and healthy eating into the daily care.

To analyze the obtained data, the focus groups and interviews were audio taped with a digital Dictaphone. The focus groups lasted about 1.5 hours and were conducted in the offices of the SHOs in the period December 2009. The interviews lasted between 30 and 45 minutes and were also conducted in the offices or at the participants' home in the period December 2009-January 2010. The focus groups and individual interviews were conducted by the same member of the research team.

Data analysis

The "Environmental Research Framework for Weight Gain Prevention" (EnRG framework) (Kremers *et al.* 2006) was used to gain insight into the relationships and complexities of the factors influencing the integration of physical activity and healthy eating into the daily care of individuals with mental disorders in sheltered housing. The EnRG framework (figure 1) is a useful tool to gain insight into the behaviors that may positively or negatively influence the dietary and physical activity behavior and into the causal mechanisms that underlie these behaviors.

Figure 1 The EnRG framework



In brief, the framework consists of environmental determinants that influence dietary and physical activity behavior both directly and indirectly. The indirect causal mechanism reflects the mediating role of behavior-specific cognitions in the influence of the environment on behavior. The direct influence reflects the automatic influence of the environment on behavior (Kremers *et al.* 2006).

Qualitative content analysis techniques (Krueger RA 1998) were used to analyze the obtained data. First, the audio taped data were transcribed verbatim by the interviewer and completed with additional notes taken during the focus groups and interviews and read through several times to become familiar with the diversity of the data and to get an overall impression. Next, standard thematic analysis was performed by one researcher (NV) to analyze the transcripts. In this process, statements were identified and grouped to develop categories. Within these categories a search for similarities and differences in the statements was performed. This resulted in a report including the key findings of the focus groups and one with the results of the interviews. In addition, quotations were searched that appeared eligible for the report. The integrated results from the study were read by all co-authors to discuss the reproduction and interpretation of the analysis.

Ethics

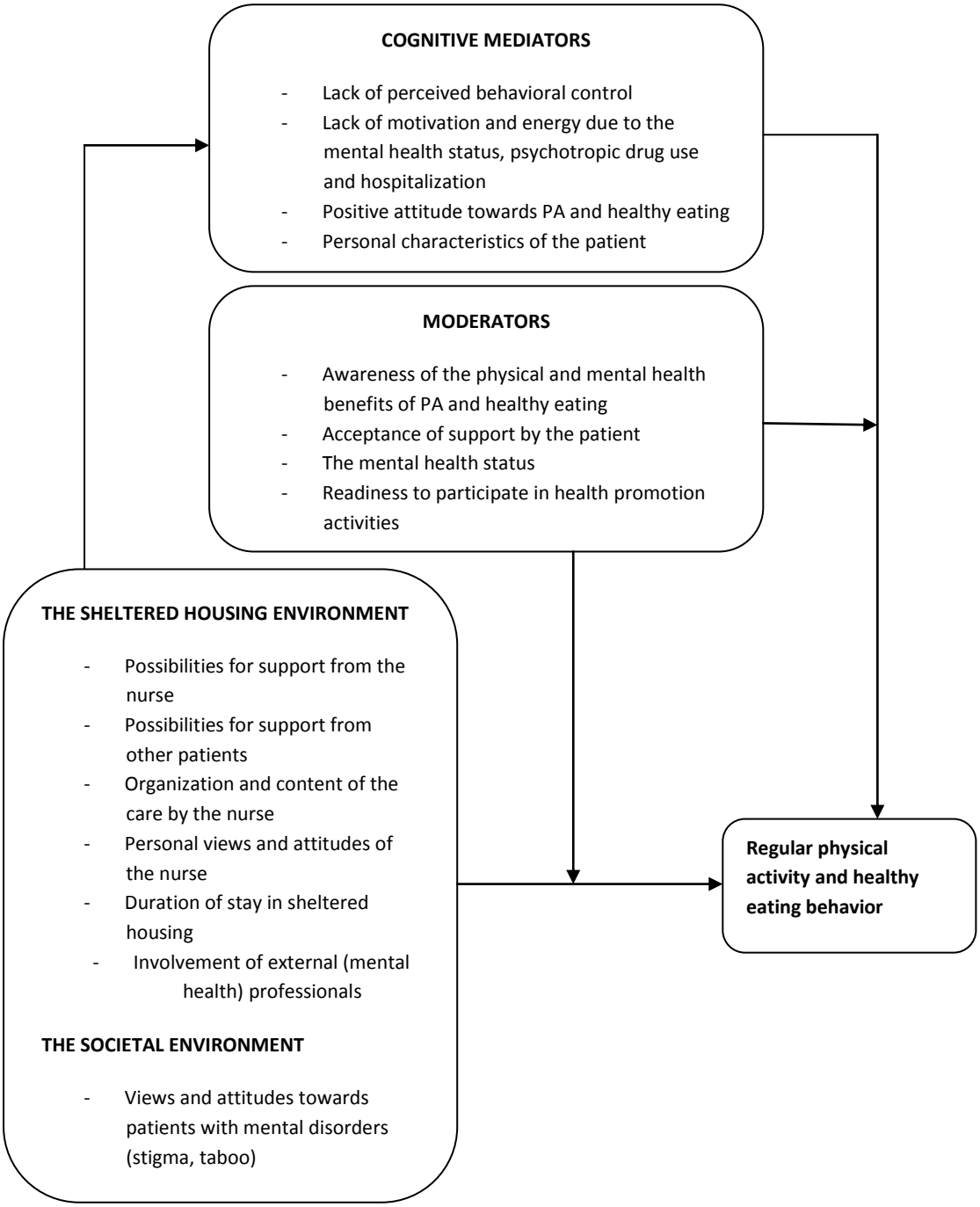
Permission to perform the study was obtained from the Ethics Committee of the University Hospital of Ghent (Belgium). A written informed consent was obtained from all the participants. They were informed that participation in the study was voluntary, and that the data analysis would be

anonymous. They were also informed that the audio taped data would be erased after the data analysis and that they could withdraw from the study at any time. At the time of the interview, it was repeated that the participant could withdraw from the study at any time.

RESULTS

Figure 2 provides a schematic overview of the results obtained from the study based on the EnRG framework (Kremers *et al.* 2006). The different items that are included into the framework are described in detail below.

Figure 2 Adapted EnRG framework, "Physical activity and eating behavior in sheltered housing



Awareness of the importance of physical activity and healthy eating

All participating patients and mental health nurses identified physical activity and healthy eating as beneficial for the physical health (e.g. general health, physical shape). Beside these benefits also mental health benefits like distraction, less stress and frustration, and social contacts were reported. As one patient mentioned:

> *'When I go for a run, it enables me to get rid of some stress. I usually meet the same runners and we run some time together. In this sense, it gives me the opportunity to get to know these guys and I feel good about it'*

Barriers of regular physical activity and healthy eating

Despite the identified physical and mental benefits, several barriers to change unhealthy lifestyle behavior were reported. There was agreement among the mental health nurses that the mental disorder itself could negatively affect physical activity levels and eating habits. For example, no energy to cook or to exercise was frequently reported to be present in people having a depressive disorder. This was congruent with the perceptions of some patients. The use of psychotropic drugs was another identified barrier to engage in health promotion activities.

> *'When I am feeling down or depressed, I have almost no energy. In these periods, I have to take more psychotropic drugs, resulting in even less energy'*

Admission to an inpatient mental health care facility was also identified by some patients as a barrier. They reported having no motivation or energy to focus on healthy lifestyle behavior as a result of the severity of the mental suffering during the hospitalization.

According to the majority of the participating mental health nurses, personal characteristics of the patients such as the readiness and motivation to change unhealthy lifestyle behavior are an important element. A lack of mental flexibility was reported as common in populations of people with mental disorders resulting in little or even no readiness or flexibility to change unhealthy behaviors. In this sense, respondents described discussing lifestyle issues with their patients as sometimes useless or frustrating.

> *'Sometimes, you don't discuss lifestyle issues any longer because of the lack of results. Inherently, it depends on the readiness of the individual to change unhealthy lifestyle behavior. Some patients refuse to work on it'*

This is congruent with the opinion of most of the patients declaring that lack of motivation, due to the mental disorder is a major barrier.

> *'When I am feeling depressed, it is very difficult to motivate myself to cook or to exercise. It takes too much energy. Energy that I do not have in these periods'*

Mental health nurses commonly reported lack of time as an important issue. They stated that most of the patients living in sheltered housing suffer from a wide variety of problems (e.g. psychiatric, financial, administrative, relational problems). Both patients and nurses identified the views and attitudes of the society as a barrier to integrate individuals with mental disorders into sport clubs or leisure time organizations and activities.

> *'It is not easy for our target population to participate into sport clubs. They are regularly faced with taboos and prejudices from these organizations. As a consequence, our residents are having fear or have no longer the motivation to integrate into these organizations'*

Health promotion: the importance of support from mental health nurses

Support and discussing lifestyle issues was considered important and desirable by a majority of the participating patients because it made them feel respected as an individual. They stated that, by asking them about lifestyle issues, mental health nurses showed interest. Moreover, some patients described that they indeed would follow the advice of the mental health nurse.

> *'When she [nurse] gives me advice how to cook using healthy ingredients or to go to the fitness, I would follow this advice. The fact that she mentions it means for me that there is a problem. In this sense, I would follow her advice'*

Three patients reported that they never discussed lifestyle issues because there were *'already enough other domains of care to discuss'*, *'already doing enough for my health'*, and because of *'feeling ashamed to discuss these items'*.

The mental health nurses considered themselves as the most appropriate persons to support the patients in changing their unhealthy lifestyles. No consensus although existed if it is desirable to invoke external (mental health) professionals in the promotion of healthy lifestyles. Some argued that involving external professionals can be beneficial and required. Others disagreed by questioning to what extent non-mental health professionals are familiar to work with people with mental disorders.

The visions and attitudes of the mental health nurses regarding the importance of physical activity and healthy eating as part of the treatment process is another key element. There was no agreement about the responsibility of nurses to change unhealthy lifestyles. Some stated that healthy lifestyles have to be stimulated by the nurses, but attributed the main responsibility to the patients with a supporting role of the nurse.

> *' You can stimulate healthy lifestyle behavior, but finally it is him or her [the patient] responsibility to change their unhealthy lifestyle behavior'*

Others found it important only to discuss unhealthy lifestyle behavior when it was directly associated with the mental disorder itself, even if the patient disagreed.

> *'Unless the unhealthy behavior is directly associated with the MD, to my opinion, lifestyle issues pertain to the private life of our patients'*

Two mental health nurses questioned whether it is always recommended to intervene into lifestyle issues of their patients. In each focus group, some respondents stated that their own vision towards physical activity and eating habits influences the way in which they provide care.

> *'Do we have to insist that patients live a healthy lifestyle? Often, the unhealthy eating habits are more or less considered as compensation for the mental suffering?'*

The integration of health promotion activities into the daily care

There was agreement among the participating nurses that the integration of health promotion activities targeting physical activity and healthy eating into the daily care of patients is time consuming. Health promotion was considered as a continuous process of discussing and motivating patients to change their unhealthy lifestyles. Contrary, the organization and content of the care resulting in lack of time to focus on the integration of physical activity and healthy eating was reported by the majority of the nurses. There was agreement that the possibility to successfully change unhealthy lifestyle behavior increased as people are staying longer in sheltered housing. This was explained by the fact that stability on other domains of care was a prerequisite to focus on health promotion activities.

The results also indicated that the majority of the participating patients were interested in informative and educational sessions targeting physical activity and healthy eating. Eleven of 15 respondents expressed their interest in such sessions. Nine preferred group sessions above individual sessions. Reported reasons were social contacts, to learn from each other, to exchange experiences, and to receive advice and support.

DISCUSSION

The aim of this study was to examine the factors influencing the integration of physical activity and healthy eating in individuals with mental disorders living in sheltered housing and to gain insight into the relationships and complexities of these factors. Although physical and mental health benefits of physical activity and healthy eating are described by the respondents, several barriers to integrate this healthy lifestyle behavior into the daily life are identified. The findings indicate that support from the mental health nurses is considered desirable and important by the participating patients. This is congruent with the vision of the participating mental health nurses considering themselves as most appropriate to support the patients in changing their unhealthy lifestyles. Lack of time is however reported by the mental health nurses as an important barrier to integrate health promotion activities into the daily care of patients. A majority of the interviewed patients expresses interest in informative and educational sessions targeting physical activity and healthy eating, whereby group sessions are preferred.

The EnRG framework is developed as a guide to gain insight into the behaviors that may influence the dietary and physical activity behavior and into the causal mechanisms that underlie these behaviors (Kremers *et al.* 2006). It was in this sense a useful tool to analyze the data obtained from the study. We are however aware that, based on the data that was collected, it was not possible to represent all the elements that are incorporated in the model as shown in figure 1. Nevertheless, it enabled us to gain insight into some important behaviors influencing the integration of physical activity and healthy eating into the daily care of individuals with mental disorders living in sheltered housing.

In our study, support from the mental health nurses to change unhealthy lifestyle behaviors was identified by the participating patients as a substantial need. Contrary, despite the awareness of the mental health nurses of the physical and mental health benefits of regular physical activity and healthy eating, lack of time was identified as an important barrier to focus on health promotion targeting physical activity and healthy eating. Beside lack of time, the views and attitudes of mental health nurses towards physical activity and eating habits also influenced the way in which they integrated health promotion in their work. From the literature, other important reasons hampering the integration of physical activity and healthy eating into mental health care were already identified by mental health nurses such as feeling more secure when focusing on the mental disorder, because of the association with the traditional nursing role (Jormfeldt *et al.* 2003b). In acute mental health care settings, physical activity is sometimes considered as a lifestyle choice and not as ‘treatment’ (Faulkner and Biddle 2002b). Nurse educational programs must therefore teach nurses how to

recognize the potential for health promotion opportunities, as well as how to develop and plan for health promotion so that it becomes a recognized part of the treatment (Casey 2007) .

Several barriers to integrate regular physical activity and healthy eating into the daily life were reported by the participating patients. Some of them are attributed to the mental disorder itself such as no energy as a result from the mental disorder, side effects of psychotropic medication, and hospital admission. Ameliorating the health of this population through diet and exercise is also complicated by the mental disorder itself, poverty, poor access to medical care and the stigma associated with both the mental disorder and obesity (Dragatsi and Deakins 2009). For example, in a study of perceptions of patients with mental disorders living in group home facilities, several respondents argued that they had little energy for exercise due to psychiatric medication and physical health limitations (Xiong *et al.* 2010).

A study of the acceptability of physical activity programming for individuals with mental disorders showed that the majority of the 109 respondents described being interested in assistance in becoming more active and eating a healthier diet (Faulkner *et al.* 2007). A majority of the patients in our study described being interested to participate in preferably group-based health promotion programs. This is in agreement with the results of previous research on the effectiveness of a structured exercise program for people with mental disorders. Participants who completed the intervention reported the value of group support both from other members as from staff (Pelletier *et al.* 2005). However, in a review of integrating physical activity into mental health services, the authors concluded that, especially in people with mental disorders, individual interventions play an important role in behavior change (Richardson *et al.* 2005b).

The participating mental health nurses agreed that they have to stimulate healthy lifestyle choices of the patients, but the main responsibility is attributed to the latter. Similar results were found in a study about nurses' conceptions of health promotion in mental health care. The participants reported that they have to strengthen the patients' ability to make their own decisions and taking the consequences of these decisions with support from the nurse (Jormfeldt *et al.* 2003a). Encouraging and supporting patients to live an independent life is one of the mental health nurses' main areas of responsibility. However, if the patients' mental state is deteriorating, the nurse must take control (Magnusson *et al.* 2004).

The literature on perceptions of mental health nurses and patients about health promotion in mental health care principally consist of qualitative studies using interviews and focus groups. A common limitation of this kind of research is the impracticality of using large, representative samples to collect data. As a consequence, it is questionable whether results can be generalized to a wider

population (Horberg *et al.* 2004). However, it is not the purpose in qualitative research to generalize to larger populations but to gain insight and understanding by hearing from people in depth whereby meanings, experiences, and visions of participants can be emphasized (Morgan DL 1998, Pope and Mays 1995). By using focus groups and interviews it was our aim to receive more insight into the perceptions of patients and mental health nurses about health promotion targeting physical activity and eating habits in mental health care. In this sense, it appeared appropriate to involve the mental health nurses of the three SHOs in the recruitment process of patients to participate. By using this purposive sampling strategy, it was the aim to avoid the selection of only patients already living a more or less healthy lifestyle or contrary only selecting people with unhealthy lifestyle behavior. This allowed us to recruit individuals who would be relevant to the study purpose and be the most informative in answering the questions.

The focus of this study was to gain insight into the perceptions of patients and mental health nurses in sheltered housing which is aimed at individuals with 'severe and persistent psychiatric difficulties' (Sheltered Housing Federation 2004). It is also already well established that overweight and obesity is affecting individuals with mental disorders irrespective of their psychiatric diagnosis (Davidson *et al.* 2001, Dickerson *et al.* 2006, Mackin *et al.* 2007). In this sense, health promotion targeting physical activity and healthy eating is likely to be important for individuals with mental disorders independent from their diagnosis. For these reasons, we decided to include not only individuals with a specific diagnosis. Further research is yet required to examine if tailoring of health promotion activities for specific diagnosis groups is desirable. We are aware that lifestyle behavior also comprises other lifestyle issues like smoking habits and alcohol use. The target population of this study consisted of patients living in sheltered housing. It is important to note that eating habits and physical activity levels between inpatients and outpatients may vary. For example, in inpatient settings patients do not have to cook for themselves, and exercise may probably be a part of the treatment. Analysis of qualitative research of perceptions of health promotion targeting physical activity and healthy eating in inpatient and outpatient settings may probably lead to different results.

Growing attention is given to the effects of 'healthy living interventions' targeting physical activity and healthy eating. In the general population, the effectiveness of such interventions is already well established (Clark *et al.* 2004, Eriksson *et al.* 2006). Furthermore, several guidelines already emphasized the importance of physical activity and healthy eating as contributing to a better physical and mental health (NICE 2006, U.S.Department of Health and Human Services 2008). The relevance of health promotion in mental health care is also acknowledged by the European Psychiatric Association declaring that maintaining a healthy body weight and shape by healthy eating and regular physical activity is a key component in order to reduce the risk of some important somatic

diseases and to improve the overall health and well-being of people with mental disorders (De Hert M. *et al.* 2009). A limited understanding of health promotion is an significant barrier to effective nursing-related health promotion in mental health care. The main challenge for nursing is how to effectively integrate and apply health promotion principles into practice. Considering health promotion in this context requires an understanding of how an individual's health is influenced by social, cultural, political, and economical conditions in which he lives (Whitehead 2009). Health promotion activities for particular target populations such as people with mental disorders are complex interventions referring to the fact that these interventions could be aimed at several domains like physical activity, healthy eating, smoking cessation… that are to be adapted to and offered next to other important treatment aspects like psychological and medical treatment. Complexity also refers to the context within the health promotion intervention is offered, like the characteristics of the population, the health service provision model, cultural aspects… To our opinion, this paper provides a contribution to the knowledge about the context by providing insight into the factors influencing the lifestyle behavior of people with mental disorders living in sheltered housing.

CONCLUSION

The results of the current study contribute to the understanding of the factors influencing the integration of health promotion activities targeting physical activity and healthy eating in individuals with mental disorders living in sheltered housing and into the relationships and complexities of these factors. Both physical and mental benefits of regular physical activity and healthy eating were identified. However, several barriers hampering the integration of healthy lifestyle behavior into the daily life were also identified. Different perceptions about the responsibility to change unhealthy lifestyles were reported.

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CHAPTER 5

Health promotion intervention in mental health care: design and baseline findings of a cluster preference randomized controlled trial

Verhaeghe N, De Maeseneer J, Maes L, Van Heeringen C, Bogaert V, Clays E, De Bacquer D, Annemans L.
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ABSTRACT

Background: Growing attention is given to the effects of health promotion programs targeting physical activity and healthy eating in individuals with mental disorders. The design of evaluation studies of public health interventions poses several problems and the current literature appears to provide only limited evidence on the effectiveness of such programs. The aim of the study is to examine the effectiveness and cost-effectiveness of a health promotion intervention targeting physical activity and healthy eating in individuals with mental disorders living in sheltered housing. In this paper, the design of the study and baseline findings are described.

Methods/design: The design consists of a cluster preference randomized controlled trial. All sheltered housing organizations in the Flanders region (Belgium) were asked if they were interested to participate in the study and if they were having a preference to serve as intervention or control group. Those without a preference were randomly assigned to the intervention or control group. Individuals in the intervention group receive a 10-week health promotion intervention above their treatment as usual. Outcome assessments occur at baseline, at 10 and at 36 weeks. The primary outcomes include body weight, Body Mass Index, waist circumference, and fat mass. Secondary outcomes consist of physical activity levels, eating habits, health-related quality of life and psychiatric symptom severity. Cost-effectiveness of the intervention will be examined by calculating the Cost-Effectiveness ratio and through economic modeling. Twenty-five sheltered housing organizations agreed to participate. On the individual level 324 patients were willing to participate, including 225 individuals in the intervention group and 99 individuals in the control group. At baseline , no statistical significant differences between the two groups were found for the primary outcome variables.

Discussion: This is the first trial evaluating both the effectiveness and cost-effectiveness of a health promotion intervention targeting physical activity and health eating in mental health care using a cluster preference randomized controlled design. The baseline characteristics already demonstrate the unhealthy condition of the study population.

Trial registration: This study is registered at clinicaltrials.gov – NCT 01336946

BACKGROUND

People with mental disorders are at increased risk for overweight (Body Mass Index 25-29 kg/m²) and obesity (Body Mass Index >30 kg/m²) compared with the general population (Filik *et al.* 2006, Limosin *et al.* 2008). Beside the side effects of especially atypical antipsychotics on body weight (Parsons *et al.* 2009), the higher prevalence of these conditions is associated with more sedentary lifestyles, which include less mild or strenuous forms of physical activity (Brown *et al.* 1999, Osborn *et al.* 2007), and poorer dietary choices compared with the general population (Roick *et al.* 2007, Strassnig *et al.* 2003).

Growing attention is given to the effects of lifestyle interventions targeting physical activity and healthy eating in mental health care. The importance of health promotion in mental health care is acknowledged by the European Psychiatric Association declaring that maintaining a healthy body weight and shape by healthy eating and regular physical activity is a key component in order to reduce the risk of some important somatic diseases and to improve the overall health and well-being of patients (De Hert M. *et al.* 2009). However, the current literature on weight reduction interventions in mental health care appears to provide only limited evidence on the effectiveness of either psycho-educational programs or programs combining educational and exercise components (Lowe and Lubos 2008).

Most attention of health economic research goes to health economic evaluations of medicines and technologies. Recently, more emphasis is given to health economic evaluations of preventive health care. In general populations, these kind of studies yield no conclusive evidence (Muller-Riemenschneider *et al.* 2009, Roux *et al.* 2008), which is probably explained by wide differences in program contents. In mental health care, the cost-effectiveness of health promotion interventions targeting physical activity and healthy eating has thus far not been investigated (Verhaeghe *et al.* 2011). Consequently, the study of both the effectiveness and cost-effectiveness of health promotion interventions targeting physical activity and eating habits in mental health care is required to determine and compare the efficiency of these kinds of interventions.

The design of evaluation studies of public health interventions, like health promotion interventions, poses several problems and they require multiple, flexible, and community driven strategies (Rychetnik *et al.* 2002). In most clinical trials, participants are randomized as individuals to intervention or control groups. However, when individual randomization is not possible or desirable, groups of individuals can be randomized to intervention or control groups (Puffer *et al.* 2003). This kind of design is known as a cluster or group or community randomized trial (Christie *et al.* 2009). According to the British Medical Research Council (Medical Research Council 2002) a cluster randomized design has to be considered when the intervention is designed to be delivered to groups

rather than to individuals. Cluster randomization may also be appropriate when there is a risk of contamination, i.e. when individuals randomized to the intervention group may influence others within the group (Christie *et al.* 2009).

Another concern in studies evaluating behavioral or psychosocial interventions is that the participants are typically informed about their experimental assignment soon after randomization. Being assigned to a non-preferred intervention condition could be disappointing, or even demoralizing and reduce participants' interest to participate so that they may withdraw from the study (Howard and Thornicroft 2006, Macias *et al.* 2009). An alternative design for the randomized controlled trial is the 'patient preference design', in which subjects are allowed to select the intervention assignment. Preference designs are useful when strong preferences among potential participants threaten either the ability to recruit an adequate sample size of representative participants or when such preferences threaten participants' acceptance of treatment assignment, adherence, or retention in the trial (TenHave *et al.* 2003).

This paper describes the design and baseline findings of a health promotion intervention targeting physical activity and healthy eating in people with mental disorders living in sheltered housing, whereby the above mentioned design issues were accounted for. Our design is innovative in a way that preference occurred at the level of the sheltered housing organization (SHO) and not on the level of the individual patients. The description of the study protocol is in agreement with the checklist of the CONSORT statement for cluster randomized trials (Campbell *et al.* 2004).

METHODS AND DESIGN

Aim of the study and hypotheses

The aim of the study is to evaluate the effectiveness and cost-effectiveness of a health promotion intervention targeting physical activity and healthy eating in people with mental disorders living in sheltered housing. We hypothesize that:

- Between baseline and the end of the intervention and after a 6-month follow up period, significant differences in the primary outcomes 'body weight', 'Body Mass Index' (BMI), 'waist circumference', 'fat mass' between the intervention and control group will be identified;
- Between baseline and the end of the intervention and after a 6-month follow up period, significant differences in the secondary outcomes 'quality of life' (QOL), 'PA levels', 'eating

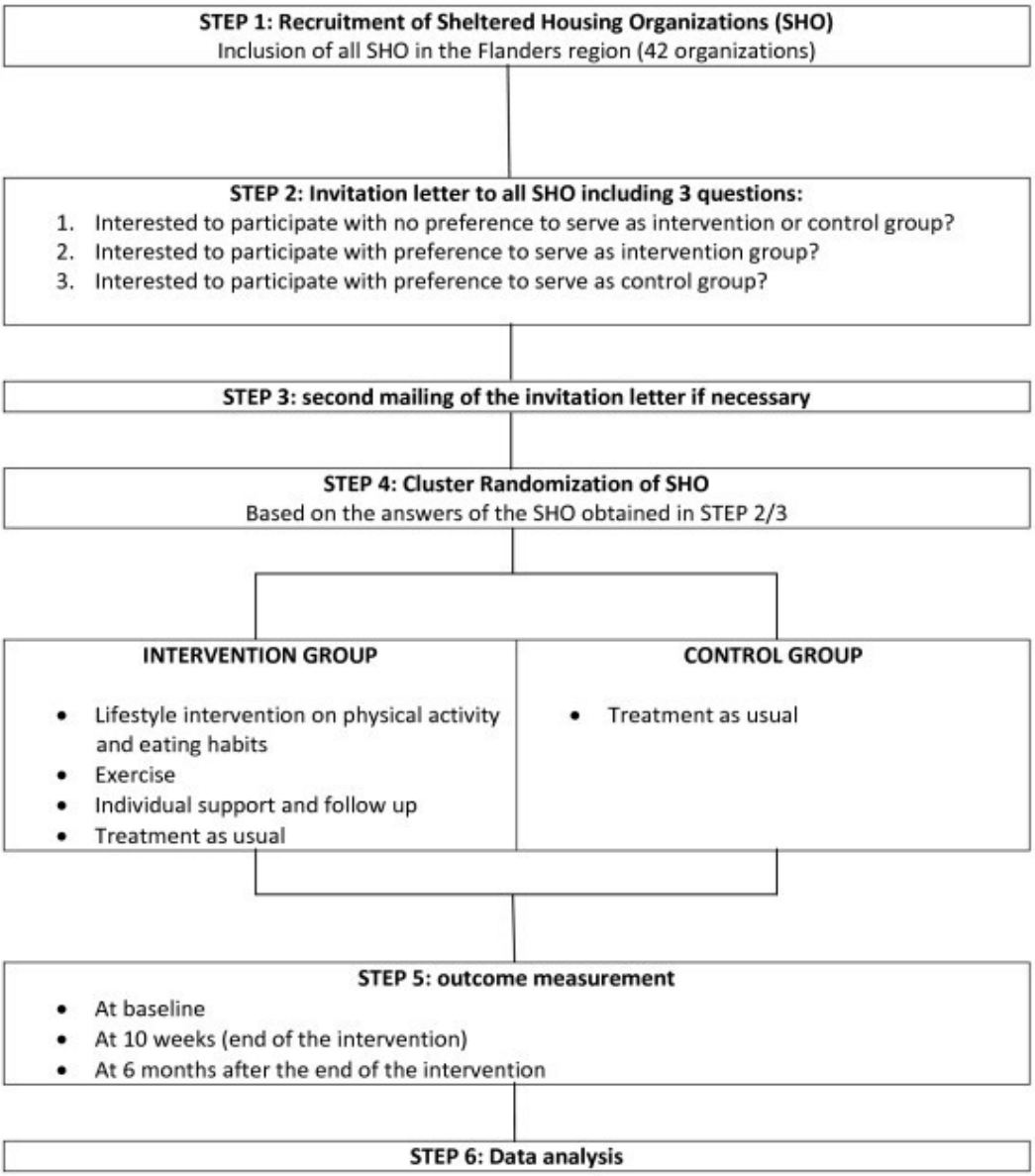
habits', and 'psychiatric symptom severity' between the intervention and the control group will be identified;

- The health promotion intervention is cost-effective.

Study design and setting

The design consisted of a cluster preference randomized controlled trial. An overview of the study design can be found in figure 1.

Figure 1 Health promotion intervention: Study design



The study was conducted in sheltered housing organizations (SHOs) in the Flanders region (Belgium) with the SHOs as the unit of randomization. In SHOs, support on several domains (e.g. psychological, domestically, occupational, relational) is offered to the patients. In this type of health care service, patients are living alone in a studio or apartment or together with other patients in 'community houses'. For this reason, cluster randomization was appropriate. Individual randomization at the level of the individual patient would decisively cause contamination bias due to the risk of participants in the intervention and control group living together. Cluster randomization to the intervention or control group therefore occurred at the level of the SHOs.

Mental health professionals working in the intervention SHOs were asked to lead and to support the health promotion intervention. This implied a significant involvement and workload above their usual workload. Also, as mentioned before, centers being assigned to a non-preferred intervention could be disappointed, which may reduce their interest to participate in the study. Moreover, a substantial risk of non-participation was also assumed based on the results of previous qualitative research indicating that lack of time due to the high workload in the daily care of patients is a common barrier for mental health professionals to engage in health promotion programs (Casey 2007, Jerden *et al.* 2006). Consequently, it appeared to be necessary to provide a detailed explanation about the expectations when serving as an intervention SHO. For this reason, preference randomization appears to be appropriate.

An invitation letter and response form with a self-addressed postage envelope was sent to the managers of all SHOs in the Flanders region. They were asked if they were interested to participate in the study having (i) no preference to serve as intervention or control group and to be randomized or, (ii) a preference to serve as intervention group (see a detailed description of the intervention below) or, (iii) a preference to serve as control group. A concise explanation of the aim of the study and of the expectations and content when participating as intervention group was included in the letter. If necessary, a second mailing was foreseen. If a SHO was not prepared to participate, they were asked to report the reason for non-participation.

Subsequently, based on the responses, SHOs were either assigned to the intervention or control group according to their preference or randomly assigned to the intervention or control group when they expressed no preference. Randomization occurred by an external person not involved in the study. Finally, the patients living in the intervention and control SHOs received both written and oral information about the study. The written information consisted of a detailed explanation about the study and an informed consent.

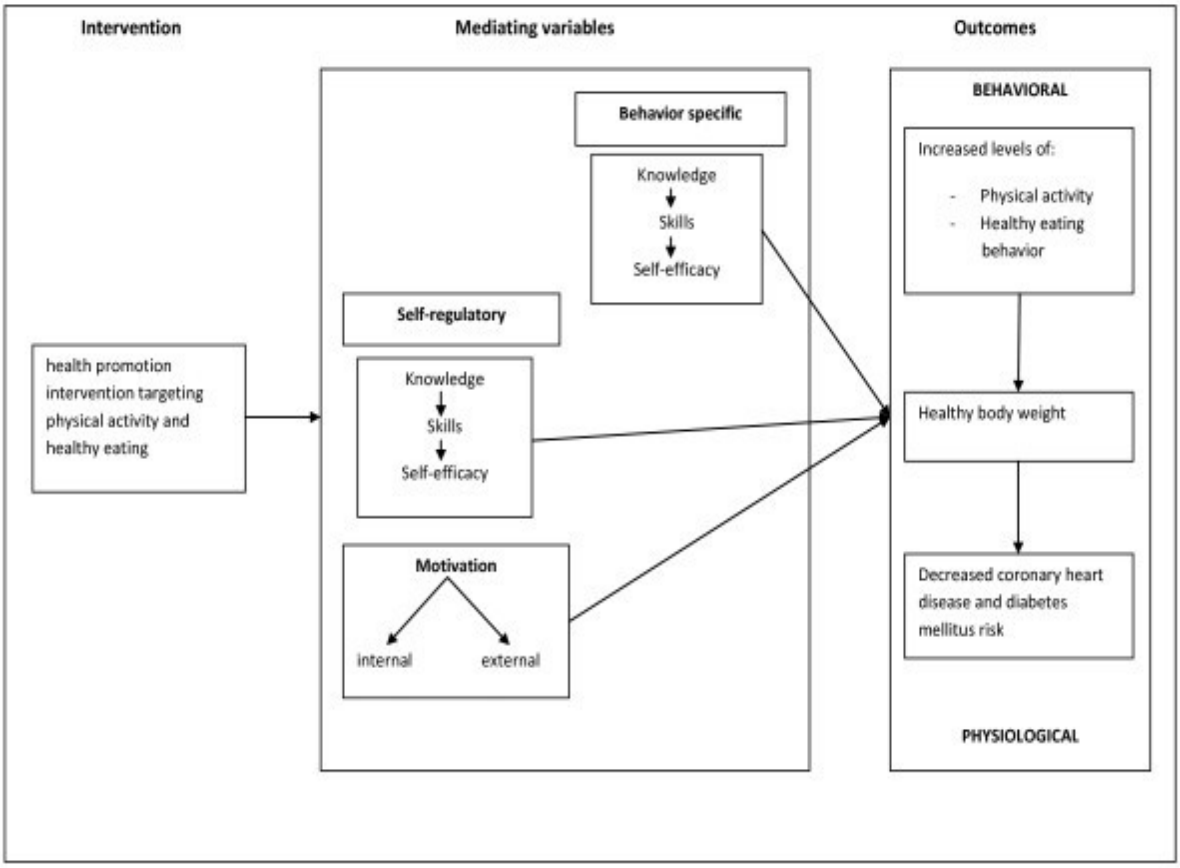
Study population

The study population consisted of people with mental disorders aged between 18 and 75 years living in a SHO in the Flanders region (Belgium). There are 42 SHOs in the Flanders region, including 2662 approved places (Federal Public Service Health 2011). Exclusion criteria included people aged <18 or older than 75 years, having a gastric ring or pacemaker placed , having cognitive impairments (assessed by the mental health professionals) compromising the understanding of the psycho-educational and behavioral sessions of the health promotion intervention.

Development of the materials

The theoretical framework of the intervention was developed using elements of several theories including the social-cognitive theory (Bandura 2004), the self-determination theory (Ryan and Deci 2000), and the control theory (Carver and Scheier 1982). The health promotion intervention was developed using the mediating variable approach including the mediating variables knowledge, skills, self-efficacy and motivation (Bandura 2004, Ryan and Deci 2000). A schematic overview of the theoretical framework can be found in figure 2.

Figure 2 Theoretical framework of the health promotion intervention targeting PA and healthy eating



Knowledge is a necessary component of behavior change (Bandura 2004). For example, how to select appropriate food portion sizes, how to distinguish between sedentary and moderate or vigorous physical activities. Behavior-specific skills are those specifically related to the targeted behavior (Thompson *et al.* 2010). For example, how to interpret the level of physical shape by measuring the pulse rate. Self-regulatory skills include goal setting and problem solving (Thompson *et al.* 2010). Self-efficacy is confidence in one's ability to successfully perform a task or behavior and is influenced in two ways: personal success and observing others successfully perform the behavior (Bandura 2004). Two types of motivation can be distinguished. People can be motivated because they value an activity either from a sense of personal commitment or because there is strong external motivation and support (Ryan and Deci 2000).

The staff manual was developed based on the manual 'Health promotion on well-balanced eating and healthy physical activity' developed by the Flemish Institute of Health Promotion and Disease Prevention (Flemish Institute of Health Promotion and Disease Prevention 2007). As the target population of this manual is the general population , some adjustments were made to focus especially on the lifestyle behavior of our target population (for example how to choose a more healthy lifestyle despite the presence of barriers associated with the mental disorder). The manual was built around ten themes focusing on physical activity and healthy eating: 1) physical activity and healthy eating: Introduction, 2) Awareness of the consumption of fat and fibers, 3) A healthy lifestyle: advantages and barriers, 4) The food triangle, 5) Using the food triangle throughout the day, 6) Label reading, 7) The influence of the environment & Budget issues, 8) & 9) Physical activity, 10) A quiz regarding physical activity and healthy eating.

Study duration and intervention components

The study period consists of an intervention period of 10 weeks followed by a post-intervention period of six months. In addition to treatment as usual, the intervention groups (n=14) receives the 10-week health promotion program targeting physical activity and healthy eating. In the intervention group the following intervention components are offered:

- Psycho-educational and behavioral group sessions

This part of the program consists of 10 group sessions in a 10-week period and includes discussions on physical activity and healthy eating, problem solving, written exercises, quizzes and plans to increase physical activity levels and to stimulate a more healthy eating behavior. All participants in the intervention group receive the same information in the same format. The program is delivered by the mental health professionals working in the intervention SHOs.

- Supervised exercise

In the same 10-weeks period a weekly 30-minutes supervised walking session is organized. These sessions are also led by one or more mental health professionals.

- Individual counseling

During the 10-week intervention period, all participants in the intervention group receive individual support from the mental health professionals (for example motivation to persist, discussing of experiences).

Implementation of the intervention

The manager of each SHO in the intervention group was asked to discuss with their team of mental health professionals the selection of one or two persons, who would serve as contact person with the research team and who would be responsible for the sessions. Every intervention SHO was visited by the same researcher. The aim of this visit was to instruct the mental health professionals who would lead and supervise the sessions. Preferably, also other staff members were present during this training session. During the study period, it is possible to contact one of the researchers by phone or e-mail. If necessary, visits of one of the researchers to the SHO will also be possible.

Evaluation of the intervention

At the end of the study period, a process evaluation of the health promotion program will be organized for all participating SHOs in the intervention group. This evaluation will consist of a questionnaire with both closed and open-ended questions including topics on experiences, advantages and disadvantages of the program, lessons learned, and suggestions for further research.

Sample size calculation

The sample size calculation is based on an average change of the primary outcome body weight of 3.5 kg between the intervention and the control group at the end of the study. This change is based on the results of a previous literature review performed by the research team on the effectiveness and cost-effectiveness of lifestyle interventions on physical activity and eating habits in people with mental disorders (Verhaeghe *et al.* 2011). Cluster randomized trials require larger sample sizes than the individually randomized design. This can be explained by the fact that observations on individuals in the same cluster tend to be correlated, and so the effective sample size is less than the total number of individual participants. This reduction in effective sample size and the degree of correlation within clusters is known as the intraclass correlation coefficient (ICC) (Campbell *et al.*

2004, Hayes and Bennett 1999). As no ICC for this kind of intervention in people with mental disorders was found in the literature, an assumption was made by multiplying the sample size with a design factor of 1.5. A sample size of 371 participants in each group would provide a sample large enough to detect a difference in mean body weight change of 3.5 kg across the two groups with 80% power at a significance level of 0.05.

Data collection and outcome measurements

Sociodemographics

Participants will be asked to complete a questionnaire on sociodemographics including sex, age, duration of stay in sheltered housing, marital status, occupational status, contacts with relatives, tobacco and alcohol use, and medication use.

Primary outcome measures

The primary outcomes of the study consists of changes in body weight, BMI, waist circumference and fat mass. Body weight is measured in all participants wearing light clothing without shoes by a member of the research team using a TANITA BC-420 SMA digital weighing scale (TANITA, Tokyo, Japan). A member of the research team measures height in a standardized way using a Seca 225 stadiometer (Seca GmbH & KG, Hamburg, Germany). The BMI is calculated by dividing the body weight in kilograms by the square of the height in meters. Waist circumference is measured with a Seca 200 tape (Seca GmbH & KG, Hamburg, Germany) by one of the researchers according to the guidelines described in the National Heart, Lung, and Blood Institute report 'Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults. The evidence report' (National Heart Lung and Blood Institute 1998). The calculation of the fat mass occurs using the TANITA BC-420 SMA digital weighing scale (TANITA, Tokyo, Japan). This occurs at the same time as the weight assessment. Both the stadiometer and the digital weighing scale were placed on a flat surface to assure correct measurement of height, body weight, and fat mass.

Secondary outcome measures

Changes in physical activity are assessed using the Dutch long version of the self-administered International Physical Activity Questionnaire (IPAQ), as this questionnaire appears to be a reliable and valid physical activity measurement tool (Vandelanotte *et al.* 2005). The analysis of the IPAQ is based on self-reported data. Therefore, physical activity levels are also measured using pedometers as a more objective tool. The Yamax Digiwalker SW-200 (Yamax, Tokyo, Japan) is used as this is known as accurate and reliable for counting steps (Crouter *et al.* 2003). Dietary habits of the

participants are assessed using an adapted version for adults of the "Young Children's Nutrition Assessment on the Web" (Vereecken *et al.* 2009). Quality of life is assessed using the SF-36 Health Survey questionnaire. Finally, psychiatric symptom severity is assessed through the use of the Brief Symptom Inventory (BSI). This questionnaire is considered as a reliable and a valid tool useful in patient groups with different psychiatric diagnoses (de Beurs and Zitman F 2005).

Data on all primary and secondary outcome measures are collected at baseline and at 10 weeks. At the end of the study (at 36 weeks) only data on body weight, waist circumference and fat mass will be collected and BMI will be calculated. At that time participants will be asked to only complete again the SF-36 Health Survey.

Cost-effectiveness

As there is growing need for health economic research in health care and health policy, the cost-effectiveness of the health promotion intervention will also be examined. This will occur by calculating the difference in costs between intervention and no intervention (usual care), by calculating the expected health gain expressed in quality-adjusted life years (QALY) through health economic modeling, and by calculating the Incremental Cost-Effectiveness Ratio (ICER). The ICER is calculated as the ratio of the net cost to the net health gain: $ICER = (COST_I - COST_{NI}) / (QALY_I - QALY_{NI})$ where I is intervention and NI is no intervention.

QALYs are calculated by multiplying the utility level for a given disease status (a health-related quality-of-life weight ranging between 0 and 1) with the number of years an individual suffers from that disease. A utility of 0 is assigned to death, while a utility of 1 represents perfect health.

Data analysis

Parametric and non-parametric tests are used at the individual level to compare the intervention and control group at baseline, depending on the distributions of the quantitative variables. The X^2-test is used in qualitative variables. Repeated measure analyses will be used to evaluate differences in the primary outcome variables body weight, BMI, waist circumference and fat mass between pre- and post-intervention in the intervention and control group . Because preference randomization occurred at the level of SHO and not at the level of the individual patient, cluster effects will also be examined. The analyses of the primary outcomes will be performed on an intention to treat (ITT) basis. Secondary outcome variables will be evaluated per protocol. A P-value ≤ 0.05 is considered statistically significant. For statistical analyses, SPSS®19 will be used.

To examine the cost-effectiveness of the intervention, a Markov decision-analytic model assuming a public payer perspective will be constructed to project health outcomes and costs of the health promotion intervention compared with usual care. Overweight and obesity are substantial risk factors for the high prevalence of type 2 diabetes and cardiovascular disease in individuals with mental disorders (Osborn *et al.* 2006, Scott and Happell 2011). Therefore, the Markov model will be used to estimate, for both the intervention and control group, the development of cardiovascular disease and type 2 diabetes over time and the associated costs. The time horizon will be a 10-year period. In both the intervention and control arm several health states will be included in the Markov model. All future costs and health outcomes will be discounted respectively at 3% and 1.5% annually. The costs will be calculated by analyzing the direct health care costs and the costs of the program. The direct health care costs include hospitalization, medication, GP consultations, and other health professionals costs. The program related resource use (staff time, materials) and resulting costs will be calculated making a distinction between the resource used and costs related to the research purpose and those related to the intervention itself.

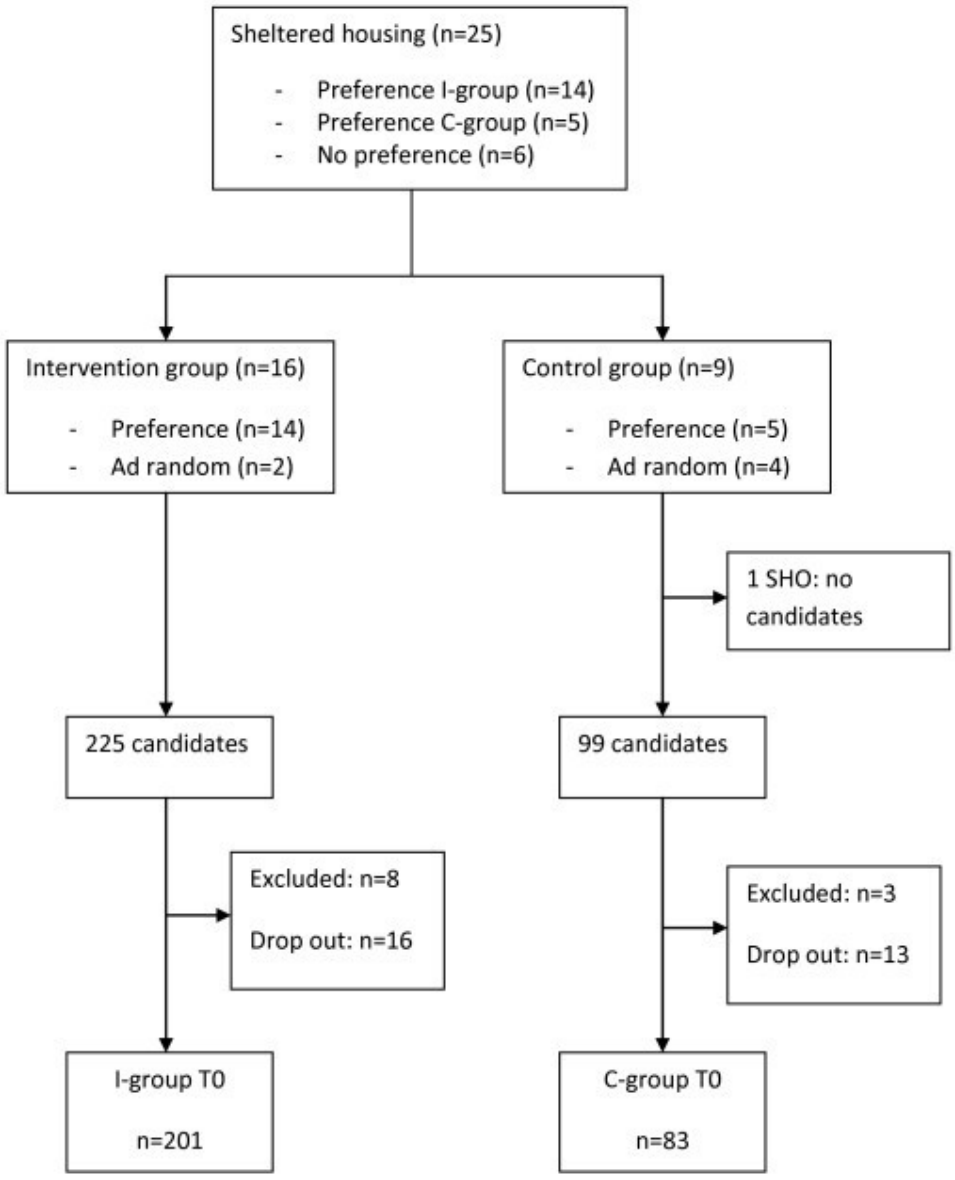
Ethics

Permission to perform the study was obtained from the Ethics Committee of the University Hospital of Ghent (Belgium). Written consent for participation is obtained from all participants. Participation in the study is voluntary and all participants are informed that the data analysis will be anonymous and that they could withdraw from the study at any time. A reward (pedometer) for the participants in the intervention group who completed the program was foreseen.

BASELINE STUDY POPULATION CHARACTERISTICS

A schematic overview of the recruitment process is shown in figure 3.

Figure 3 Health promotion intervention: Recruitment process



I-group, Intervention Group; C-group, Control Group; SHO, sheltered housing organization; T0, baseline measurement

Twenty-five SHOs were interested to participate. Fourteen of these expressed a preference to serve as intervention group, while five preferred to serve as control group. Six expressed no preference neither for the intervention nor for the control group. These six were randomly assigned to the

intervention group (n=2) and to the control group (n=4). In one of the SHOs serving as controls no patients were interested to participate.

On the individual level 324 patients were willing to participate, including 225 and 99 candidates in respectively the intervention and control SHOs. This accounted for a response rate of 24% in the intervention group and 21.1% in the control group. Eleven respondents were excluded because of age (n=2), cognitive impairments (n=4), having a gastric ring placed (n=1), and the impossibility to be weighed using the digital weighing scale (n=4). Of these four patients, three had a pacemaker and one patient had an artificial limb. Twenty-nine (9.3%) of the remaining 313 candidates withdrew before the baseline measurement due to hospital admission (n=4), no further interest (n=24), and one patient died in the period prior to the baseline measurement. This resulted in 284 patients for whom baseline data are available.

The sociodemographic characteristics for the overall study population and by treatment group are listed in table 1. The overall study population consisted of 174 men (61.3%) and mean age at enrollment was 46.3 years. Two-thirds of the patients (67.7%) were living together. Sixty-one percent of the participants were daily smokers and 46% used alcohol on a regular basis. The most frequent psychiatric diagnosis consisted of schizophrenia (37.9%), followed by mood disorders (24.5%).

No statistical significantly differences were observed between the intervention and control group for the sociodemographic variables, except for the variables ‘living situation’, and ‘duration of stay in sheltered housing’. Length of stay in sheltered housing was significantly longer in participants in the intervention group (median 4.4 vs. 2.5, $p<.05$). A statistically higher proportion of controls was living together compared with those in the intervention group (81 vs. 62%, $p<.05$). Psychotropic medication use was found to be statistically different between the two groups for only the antipsychotics ($p=.05$).

Table 1 Baseline sociodemographic data

Variable	All (n=284)	Intervention group (n=201)	Control group (n=83)	p
Sex				.27§
men, *n (%)*	174 (61.3)	119 (59.2)	55 (66.3)	
women, *n (%)*	110 (38.7)	82 (40.8)	28 (33.7)	
Age (year), *mean±SD*	46.3±12.3	46.2±12.5	46.5±11.9	.83‡
Smoking status, *n (%)*				.22§
no smoking	103 (39)	77 (41.4)	26 (33.3)	
smoking	161 (61)	109 (58.6)	52 (66.7)	
Alcohol use, *n (%)*				.81§
regular	122 (46)	87 (46.5)	35 (44.9)	
never	143 (54)	100 (53.5)	43 (55.1)	
Employment, *n (%)*				.51§
regular	13 (4.9)	11 (5.9)	2 (2.5)	
sheltered	105 (39.6)	73 (39.2)	32 (40.5)	
no	147 (55.5)	102 (54.8)	45 (57)	
Living situation, *n (%)*				<.05§
alone	86 (32.3)	71 (38)	15 (19)	
with others	180 (67.7)	116 (62)	64 (81)	
Stay in SH (years), *median (range)*	4 (0.1-22.3)	4.4 (0.1-22.3)	2.5 (0.1-16.3)	<.05†
DSM-IV diagnosis, *n (%)*				
schizophrenia	105 (37.9)	80 (41.2)	25 (30.1)	.08§
mood disorder	68 (24.5)	44 (22.7)	24 (28.9)	.27§
substance misuse	44 (15.9)	30 (15.5)	14 (16.9)	.77§
personality disorder	40 (14.4)	29 (14.9)	11 (13.3)	.71§
other	20 (7.2)	11 (5.7)	9 (10.8)	.13§
Medication, *n (%)*				
sedatives/anxiolytics	7 (2.8)	3 (1.7)	4 (5.7)	.09§
antipsychotics	56 (22.8)	46 (26.1)	10 (14.3)	.05§
antidepressants	12 (4.9)	8 (4.5)	4 (5.7)	.70§
sedatives/antipsych/antidepres.	49 (19.9)	31 (17.6)	18 (25.7)	.15§
sedatives/antipsychotics	20 (8.1)	16 (9.1)	4 (5.7)	.38§
sedatives/antidepressants	16 (6.5)	9 (5.1)	7 (10)	.16§
antipsychotics/antidepressants	75 (30.5)	58 (33)	17 (24.3)	.18§
no medication	11 (4.5)	5 (2.8)	6 (8.6)	

§Pearson Chi-Square

‡Independent samples *t*-test

†Mann-Whitney *U* test

SH, sheltered housing; DSM-IV, Diagnostic and Statistical Manual of Mental Disorders

Mean baseline body weight was 87.1 kg. Sixty point three percent of men had a baseline waist circumference of >102 cm. In women, 86.4% had a waist circumference of >88 cm. Of the total sample, 33.4% were classified as overweight and 47.2% as obese (table 2).

Table 2 Baseline anthropometric data

Variable	All (n=284)	Intervention group (n=201)	Control group (n=83)	p
Weight (kg), *mean±SD*	87.1±19.5	87.9±20.7	85.2±16.0	.23‡
BMI (kg/m²), *mean±SD*	30.0±5.9	30.2±6.1	29.5±5.4	.37‡
Waist circumference (cm), *mean±SD*	105.9±16.1	106.2±16.8	105.2±14.4	.65‡
men wc >102 cm, *n (%)*	105 (60.3)	76 (63.9)	29 (52.7)	.16§
women wc >88 cm, *n (%)*	95 (86.4)	70 (85.4)	25 (89.3)	.60§
Fat mass (%), *mean±SD*	33.9±10.6	34.2±10.5	33.4±10.6	.57‡
BMI class (kg/m²), *n (%)*				.70§
underweight (<18.5)	3 (1.1)	3 (1.5)	0 (0)	
normal weight (18.5-24.9)	52 (18.3)	36 (17.9)	16 (19.3)	
overweight (25-29.9)	95 (33.4)	66 (32.8)	29 (34.9)	
obesity (≥30)	134 (47.2)	96 (47.8)	38 (45.8)	

§Pearson Chi-Square

‡Independent samples *t*-test

kg., kilogram; BMI, Body Mass Index (kg/m²); wc, waist circumference

No statistical significant difference between the intervention and the control group was found for the primary outcome variables 'body weight' (p=.23), BMI (p=.37), waist circumference (p=.65) and fat mass (p=.57).

DISCUSSION

In this paper the study design and baseline characteristics of a health promotion intervention targeting physical activity and healthy eating in people with mental disorders living in sheltered housing is described. At baseline, statistical analysis of the characteristics found only a significant difference between the intervention and the control group for the variables 'living situation', 'duration of stay in sheltered housing', and 'antipsychotic medication use'.

The baseline characteristics demonstrate the unhealthy condition of the study population. A higher prevalence of overweight and obesity was found in the study population compared with the general population in Belgium. Eighty percent of the study population has a BMI of >25 of which 47% is classified as obese, compared with respectively 47 and 14% in the general population (Van der Heyden *et al.* 2010). Smoking prevalence in the study population also exceeds that of the general population in Belgium. Amongst the study population, 61% are daily smokers compared with 21% in the general Belgian population (Van der Heyden *et al.* 2010). According to the results of several

studies, the measurement of the waist circumference and waist-hip ratio is more appropriate than measuring the BMI to estimate the risk for future cardiovascular events (Dalton *et al.* 2003, Janssen *et al.* 2004). A waist circumference above 102 cm for men and 88 cm for women is associated with an increased risk of developing health problems such as cardiovascular disease, type 2 diabetes and hypertension (National Heart Lung and Blood Institute 1998). Sixty percent of men and 86 percent of women in our study population had a baseline waist circumference above this threshold.

Given the high burden of overweight and obesity in people with mental disorders, research on the effectiveness and cost-effectiveness of lifestyle interventions in this population is of substantial importance. Yet, there are several challenges in setting up trials involving individuals with mental disorders. Previous research has identified a number of barriers to engagement in health promotion programs like the mental disorder itself, side effects of psychotropic medication, financial barriers, poor motivation or unwillingness to participate, and absence of support (McDevitt *et al.* 2006, Shiner *et al.* 2008, Ussher *et al.* 2007).

According to the results of previous research on the effectiveness of weight management interventions in mental health care, significant reductions in weight gain are possible (Mauri *et al.* 2008, McKibbin *et al.* 2006). The results of these trials must however be interpreted cautiously because they are frequently limited by small sample sizes and short intervention periods. It is nevertheless promising that small weight reduction in this population is possible.

As far as known to the authors, this is the first trial evaluating both the effectiveness and cost-effectiveness of a health promotion intervention targeting physical activity and healthy eating in mental health care. Cost-effectiveness evaluations have a great social value as health promotion and prevention have an economic cost, but they can also increase healthy life expectancy and save money because diseases and complications can be avoided. It is likely that the results of this intervention in SHOs will lead to further health promotion programs targeting other populations in mental health care , such as inpatients.

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CHAPTER 6

Effectiveness of a health promotion intervention in individuals with mental disorders: a cluster preference randomized controlled trial

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ABSTRACT

Background: The existing literature on weight management interventions targeting physical activity and healthy eating in mental health care appears to provide only limited evidence. The aim of the study was to examine the effectiveness of a 10-week health promotion intervention, followed by a 6-month follow-up period in individuals with mental disorders living in sheltered housing in the Flanders region (Belgium).

Methods: The study had a cluster preference randomized controlled design. Twenty-five sheltered housing organizations agreed to participate (16 in the intervention group, nine in the control group). In the intervention group, 225 individuals agreed to participate, while in the control group 99 individuals entered into the study. The main outcomes were changes in body weight, Body Mass Index, waist circumference and fat mass. Secondary outcomes consisted of changes in physical activity levels, eating habits, health-related quality of life and psychiatric symptom severity.

Results: A significant difference was found between the intervention group and the control group regarding body weight (-0.35 vs. +0.22 kg.; p=0.04), Body Mass Index (-0.12 vs. +0.08 kg/m²; p=0.04), waist circumference (-0.29 vs. 0.55 cm; p<0.01), and fat mass (-0.99 vs. -0.12%; p<0.01). The decrease in these outcomes in the intervention group disappeared during the follow-up period, except for fat mass. Within the intervention group, a larger decrease in the primary outcomes was found in the participants who completed the intervention. No significant differences between the two groups in changes in the secondary outcomes were found, except for the pedometer-determined steps/day. In the intervention group, the mean number of daily steps increased, while it decreased in the control group.

Conclusions: The study demonstrated that small significant improvements in the primary outcomes are possible in individuals with mental disorders. Integration of health promotion activities targeting physical activity and healthy eating into daily care are, however, necessary to maintain the promising results.

Trial registration: This study is registered at ClinicalTrials.gov NCT 01336946

INTRODUCTION

Several studies have shown that individuals with mental disorders including schizophrenia, bipolar disorders, depression, and anxiety disorders are at a greater risk of being overweight (Body Mass Index 25-29.9 kg/m²) or obese (Body Mass Index ≥30 kg/m²) than the general population (Dickerson *et al.* 2006, Limosin *et al.* 2008, Scott and Happell 2011). These conditions and other related metabolic disturbances (Fagiolini and Goracci 2009, Osborn *et al.* 2006) are substantial risk factors for the high prevalence of cardiovascular disease (CVD) and associated mortality in this population (Brown *et al.* 2010, Osby *et al.* 2001).

In people with mental disorders, excessive weight gain has been associated with the use of especially second generation antipsychotics (SGAs), the degree of which is variable according to the type of antipsychotic used (Allison and Casey 2001, Parsons *et al.* 2009). Beside the side effects of these drugs, the high prevalence of overweight and obesity in this population is also associated with lower physical activity levels and more unhealthy eating habits. The former include less moderate or vigorous physical activity and exercise than the general population or physical activity guidelines (Nyboe and Lund 2012, Osborn *et al.* 2007, Ussher *et al.* 2011).The latter include eating fresh fruit, vegetables, wholegrain bread and, milk products less frequently, eating more instant meals (Henderson *et al.* 2006, McCreadie 2003, Roick *et al.* 2007) and fat (Brown *et al.* 1999), and having less variety of food in the diet (Strassnig *et al.* 2003). Growing attention is being given to lifestyle interventions targeting physical activity and healthy eating, the effectiveness of which in the general population is already well established (Clark *et al.* 2004, Eriksson *et al.* 2006). The current literature on weight reduction interventions in mental health care appears to provide only limited evidence for the effectiveness of either psycho-educational or programs including educational and exercise components (Lowe and Lubos 2008). More research is therefore required to examine the effectiveness of these kinds of interventions in populations of individuals with mental disorders.

This paper describes the results of a health promotion intervention targeting physical activity and healthy eating in individuals with mental disorders living in sheltered housing in the Flanders region (Belgium). The study consisted of a 10-week intervention period followed by a 6-month follow up period.

MATERIALS AND METHODS

Study design and setting

The study design consisted of a cluster preference randomized controlled trial (RCT) . The study was conducted in sheltered housing organizations (SHOs) in the Flanders region (Belgium), where there were 42 SHOs amounting to 2662 approved places at the time (Federal Public Service Health 2011).

In Belgium, sheltered housing is aimed at people with mental disorders aged 18 years and older who do not need to stay in a psychiatric inpatient facility on a permanent basis. The main goal is the psychiatric rehabilitation of the patients (usually known as 'residents'). In the rehabilitation process, patients receive support to develop the emotional, social and intellectual skills needed to live, learn and work in the community with the lowest amount of support (Anthony *et al.* 2002). In practice, the usual treatment consists of weekly meetings between the mental health nurse and the resident to discuss topics such as how to cope with the psychiatric disease, somatic health, household tasks, and financial issues. The main objective is to maximize the personal autonomy of each resident. They are encouraged to do as much as possible for him/herself including self-care, shopping, cooking, domestic chores, and leisure time activities with the support of the mental health professionals. Particular attention is given to the search for a meaningful daily occupation such as regular or sheltered employment, or voluntary work.

Residents can live alone or they can live together with other patients in 'community houses'. In these settings, residents have their own bedrooms but share communal areas such as the kitchen, bathroom, and living room. As well individuals living alone or living in 'community houses' were eligible for participation. Assignment to the intervention or control group at the individual level was not possible because of the high risk of contamination by participants living together in the same 'community house'. Based on the literature (Howard and Thornicroft 2006, Shapiro *et al.* 2002) on possible problems in the design of studies evaluating behavioral or psychosocial interventions, it was assumed that being assigned to a non-preferred intervention condition could reduce the SHOs' interest in participating in the study. For this reason, it was decided to use a preference design. In this design, subjects are allowed to select the intervention assignment. This is useful when strong preferences among potential participants threaten either the ability to recruit an adequate sample size of representative participants or when such preferences threaten participants' acceptance of treatment assignment, adherence, or retention in the trial (Campbell *et al.* 2004). In this study, SHOs with strong preferences were offered their preferred condition, while those without were randomized in the usual way.

Recruitment and study population

Recruitment of participants took place from June 2010 until January 2011. An invitation letter and response form with a self-addressed stamped envelope was sent to the managers of all SHOs in the Flanders region. The letter included a concise explanation of the aim of the study and the expectations and content if an organization was willing to serve as intervention group. The administrators were asked to discuss the study proposal with their staff to decide whether they were interested in participating. Involving the staff members in the decision process was considered important because, if an organization was willing to serve as intervention group, one or more staff members would be involved in the intervention. They were asked if they were interested in participating in the study with (i) no preference to serve as intervention or control group and to be randomized or, (ii) a preference to serve as intervention group or, (iii) a preference to serve as control group. A concise explanation about the aim of the study and about the expectations and content when participating as intervention group was included in the letter. SHOs which did not respond after six weeks were sent a reminder. SHOs which were not prepared to participate were asked to report the reason for non-participation. The administrators and staff were also instructed to not consult the residents in the decision process.

Based on responses to the letter, the SHOs were subsequently either assigned to the intervention group or control group according to their preference or, when no preference had been expressed, randomly assigned to the intervention or control group. Randomization occurred by means of simple randomization using a lottery method conducted by an external person not involved in the study. Finally, the residents living in the intervention and control SHOs received both written and oral information about the study. The written information consisted of a detailed explanation of the study and an informed consent. The content of these documents was also orally explained to the residents by the mental health nurse.

The study population consisted of individuals with mental disorders aged between 18 and 75 years living in sheltered housing in the Flanders region. Exclusion criteria included individuals older than 75 years, those fitted with a gastric ring or pacemaker and those with cognitive impairments which would prevent them being able to follow and understand the psycho-educational and behavioral sessions of the health promotion intervention (as assessed by the mental health professionals).

Development of the materials

The theoretical framework for the intervention is based on elements of social-cognitive theory (Bandura 2004), self-determination theory (Ryan and Deci 2000), and control theory (Carver and

Scheier 1982). The intervention was developed using the mediating variable approach including the mediating variables of knowledge, attitude, skills, self-efficacy and motivation (Bandura 2004, Ryan and Deci 2000). For instance, based on the social-cognitive theory, it was decided to develop a workshop with sessions spread over ten weeks as this stimulates interaction and exchange of experiences among the participants and with the workshop leader. Based on the self-determination theory and the control theory, emphasis was put on the motivation to change lifestyle through discussions on the advantages and disadvantages of healthy eating and physical activity on quality of life and long term health benefits. Individual support was also available and participants were stimulated to define specific personal goals for eating habits (for example : eating less energy dense food) or engaging in physical activity. These personal goals could be further discussed and followed up with the nurses.

A detailed staff manual was developed based on the manual 'Health promotion on well-balanced eating and healthy physical activity' developed by the Flemish Institute of Health Promotion and Disease Prevention (Flemish Institute of Health Promotion and Disease Prevention 2007). The target population of this manual was the general population. For this reason, some adjustments were made to the manual to better meet the needs of our study population (e.g. how to live a healthier lifestyle despite the presence of barriers associated with the mental disorder such as the sedative effects of certain psychotropic drugs). The manual was built around ten themes regarding physical activity and healthy eating: 1) physical activity and healthy eating: Introduction, 2) Awareness of the consumption of fat and fibers, 3) A healthy lifestyle: advantages and barriers, 4) The Active Food Triangle, 5) Using the Active Food Triangle throughout the day, 6) Label reading, 7) The influence of the environment & Budget issues, 8) & 9) Physical activity, 10) A quiz on physical activity and healthy eating.

Implementation of the intervention

All sheltered housing organizations in the intervention group were visited by one member of the research team (NV). The aim of the visit was to instruct the mental health nurses who would be offering and supervising the group-based sessions. During a 2-hour training session they received background information about the burden of obesity in individuals with mental disorders and the importance of health promotion targeting physical activity and healthy eating, and were instructed how to use the staff manual and how to organize the walking sessions. Other staff members were also asked to attend this training session because information and instructions concerning the "individual support" was also provided. The nurses were instructed to provide individual support to all the participants during the 10-week health promotion intervention. To minimize the workload for

the nurses, they were asked to provide this support during their weekly meeting with the resident. During the 10-week intervention, the nurses could contact one of the researchers by phone or by email if necessary.

Study duration and intervention components

The study period consisted of an intervention period of ten weeks followed by a post-intervention period of 24 weeks. In addition to treatment as usual, the intervention group received the 10-week health promotion program, while the control group received only treatment as usual. The program was delivered by one or more mental health professionals working in the intervention SHOs. All participants received the same information in the same format comprising the following components:

- Psycho-educational and behavioral group sessions

A weekly group session including discussions on physical activity and healthy eating, problem solving, written exercises, quizzes and plans to increase physical activity levels and to stimulate healthier eating behavior.

- Supervised exercise

In the same 10-week period a weekly 30-minutes supervised walking session was organized.

- Individual counseling

During the 10-week intervention period, the participants in the intervention group received individual support from the mental health professionals. These sessions lasted about ten minutes and the following issues were discussed: (i) “Did you understand what was discussed during the group-based sessions?”, (ii) “How difficult was it for you to follow the advice given during the sessions?”, (iii) “What made it difficult for you to follow the advice and what can be done about it?”. The nurses were also asked to inform the participants about the practical issues concerning the next session such as date, time and location .

Sample size calculation

The sample size calculation was based on an average change of the primary outcome body weight of 3.5 kg between the intervention and control group at the end of the study. This change was based on the results of a literature review performed by the research team(Verhaeghe *et al.* 2011). Cluster randomized trials require larger sample sizes than the individually randomized design because observations on individuals in the same cluster tend to be correlated, and so the effective sample size is less than the total number of individual participants. This reduction in effective sample size

and the degree of correlation within clusters is expressed as the intraclass correlation coefficient (ICC) (Hayes and Bennett 1999). The ICC can be interpreted as the proportion of group-level variance compared to the total variance. As no ICC for this kind of intervention in people with mental disorders was found in the literature, an assumption was made by multiplying the sample size by a design factor of 1.5 (Kaiser *et al.* 2006). A sample size of 371 individuals in each group provided a sample size large enough to detect a difference in mean body weight change of 3.5 kg across the two groups with 80% power at a significance level of 0.05.

Data collection and outcome measurements

Sociodemographics

Participants were asked to complete a sociodemographic questionnaire on sex, age, duration of stay in sheltered housing, marital status, occupational status, contacts with relatives, tobacco and alcohol use, and medication use.

Primary outcome measures

The primary outcomes of the study consisted of changes in body weight, Body Mass Index (BMI), waist circumference and fat mass. Body weight and fat mass were measured in all participants wearing light clothing without shoes using a TANITA BC-420 SMA digital weighing scale (TANITA, Tokyo, Japan). The measurement had to be taken with bare feet as the equipment sends a weak electrical current through the body to measure impedance (electrical resistance) of the body. Fat within the body allows almost no electricity to pass through. The degree of difficulty with which electricity passes through a substance is known as the electrical resistance, and the percentage of fat can be inferred from measurements of this resistance. To prevent a possible discrepancy in measured values, participants had to keep still during measurement. Height was measured in a standardized way using a Seca 225 stadiometer (Seca GmbH & KG, Hamburg, Germany). BMI was calculated by dividing the body weight in kilograms by the square of the height in meters. Waist circumference was measured with a Seca 200 tape (Seca GmbH & KG, Hamburg, Germany) according to the 'Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults'(National Heart Lung and Blood Institute 1998). All measurement procedures were conducted by a member of the research team. Both the stadiometer and the weighing scale were placed on a flat surface to assure correct measurement of the outcomes.

Secondary outcome measures

Changes in physical activity were assessed using the Dutch version of the self-administered International Physical Activity Questionnaire (IPAQ), which has been shown to be a reliable and valid physical activity measurement tool (Vandelanotte *et al.* 2005). Physical activity levels were also assessed with pedometers using the Yamax Digiwalker SW-200 (Yamax, Tokyo, Japan), as this is known to be accurate and reliable for counting steps (Crouter *et al.* 2003). Participants were asked to fill out the number of daily steps during seven consecutive days on a pre-printed document. If necessary they were assisted by a mental health nurse. The dietary habits of the participants were assessed using an adapted version for adults of an online dietary assessment tool, the 'Young Children's Nutrition Assessment on the Web' (Vereecken *et al.* 2009). Dietary data were collected for two non-consecutive days, one week day and one weekend day. In this tool, each day is distributed in 24 possible eating occasions. The participants were asked to report each food and beverage intake to the nearest hour of the day. For each eating and beverage occasion, the participant selected the foods consumed from a hierarchically organized menu structure, with both the interviewer and the participant sitting in front of the computer screen. Pictures (Vereecken *et al.* 2010) and measurement units (e.g. a spoon, a small bottle) were used to assess portions and portion sizes. For the present analysis all food was grouped into 13 food groups. Health-related quality of life was examined using the SF-36 Health Survey Questionnaire (Ware *et al.* 1993). Psychiatric symptom severity was assessed using the Brief Symptom Inventory (BSI) (Derogatis and Melisaratos 1983). This questionnaire is considered a reliable and valid tool useful in patient groups with different psychiatric diagnoses (de Beurs and Zitman F 2005).

Data on all primary and secondary outcomes were collected at baseline and at ten weeks. At the end of the study (at 36 weeks) only data on body weight, waist circumference and fat mass were collected and BMI was calculated. At that time, participants were also asked to complete the SF-36 questionnaire again.

Data analysis

Depending on the distribution of the quantitative variables, the independent samples T-test or the Mann Whitney U Test were used to compare the intervention and control group at baseline. The X^2-test was used in qualitative variables.

First, change scores for the primary outcomes of body weight, BMI, waist circumference, and fat mass from baseline to the end of the intervention period (at ten weeks) and from baseline to the end of the study (at 36 weeks) were computed. Next, an intention to treat (ITT) analysis using the

independent samples T-test was performed to evaluate differences in the change scores between intervention and control group in the primary outcome variables body weight, BMI, waist circumference, and fat mass from baseline to ten and 36 weeks. ITT analysis included all participants with baseline data. Missing data at ten and 36 weeks were imputed with the mean change in the primary outcomes in the control group (Sterne *et al.* 2009). Univariate analyses of covariance were used to control for sex, age, living situation, smoking habits, alcohol use, psychotropic medication use, and duration of stay in sheltered housing. Additional linear mixed model analysis was performed to take possible clustering effects into account because of the fact that individuals were nested within SHOs. For all primary outcomes, an ICC below 5% was found indicating a limited group-level variance compared to the total variance (Hox 2010). In addition, in all participating SHOs the number of residents that agreed to participate was limited to 23 or fewer individuals per SHO. This is less than the "30/30 rule" as suggested by Hox (Hox 2010). It is suggested that researchers should strive for a sample of at least 30 groups with at least 30 individuals per group. For these reasons, it was decided to omit mixed model analysis.

To examine whether changes in the primary outcomes were different between participants in the intervention group who completed the health promotion program (i.e. individuals who attended at least eight of ten sessions), those who did not and the controls, a per protocol analysis was performed within the subsample of participants for whom baseline data and data at ten weeks were available. A Tukey post hoc comparison test was performed to assess whether significant treatment differences between the three groups occurred. Analysis of the secondary outcomes were based on computed change scores from baseline to the end of the intervention (at ten weeks). Secondary outcome variables were evaluated per protocol using the independent samples T-test or the Mann Whitney U Test depending on the distribution of the quantitative variables to examine differences between the intervention and control group in changes in these outcomes from baseline to ten weeks. A P-value ≤ .05 was considered statistically significant. For statistical analysis, the SPSS®19 statistical software package was used.

Ethics

Permission to perform the study was obtained from the Ethics Committee of the University Hospital of Ghent (Belgium). Written consent for participation was obtained from all participants. If necessary, the mental health nurse explained the contents of the informed consent document to the candidate, but all candidates had the capacity to consent. Participation in the study was voluntary and all participants were informed that the data analysis would be anonymous and that they could withdraw from the study at any time.

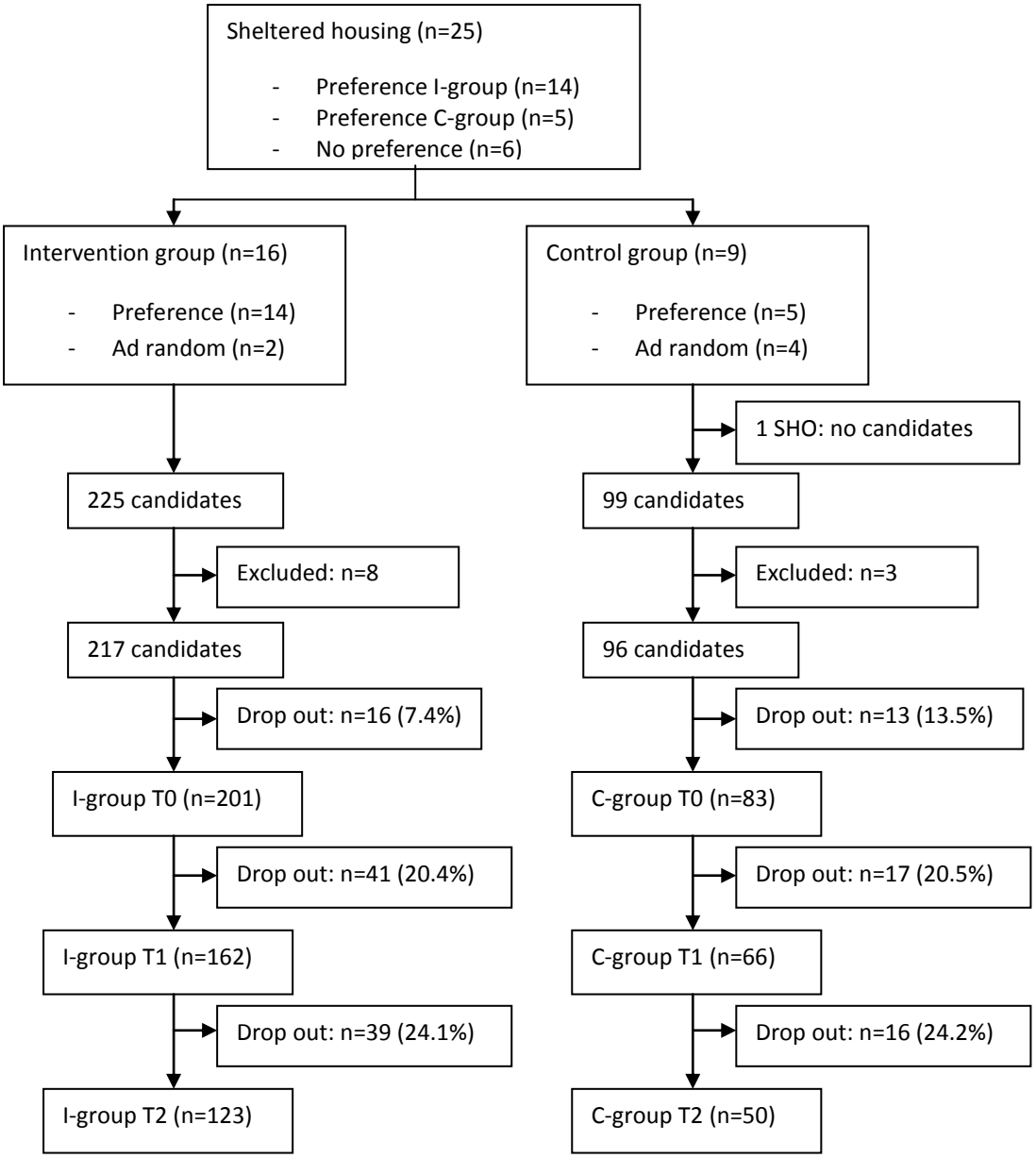
RESULTS

Recruitment process and participation rate

In figure 1 an overview is provided of the recruitment process and participation rate. Twenty-five SHOs agreed to participate, accounting for 59.5% of the total number of SHOs in the Flanders region. Fourteen of these expressed a preference to serve as intervention group, while five preferred to serve as control group. Six had no preference and were randomly assigned to the intervention group (n=2), or to the control group (n=4). In one SHO serving as control group, no residents were interested in participating. On the individual level, 324 residents were willing to engage in the study, 225 and 99 candidates in the intervention and control SHOs respectively. Based on the number of approved places in the participating SHOs, a response rate of 24% in the intervention group and 21% in the control group was obtained.

Eleven candidates were excluded because of age (n=2), cognitive impairments (n=4), having a gastric ring (n=1), or the impossibility to be weighed using the digital weighing scale (n=4). Of these last, three had a pacemaker, and one had an artificial limb. Twenty-nine (9.3%) of the remaining 313 candidates withdrew from the study prior to the baseline measurement. Prior to the baseline measurement a higher proportion of individuals in the control group withdrew from the study (13.5% vs. 7.4%). Dropout rates at ten and 36 weeks were similar in the two groups. From baseline to the end of the study, the most common reason for withdrawal were no further interest or motivation (n=60), admission to a psychiatric inpatient facility (n=9), and discharge from sheltered housing (n=8). Two-hundred and one individuals in the intervention group and 83 in the control group were included in the ITT analysis.

Figure 1 Health promotion intervention: Recruitment process



I-group, Intervention Group; C-group, Control Group; SHO, sheltered housing organization; T0, baseline measurement; T1, measurement at 10 weeks; T2, measurement at 36 weeks

Baseline assessment

At baseline, the only significant differences observed between the intervention and control group for the sociodemographic variables were for 'living situation', and 'duration of stay in sheltered housing' (table 1). A higher proportion of controls was living together than those in the intervention group (81.0% vs. 62.0%, p=0.002). Median duration of stay in sheltered housing was significantly longer in participants in the intervention group than in the control group (4.4 vs. 2.5 years, p=0.04). Psychotropic medication use was found to be significantly different between the two groups for only the SGAs (p=0.03). Fifty-eight point six per cent and 66.7% of the participants in the intervention and

control group respectively were daily smokers. Eighty-six point two per cent of the participants in the intervention group were on SGA prescription. In the control group, 54.2% were taking these drugs. At baseline, a mean BMI of 30.2 kg/m² and 29.5 kg/m² was observed in the intervention and control group respectively.

Table 1 Baseline sociodemographic data

Variable	Intervention group (n=201)	Control group (n=83)	p
Sex, *n (%)*			0.27§
men	119 (59.2)	55 (66.3)	
women	82 (40.8)	28 (33.7)	
Age (years), *mean±SD*	46.2±12.5	46.6±11.9	0.83‡
Smoking, *n (%)*			
no smoking	77 (41.4)	26 (33.3)	0.22§
smoking	109 (58.6)	52 (66.7)	
Alcohol use, *n (%)*			
regular	87 (46.5)	35 (44.9)	0.81§
never	100 (53.5)	43 (55.1)	
Employment, *n (%)*			0.51§
regular	11 (5.9)	2 (2.5)	
sheltered	73 (39.2)	32 (40.5)	
no employment	102 (54.8)	45 (57.0)	
Living situation, *n (%)*			<0.01§
alone	71 (38.0)	15 (19.0)	
with others	116 (62.0)	64 (81.0)	
Contact with family, *n (%)*			0.70§
regular	134 (72.0)	58 (74.4)	
seldom/never	52 (28.0)	20 (25.6)	
Contact with friends, *n (%)*			0.12§
regular	111 (60.0)	54 (70.1)	
seldom/never	74 (40.0)	23 (29.9)	
Stay in SH (years), *median (range)*	4.4 (0.1-22.3)	2.5 (0.1-16.3)	0.04†
DSM-IV diagnosis, *n (%)*			
schizophrenia	80 (41.2)	25 (30.1)	0.08§
mood disorder	44 (22.7)	24 (28.9)	0.27§
substance misuse	30 (15.5)	14 (16.9)	0.77§
personality disorder	29 (14.9)	11 (13.3)	0.71§
other	11 (5.7)	9 (10.8)	0.13§
Medication, *n (%)*			
sedatives/anxiolytics	60 (29.9)	34 (41%)	0.07§
first generation antipsychotics	46 (22.9)	13 (15.7)	0.17§
second generation antipsychotics	137 (68.2)	45 (54.2)	0.03§
antidepressants	106 (52.7)	46 (55.4)	0.68§

§Pearson Chi-Square; ‡ Independent samples t-test; †Mann-Whitney U test; SH, Sheltered Housing
DSM-IV, Diagnostic and Statistical Manual of Mental Disorders

No significant differences existed at baseline between the intervention and control group regarding the primary outcome measures (table 2), nor were any found regarding the secondary outcome measures, except for the food groups soft drinks (p= 0.04) and meat, fish and eggs (p= 0.04) (table 3 and 4).

Table 2 Baseline assessment and changes in primary outcomes from baseline to 10 and 36 weeks (ITT)

Variable	Intervention group (n=201)	Control group (n=83)	Between group change	p‡
Weight (kg), *mean±SD*				
baseline	87.95±20.74	85.19±16.04		0.23
at 10 weeks	87.60±20.77	85.41±16.49		
change at 10 weeks	-0.35±2.15	0.22±2.14	0.57	0.04
≥ 5% weight loss, *n (%)*	11 (5.5%)	3 (3.6%)		
at 36 weeks	88.28±21.03	86.18±16.99		
change at 36 weeks	0.33±3.51	0.99±3.01	0.66	0.14
BMI (kg/m²), *mean±SD*				
baseline	30.22±6.14	29.52±5.41		0.37
at 10 weeks	30.10±6.18	29.60±5.56		
change at 10 weeks	-0.12±0.75	0.08±0.78	0.20	0.04
at 36 weeks	30.33±6.26	29.87±5.74		
change at 36 weeks	0,11±1.23	0.35±1.05	0.24	0.14
Waist (cm), *mean±SD*				
baseline	106.16±16.81	105.21±14.39		0.65
at 10 weeks	105.87±16.73	105.76±14.72		
change at 10 weeks	-0.29±2.18	0.55±2.61	0.84	<0.01
at 36 weeks	106.32±16.82	106.43±15.10		
change at 36 weeks	0,16±3.41	1.22±3.53	1.06	0.02
Fat mass (%), *mean±SD*				
baseline	34.17±10.55	33.37±10.63		0.57
at 10 weeks	33.18±10.62	33.25±10.72		
change at 10 weeks	-0.99±2.51	-0.12±1.60	0.87	<0.01
at 36 weeks	33.76±11.21	34.56±11.04		
change at 36 weeks	-0,41±3.57	1.19±2.58	1.60	<0.001

‡ Independent samples t-test

ITT, intention to treat; kg, kilogram; BMI, Body Mass Index; cm, centimeter

Table 3 Baseline assessment and changes in secondary outcomes from baseline to 10 weeks

Variable	Intervention group	Control group	Between group change	p
Total PA[1] (METmin/week), *mean±SD*				
baseline	3282±3118	3770±3071		0.20†
at 10 weeks	4992±5089	4497±4586		
change	1709±4430	727±4887	982	0.17‡
Moderate PA[1] (METmin/week), *mean±SD*				
baseline	1568±1990	2061±2334		0.07†
at 10 weeks	2518±3026	2346±3479		
change	950±2849	285±3842	665	0.19‡
Vigorous PA[1] (METmin/week), *mean±SD*				
baseline	486±2036	311±853		0.74†
at 10 weeks	979±2992	591±1559		
change	493±2445	279±1619	214	0.54‡
Walking PA[1] (METmin/week), *mean±SD*				
baseline	1228±1441	1398±1564		0.44†
at 10 weeks	1495±1617	1560±1687		
change	266±1988	163±2096	103	0.74‡
Pedometer[2] determined steps/day, *mean±SD*				
baseline	6872±3585	7215±3368		0.61‡
at 10 weeks	8128±4050	6788±3507		
change	1256±1933	-426±2754	1340	<0.001‡
SF36 PCS[3], *mean±SD*				
baseline	40.4±7.7	41.2±5.9		0.51‡
at 10 weeks	39.4±7.5	40.2±7.8		
change	-0.9±8.5	-1.0±7.6	0.1	0.96‡
SF36 MCS[3], mean±SD				
baseline	35.6±8.7	35.8±7.9		0.89‡
at 10 weeks	34.8±7.9	35.3±7.4		
change	-0.9±7.6	-0.5±6.8	0.4	0.77‡
BSI_PST[4], *mean±SD*				
baseline	27.6±12.6	26.5±13.8		0.60‡
at 10 weeks	25.3±12.8	24.0±14.5		
change	-2.4±9.5	-2.5±7.5	0.1	0.92‡

PA, physical activity; PCS, physical component score; MCS, mental component score; BSI_PST, Brief Symptom Inventory_ Positive Symptom Total

[1]Intervention group, n=127; Control group, n=60; [2]Intervention group, n=92; control group, n=40; [3]Intervention group, n=112; control group, n=51; [4]Intervention group, n=116; control group, n=55

‡Independent Samples T-test, †Mann Whitney U test

Table 4 Baseline assessment and changes (mean - range) in food intake (g/day) from baseline to 10 weeks

Variable		Intervention group (n=152)	Control group (n=49)	Between group change	p
potatoes	baseline	96.0 (0-472.5)	99.8 (0-332.5)		0.59†
	at 10 weeks	95.3 (0-250.0)	82.6 (0-195.0)		
	change	-0.64	-17.24	16.6	0.28‡
alcohol	baseline	38.9 (0-1240.0)	38.3 (0-625.0)		0.64†
	at 10 weeks	31.6 (0-1155.0)	56.0 (0-915.0)		
	change	-7.27	17.70	24.97	0.34‡
bread & rolls	baseline	133.0 (0-702.0)	141.2 (0-420.0)		0.32†
	at 10 weeks	124.3 (0-360.0)	119.3 (0-283.5)		
	change	-8.73	-21.97	13.24	0.38‡
soft drinks	baseline	338.9 (0-2900.0)	428.1 (0-2665.0)		0.04†
	at 10 weeks	288.1 (0-2150.0)	492.2 (0-2700.0)		
	change	-50.82	64.16	114.98	0.14‡
fruit	baseline	97.2 (0-1247.5)	84.1 (0-625.0)		0.65†
	at 10 weeks	112.6 (0-1040.0)	73.9 (0-352.5)		
	change	15.42	-10.14	25.56	0.24‡
vegetables	baseline	94.3 (0-690.0)	111.6 (0-1127.5)		0.96†
	at 10 weeks	85.5 (0-520.0)	68.5 (0-430.0)		
	change	-8.87	-43.05	34.18	0.23‡
coffee & tea	baseline	696.4 (0-4125.0)	761.3 (0-2925.0)		0.73†
	at 10 weeks	542.9 (0-2475.0)	632.9 (0-2625.0)		
	change	-153.49	-128.36	25.13	0.78‡
milk	baseline	152.6 (0-1087.5)	212.6 (0-1500.0)		0.48†
	at 10 weeks	143.4 (0-1437.5)	159.4 (0-650.0)		
	change	319.20	-53.17	372.37	0.52‡
sweets	baseline	52.4 (0-385.5)	69.5 (0-552.0)		0.05†
	at 10 weeks	28.4 (0-169.0)	45.5 (0-277.0)		
	change	-24.0	-24.0	0	0.99
water	baseline	515.4 (0-2541.3)	480.3 (0-2860.0)		0.33†
	at 10 weeks	478.3 (0-2212.5)	595.9 (0-2800.0)		
	change	-37.11	115.61	152.72	0.10‡
meat, fish, eggs	baseline	130.0 (0-658.0)	150.5 (0-359.0)		0.04†
	at 10 weeks	148.7 (0-461.0)	139.3 (0-402.0)		
	change	18.19	-11.20	29.39	0.09‡
fat & sauces	baseline	53.8 (0-287.5)	54.6 (0-347.5)		0.81†
	at 10 weeks	39.3 (0-215.0)	42.2 (0-140.0)		
	change	-14.57	-12.67	1.9	0.85‡
biscuits	baseline	45.0 (0-780.0)	43.8 (0-330.0)		0.82†
	at 10 weeks	26.7 (0-240.0)	27.2 (0-160.0)		
	change	-18.35	-16.60	1.75	0.91‡

‡Independent Samples T-test, †Mann Whitney U test

Changes in primary outcomes

Using independent samples t-tests, significant differences between the intervention and control group in changes in the primary outcomes body weight (-0.35 vs. 0.22 kg, p=0.04), BMI (-0.12 vs. 0.08 kg/m², p=0.04), waist circumference (-0.29 vs. 0.55 cm, p<0.01) and fat mass (-0.99 vs. -0.12 %, p<0.01) from baseline to ten weeks were found. From ten weeks to the end of the study period, the decrease in the primary outcomes in the intervention group disappeared, with the exception for "fat mass" (33.76 vs. 34.17%). End point weight (88.28 vs. 87.95 kg), BMI (30.33 vs. 30.22 kg/m²) and waist circumference (106.32 vs. 106.16 cm) were again slightly above the baseline values.

Univariate analyses of covariance were performed for changes in the primary outcomes from baseline to ten weeks controlling stepwise for the variables of sex, living situation, smoking habits, alcohol use, SGA drug use, age and duration of stay in sheltered housing. The significant differences between the intervention and control group in changes in weight and BMI disappeared when controlling for duration of stay in sheltered housing (weight: F=2.976, p=0.086; BMI: F=2.820, p=0.094) and SGA drug use (weight: F=3.023, p=0.083; BMI: F=2.997, p=0.085), while it remained significant for changes in waist circumference (stay: F=6.214, p=0.013; SGA: F=6.286, p=0.013) and fat mass (stay: F=6.544, p=0.011; SGA: F=7.076, p=0.008). In the intervention group, a trend was found for a positive relation between duration of stay and weight loss. Participants who had already been staying longer in sheltered housing lost more weight (data not shown).

In addition, a univariate analysis of covariance was performed for changes in the primary outcomes from baseline to ten weeks controlling simultaneously for sex, living situation, smoking habits, alcohol use, SGA drug use, and duration of stay in sheltered housing. The significant differences between the intervention and control group in changes in weight (F=3.199, p= 0.075) and BMI (F=3.084, p= 0.08) disappeared, while it remained for waist circumference (F=6.122, p= 0.014) and fat mass (F=8.650p= 0.004) (data not shown).

Changes in secondary outcomes

In tables 3 and 4 the changes in the secondary outcomes from baseline to ten weeks are summarized. Differences between the intervention and control group in changes in the secondary outcomes from baseline to ten weeks were only significant for the variable of pedometer determined steps/day (p= <.001). Mean steps per day increased in the intervention group (1256±1933 steps/day), while the number of daily steps in the control group decreased (-426±2754 steps/day). Soft drink intake in the intervention group was decreased at ten weeks (-50.8 g/day), while this was increased in the control group (64.2 g/day). This latter difference between the two groups, however, not statistically

significant (p= .14). No intervention effect was observed for the other physical activity variables, food intake, health-related quality of life and psychiatric symptom severity.

Adherence to the intervention

A per protocol analysis using analysis of variance was performed to examine the differences in the primary outcomes from baseline to the end of the intervention (at ten weeks) in participants who completed the program, those who did not, and controls. Completers were defined as individuals in the intervention group who attended at least eight of ten sessions (51.2%). In the intervention group, a larger decrease in the primary outcomes was found in those who completed the program than those who did not (table 5). Significant differences in the primary outcomes were found between completers and controls in changes in body weight (-0.72 vs. 0.22 kg, p=0.03), BMI (-0.23 vs. 0.08 kg/m², p=0.04), waist circumference (-0.64 vs. 0.55 cm, p<0.01) and fat mass (-1.33 vs. 0.05%, p<0.01), but not between non-completers and controls. Participants who completed the program were significantly less likely to smoke than the non-completers (44.9 vs. 72.7% smokers, p<.001). Compared with those in the intervention group who did not complete the program, mean age in completers was, borderline significantly higher (48.9±11.7 vs. 44.9±12.9, p=.051). All the participants in the intervention group who lost at least five per cent of their baseline body weight completed the intervention (10.7%). Thirteen per cent of the completers lost between four and five per cent of their initial body weight (data not shown).

DISCUSSION

The aim of the study was to examine the effectiveness of a health promotion intervention targeting physical activity and healthy eating in individuals with mental disorders living in sheltered housing. The study period consisted of a 10-week intervention period followed by a 6-month follow up period.

From baseline to the end of the intervention period (at ten weeks), significant differences in changes in body weight, BMI, waist circumference, and fat mass between the intervention and control group were observed. In the intervention group, a decrease in these outcomes was found, while they increased in the control group. For waist circumference and fat mass, this intervention effect was independent of confounding variables. Within the intervention group, a larger decrease in weight, BMI, waist circumference, and fat mass was found in those who completed the intervention than those who did not. From baseline to the end of the study, the decreases in the intervention group in the primary outcomes have disappeared, except for fat mass. From baseline to the end of the intervention period, a significant difference between the intervention and control group was observed for the pedometer-determined steps/day. In the intervention group, the mean number of

daily steps increased, while it decreased in the control group. No other significant differences between the intervention and control group in changes in the secondary outcomes were found.

The baseline characteristics demonstrated the unhealthy lifestyle behavior of the study population. For example, a mean BMI of 30 kg/m² was found in our study population, compared with a mean BMI of 25.3 kg/m² for the general population in Belgium (Van der Heyden *et al.* 2010). Smoking prevalence in the study population also largely exceeded that of the general population in Belgium. Amongst the study population, about 60% were daily smokers, while in the general population it is about 21% (Van der Heyden *et al.* 2010).

It is well established that individuals with mental disorders are at a greater risk of being overweight or obese than the general population (Limosin *et al.* 2008, Scott and Happell 2011). Important reasons for this high prevalence consist of the use of SGAs (Parsons *et al.* 2009), lower physical activity and exercise levels (Nyboe and Lund 2012, Osborn *et al.* 2007) and unhealthy eating habits (Roick *et al.* 2007, Strassnig *et al.* 2003). It is therefore promising that growing attention is being given to the importance of health promotion interventions targeting physical activity and healthy eating in this population. Several guidelines already emphasized the importance of physical activity and healthy eating (NICE 2006, U.S.Department of Health and Human Services 2008, World Health Organization 2004) and the relevance of health promotion in mental health care is also acknowledged by the European Psychiatric Association (De Hert M. *et al.* 2009).

The results of the study demonstrate that relatively small but significant reductions in body weight, BMI, waist circumference, and fat mass are possible following a 10-week health promotion intervention targeting physical activity and healthy eating. Previous research has shown that weight loss through lifestyle interventions in individuals with mental disorders is possible. The results of these studies must, however, interpreted cautiously due to their methodological limitations such as small sample sizes or the absence of a control group (Chacon *et al.* 2011, Verhaeghe *et al.* 2011). The results of our study are more promising in those participants who completed the intervention. It is also important to note that 68% of the participants in the intervention group were taking a SGA. It is well established that these drugs are associated with weight gain in individuals with mental disorders (Allison and Casey 2001, Parsons *et al.* 2009).

The decreases in weight, BMI, waist circumference, and fat mass in the intervention group disappeared in the period from the end of the intervention period to the end of the study. So, although emphasis on health promotion targeting physical activity and healthy eating during a certain period of time is beneficial, it probably needs to be continued. Therefore, the integration of health promotion activities, alongside other treatment aspects such as psychological and medication

treatment, into the daily care of individuals with mental disorders should be considered. Lifestyle interventions are essential in lowering the risk and morbidity associated with obesity and should be integrated into the daily care of individuals with mental disorders (Cabassa *et al.* 2010, Robson and Gray 2007).

All mental health nurses involved in the study received the same training by one (the same) member of the research team. They received detailed instructions concerning the delivery of the group-based sessions as well as how to support the participants individually. The aim was to obtain as much consistency as possible concerning the information provided. We are, however, aware that the views and attitudes of individual nurses towards physical activity and healthy eating may to some extent have influenced the way in which they communicated with the participants.

The design of evaluation studies of public health interventions, like health promotion programs, poses several problems and they require multiple, flexible, and community driven strategies (Rychetnik *et al.* 2002). Randomization at the individual level may cause contamination bias if individuals in the control group receive some aspects of the intervention by being in proximity to individuals in the intervention group (Christie *et al.* 2009, Taljaard *et al.* 2009). To avoid the risk of contamination bias arising from the fact that participants in the intervention and control group could be living together in the same SHO, it was decided to use a cluster design with the SHO as the unit of clustering. It was assumed that if SHOs were assigned to a non-preferred study arm, they could be disappointed and their interest in participating in the study could be reduced as a result (Howard and Thornicroft 2006, Macias *et al.* 2009). A substantial risk of non-participation on the SHO-level was also assumed based on the results of previous qualitative research which has identified lack of time due to the high workload in the daily care of patients with mental disorders as a common barrier for mental health professionals to engage in health promotion programs (Casey 2007, Jormfeldt *et al.* 2003). For these reasons, a preference design appeared to be appropriate. As far as is known to the authors, this is the first trial examining the effectiveness of a health promotion intervention using a cluster preference RCT design.

Besides the significance of the results it is also important to consider their clinical relevance. According to the UK Department of Health (Department of Health 2006), reductions in body weight of 5% or more are considered to greatly reduce the risks of physical health problems. At the end of the intervention period (at ten weeks), only 5.5% of the participants in the intervention group reached this target. Among those who completed the intervention, however, the figure jumps to 10.7%. With a further 13% losing between four and five percent of their body weight. To our opinion,

integrating physical activity and healthy eating into the daily care of individuals with mental disorders has the potential to increase the number of them losing at least 5% of their body weight.

The "Health promotion on well-balanced eating and healthy physical activity" program (Flemish Institute of Health Promotion and Disease Prevention 2007) served as the basis for that used in our study. The use of this program appeared reasonable to us as its target population consists of the general population in the Flanders region (Belgium). Some adjustments were made to it to better meet the needs and interests of the population of individuals with mental disorders included in our study. At this point, it is important to emphasize that, as far as is known to the authors, the efficacy of this general population program has not been tested, resulting in no information on possible effect size. For this reason, the sample size calculation for our study was performed using a between group change of 3.5 kg found in a systematic review we performed (Verhaeghe *et al.* 2011). The mean between group change of 0.57 kg found in our study was yet to a large extent lower as the change of 3.5 kg. To our opinion, two possible explanations for the deviation between the weight loss of 3.5 kg found in our review and the amount of weight loss of 0.57 kg found in our study exist. First, the larger amount of weight loss found in the review may be explained by the fact that all but two of the fourteen studies reviewed consisted of an intervention duration in excess of the 10-week intervention period of our study (range: 2-12 months). Second, the studies included in the review consisted of a psycho educational and /or behavioral intervention. In seven of them, this was combined with supervised exercise. Additionally, in some studies, the intervention also included restricted energy intake. This may be a second explanation for the larger amount of weight loss observed in the review. The health promotion program assessed in our study did not include individualized energy restriction or energy expenditure goals such as low fat or low calorie diets. Based on the results of previous qualitative research (Verhaeghe *et al.* 2013), it was assumed that such an intervention would be too demanding for both the patients and the mental health nurses.

The sample size calculation identified that 371 individuals in each group were needed. This sample size was not reached as only 201 individuals in the intervention group and 83 in the control group agreed to participate. This number represents about only 20 per cent of the individuals living in these settings in the Flanders region, which places a limitation on the generalizability of the findings to the wider population of individuals living in sheltered housing. Compared with the most recent available data from the Federal Public Service of Health (Federal Public Service Health 2012) on the sheltered housing population in the Flanders region, our study population had a higher proportion of women (39 vs. 30%), mean age was slightly lower (46.3±12.3 vs. 50.0±13.0 years), and it was more frequently diagnosed with mood disorders (25% vs. 16%). Data on the duration of stay in sheltered housing (4 vs.

4.2 years) and the proportion of individuals with schizophrenia (38% vs. 39%), substance misuse (16% vs. 18%), and personality disorders (14% vs. 12%) were comparable.

The study sample was characterized by high drop out rates. At the end of the study, 40 percent of the participants in both the intervention and control group were lost to follow-up. The main reason for dropping out was no further interest or motivation to participate. This is congruent with the results of previous research on barriers to individuals with mental disorders engaging in health promotion activities which report lack of motivation and energy as a consequence of the mental disorder and side effects of psychotropic drug use like sedation (McDevitt *et al.* 2006, Shiner *et al.* 2008, Ussher *et al.* 2007).

Another element of concern was the high number of individuals who did not fill out the various questionnaires at the end of the intervention period. This was related to the considerable drop-out rates from the study as a result of the lack of further interest and/or motivation to participate. For example, only 56 per cent in the intervention group and 61 percent in the control group filled out the SF36 Health Survey questionnaire at the second measurement at ten weeks. Only 46 and 48 percent of the participants in the intervention and control group respectively registered the number of daily steps during the second registration period (at ten weeks). For this reason, the promising results of the increase in steps/day from baseline to the end of the intervention period must be interpreted cautiously.

We are aware that omitting mixed model analysis is another limitation of the current study. The decision to omit this analysis was based on the fact that a limited group-level variance compared to the total variance was present. For all primary outcomes, an ICC below 5% was found, indicative of a low level of variance at the level of the SHOs (Hox 2010). Moreover, the number of participating SHOs and the number of individuals per SHO was below the minimum numbers of groups and individuals recommended for mixed model analysis (Hox 2010). We nevertheless performed unadjusted mixed model analysis to examine whether the SHO clustering had an impact on the intervention effect for the primary outcomes from baseline to the end of the intervention period at ten weeks. The significant differences between the intervention and the control group in changes in body weight ($p=0.111$) and BMI ($p=0.109$) disappeared, while they remained significant for waist circumference ($p=0.006$) and fat mass ($p=0.013$) (data not shown). No ICC related to health promotion programs with a cluster randomized controlled design in individuals with mental disorders was found in the literature. To account for the degree of correlation within the several clusters in our study, the calculated sample size was multiplied with a design factor. As for the ICC, no design factor

for the type of intervention assessed in our study was found in the literature. So, an assumption was made based on a design effect of 1.5 used in previous studies (Kaiser *et al.* 2006, Rowe *et al.* 2002).

The target population of our study comprised individuals with a wide variety of psychiatric diagnoses such as schizophrenia, mood disorders, and personality disorders. From a methodological point of view it may have been more suitable to focus only on individuals with a specific diagnosis, which would probably have lead to different results. However, it has already been well established that overweight and obesity affects individuals with mental disorders irrespective of their specific psychiatric diagnosis (Davidson *et al.* 2001, Dickerson *et al.* 2006, Mackin *et al.* 2007). In this sense, health promotion targeting physical activity and healthy eating appears to be important and desirable for individuals with mental disorders independent of their diagnosis. In any case, sheltered housing is aimed at individuals with a wide variety of mental health problems. For these reasons, it was decided to include individuals irrespective of their diagnosis into the study population. Further research is nevertheless required to examine the effects of this kind of intervention in individuals with a specific psychiatric diagnosis.

CONCLUSIONS

In conclusion, the study described in this paper has shown that small significant improvements in body weight, BMI, waist circumference, and fat mass are possible in individuals living in sheltered housing following a psycho-educational, behavioral and exercise group-based intervention. The results are more promising in those participants who completed the intervention. The results of the present study emphasize the need to Integrate lifestyle counseling into the daily care of individuals with mental disorders in order to lower the risk of serious somatic diseases including CVD and type 2 diabetes. Additional controlled trials of longer duration are necessary in order to examine the long-term effects of maintained health promotional efforts. In this context, research on the optimal "intervention dose" in terms of acceptability, effectiveness and cost-effectiveness of the intervention is also required. Further research is additionally required to examine the effectiveness of such programs in other settings, for example inpatient settings, and under other conditions such as group-based verses individually-based interventions or programs limited to individuals with BMI >25 kg/m² or on the same medication regimen. Further research is also needed to examine the most effective ways to motivate individuals with mental disorders to participate and persist in health promotion programs.

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CHAPTER 7

Health economic evaluation of a health promotion intervention in mental health care

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ABSTRACT

Background

Overweight and obesity result in considerable health care costs and reduced health-related quality of life. In individuals with mental disorders, prevalence rates of these conditions are higher than in the general population. Health promotion programs targeting physical activity and healthy eating are a substantial pathway in the prevention and treatment of overweight and obesity.
In mental health care, there is a lack of health economic evaluations assessing the cost-effectiveness of such interventions. The aim of this study was to examine the cost-effectiveness of a health promotion intervention targeting physical activity and healthy eating in individuals with mental disorders.

Methods

An age- and gender-dependent Markov decision-analytic model assuming a public payer perspective was used, projecting the one year results of a 10-week health promotion program over a time horizon of 20 years, assuming a repeated yearly implementation of the program. Scenario analysis was applied evaluating the effects of three alternative modeling assumptions on the results. One-way sensitivity analysis was performed to assess the effects of varying key parameters on the results.

Results

An incremental cost-effectiveness ratio of 44,693€/QALY in men and 63,060€/QALY in women was found in the base case. Scenario analysis assuming an increase in health-related quality of life as a direct result of a BMI decrease resulted in much better cost-effectiveness in both men (4,127€/QALY) and women (4,311€/QALY). The results of the one-way sensitivity analysis identified that the model was most sensitive to the intervention effect.

Conclusion

As far as known to the authors, this is the first study assessing the cost-effectiveness of a health promotion intervention targeting physical activity and healthy eating in individuals with mental disorders. Although this health promotion intervention was not cost-effective in the base case, further health economic evaluations in this domain are required to provide payers and governments with better insights how to spend the available resources in the most efficient way.

BACKGROUND

Overweight and obesity are, at least partially, associated with unhealthy lifestyle behavior including low physical activity levels, sedentary lifestyles and poor eating habits (Cameron *et al.* 2003, Sanchez *et al.* 2008). These conditions contribute to the development of cardiovascular disease (CVD), type 2 diabetes and certain cancers (World Health Organization 2004a). In individuals with mental disorders including schizophrenia, bipolar disorders, anxiety disorders and depressive disorders, the prevalence of overweight and obesity is even higher compared with the general population (Dickerson *et al.* 2006, Filik *et al.* 2006, Mackin *et al.* 2007). Important reasons of the high burden of these conditions in this population consist of the use of especially second generation antipsychotic drugs (Parsons *et al.* 2009), lack of regular PA and unhealthy eating behavior (Osborn *et al.* 2007b, Roick *et al.* 2007).

Overweight and obesity result in considerable direct and indirect health care costs. Direct costs include the costs of diagnosis and treatment (for example hospital stay, medicines, physician visits). The indirect health care costs are those resulting in absence from work, early retirement, and mortality (Anderson *et al.* 2005, Degli Esposti E. *et al.* 2006, Konnopka *et al.* 2011). Beside the impact of overweight and obesity on health care costs, these conditions are also associated with reduced health-related quality of life (Tarride *et al.* 2012). Excessive weight gain can be prevented or treated by living a healthy lifestyle including regular physical activity, exercise, and healthy eating (Chaput *et al.* 2007, World Health Organization 2004b). Based on the high prevalence of overweight and obesity in individuals with mental disorders, lifestyle modification through physical activity and healthy eating is crucial to reduce the burden of important somatic diseases including CVD, type 2 diabetes and certain cancers in this population (De Hert M. *et al.* 2006, Hennekens *et al.* 2005, Hippisley-Cox *et al.* 2007).

Evaluation studies assessing the effectiveness of health promotion interventions are important to obtain knowledge on which interventions are most effective. Evidence on the effectiveness alone of an intervention is insufficient for policy making. Health care budgets are limited resulting in the fact that policy makers are facing the problem how to set priorities in the allocation of health care resources to medical or public health interventions (Littlejohns *et al.* 2012). Knowledge on this can be obtained by performing economic evaluations of health care interventions providing payers and governments with better insights how to spend the available resources in the most efficient way. In the general population, health economic evaluations of health promotion interventions targeting physical activity (Garrett *et al.* 2011) and healthy eating (Forster *et al.* 2011, van Baal *et al.* 2008) yield mixed evidence on the cost-effectiveness of these kinds of interventions. In mental health care,

there is even a lack of trials evaluating the cost-effectiveness of health promotion interventions targeting physical activity and healthy eating (Verhaeghe *et al.* 2011).

The aim of the current study was to evaluate the cost-effectiveness of a health promotion intervention targeting physical activity and healthy eating in individuals with mental disorders living in sheltered housing in the Flanders region (Belgium). Details on the design of the effectiveness study are described elsewhere (Verhaeghe *et al.* 2012). In brief, the study consisted of a 10-week health promotion intervention targeting physical activity and healthy eating, followed by a follow-up period of six months. The intervention comprised ten group-based psycho-educational and behavioral sessions, supervised exercise (walking sessions) and individual support. Individuals in the intervention group received the 10-week health promotion program on top of their treatment as usual, while individuals in the control group only received treatment as usual.

METHODS

Study design and study population

An age- and gender-dependent Markov decision-analytic model applying a public payer perspective was used to predict health outcomes and costs for the intervention and control arm. The studied target population consisted of adults between 18 and 70 years living in sheltered housing in the Flanders region (Belgium). Two hundred and one individuals were included in the intervention group and 83 individuals in the control group. Mean age of the study population was 46.3 years and 61% were male. Sixty-seven point seven per cent was living together with other patients and the median duration of stay in sheltered housing was four years. The effectiveness study showed a significant but small difference in mean BMI change from baseline to the end of the intervention period (at 10 weeks) of 0.20 kg/m² between the intervention and control group. From baseline to the end of the study (at 36 weeks), the significant difference in mean BMI change between the intervention and control group disappeared.

The model predicts health effects expressed as quality-adjusted life years (QALYs) gained (Drummond *et al.* 2005).QALYs are calculated by multiplying the utility level for a given disease status (a health-related quality of life weight ranging between 0 and 1) with the number of years an individual lives with a particular condition. A utility of 1 is equal to full or perfect health, while 0 stands for death. In the cost dimension, both the costs of the health promotion intervention and the costs of the diseases were accounted for.

The ratio of the incremental costs to the incremental QALYs is called the incremental cost-effectiveness ratio (ICER), calculated as

$$ICER = \frac{COST_I - COST_{NI}}{QALY_I - QALY_{NI}}$$

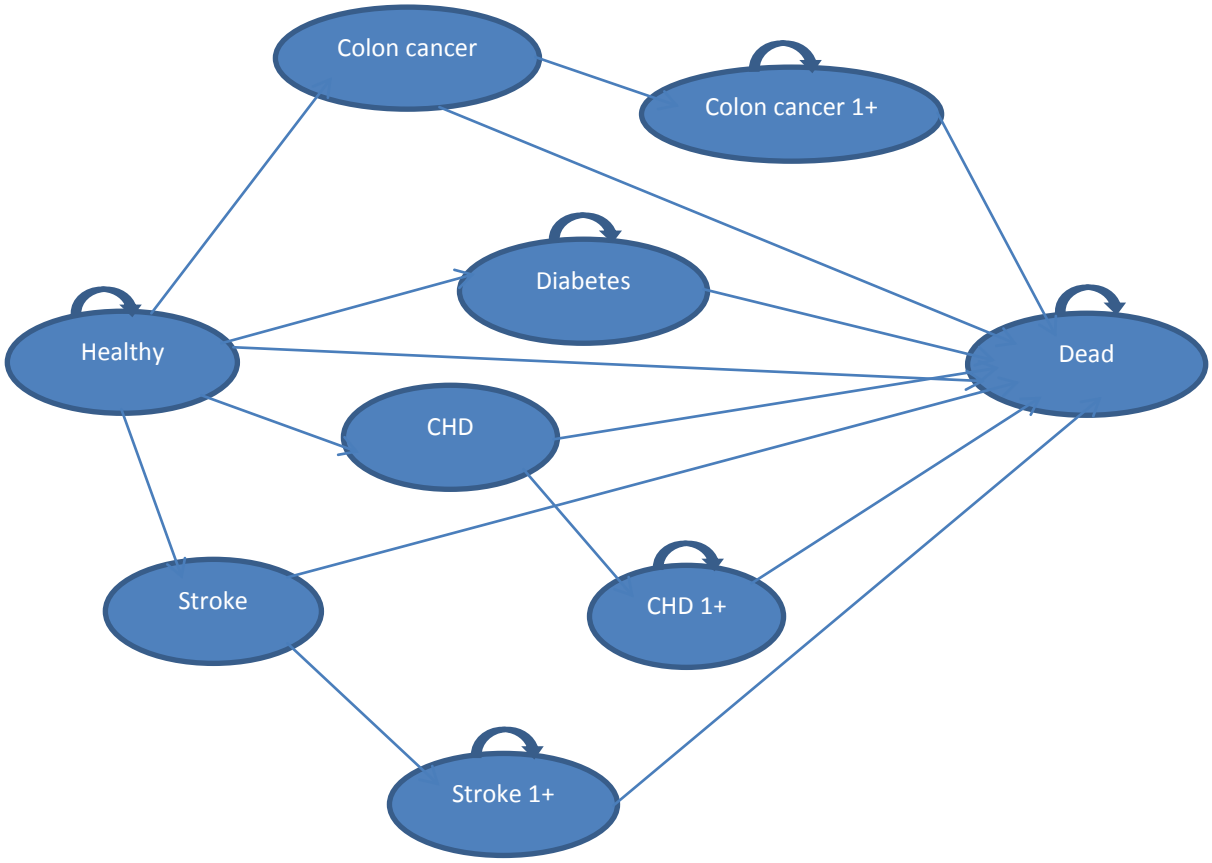
where I is intervention and NI is no intervention.

Markov decision-analytic model: description of states and transitions

The model was based on a recently published Markov model used for the health economic evaluation of a community-based physical activity intervention (De Smedt D. *et al.* 2012) and further developed using Microsoft® Excel 2007 (Microsoft Corporation, Redmond, WA, US) to account for the specific context of our study and target population.

Nine possible health states were included into the model: (i) at risk, (ii) type 2 diabetes, (iii) coronary heart disease (CHD)-first year, (iv) CHD-follow up, (v) stroke-first year, (vi) stroke-follow up, (vii) colon cancer-first year, (viii) colon cancer-follow up, and (ix) dead (Figure 1).

Figure 1 Markov decision-analytic model



The time horizon of the model was 20-years including 20 one-year periods (called 'cycles'). A simulation of the evolution of the cohort was made based on the change in BMI and the associated risk of developing BMI related diseases. Four diseases were included in the model, based on the literature suggesting that a BMI decrease is associated with a lower risk of developing diabetes, CHD, stroke, and colon cancer (Kurth *et al.* 2002, McGee 2005, Renehan *et al.* 2008, Rosengren *et al.* 2003, Schienkiewitz *et al.* 2006). As the risk of developing these diseases varies according to age and sex, a separate model for men and women including several age-bands was developed.

It was assumed that all individuals started in the "at risk" state. During each cycle, each individual has a risk of developing diabetes, CHD, stroke, colon cancer or dying from another cause. Once an individual is in the "diabetes" state (i.e. diagnosed with diabetes), he or she can only remain in this state or go to the "dead" state. Since these patients have an increased risk of developing micro- and macrovascular complications, the prevalence of these complications and associated costs were taken into account. Patients suffering from a stroke move to the "stroke" state. Once a patient has had a stroke, he or she can only move to the follow-up "stroke 1+" state or to the "dead" state. Patients who have had a fatal stroke move to the "dead" state after being in the "stroke" state for one year (one cycle). The prevalence and the associated costs of fatal and non-fatal stroke were taken into account in the "stroke" state. Individuals suffering from CHD move to the "CHD" state. CHD includes myocardial infarction and stable or unstable angina. Once a patient has suffered from CHD, he or she can only move to the follow-up "CHD 1+" state or to the "dead" state. Those developing a fatal myocardial infarction move to the "dead". As for stroke, the prevalence and associated costs of fatal and non-fatal CHD were taken into account in the "CHD" state. Patients suffering from colon cancer move to the "colon cancer" state or to the "dead" state. Subsequently, they can only move to the "colon cancer 1+" state or to the "dead" state after being in the "colon cancer" state for one cycle. Once a patient enters the "dead" state, no further transitions are possible, as this is the final state.

Clinical data inputs

Disease transition probabilities

The risk of developing a disease or dying throughout the model was specified with transition probabilities. The age- and gender-dependent transition probabilities are based on epidemiological studies. It is known that people with mental disorders are at an increased risk of having CHD (Osborn *et al.* 2007a), stroke (Osborn *et al.* 2007a), diabetes (Truyers *et al.* 2011), or colon cancer (Hippisley-Cox *et al.* 2007) (table 1).

Table 1 Relative risk of diabetes, CHD, stroke, and colon cancer in individuals with mental disorders

Disease	age (years)	incidence rate ratio	reference	mortality rate ratio			reference
				men/women	men	women	
CHD	18-49	1.42	1	3.22			1
	50-75	1.01	1	1.86			1
Stroke	18-49	1.77	1	2.53			1
	50-75	1.77	1	1.89			1
Diabetes	15-24	1.77	2		2.46	1.89	3
	25-34	1.77	2		2.46	1.89	3
	35-44	1.77	2		2.46	1.89	3
	45-54	1.77	2		2.46	1.89	3
	55-64	1.77	2		2.46	1.89	3
	65-69	1.77	2				
Colon Cancer		2.90					4
Overall mortality					2.94	2.83	5

CHD, Coronary Heart Disease; 1, (Osborn *et al.* 2007a); 2, (Truyers *et al.* 2011); 3, (Laursen *et al.* 2007); 4, (Hippisley-Cox *et al.* 2007); 5, (Brown *et al.* 2010)

In the Markov model, the calculated age- and gender-dependent transition probabilities for the general population were multiplied with those relative risk factors. An overview of the age- and gender-dependent transition probabilities used in the Markov model are listed in table 2.

The risk of developing diabetes varied between 0.027% and 1.311% depending on age and gender (RIVM 2010a, Truyers *et al.* 2011, Wens *et al.* 2001). Prevalence rates of microvascular and macrovascular complications in diabetic patients were obtained from the study by Williams et al. (Williams *et al.* 2002). The probability of developing CHD varied between 0.009% and 1.198% depending on age and gender (De Backer 2006, Osborn *et al.* 2007a, RIVM 2010c). The risk of developing stroke varied between 0.011% and 0.559% (Intego 2010, Osborn *et al.* 2007a, RIVM 2010b). Finally, the risk of developing colon cancer was derived from the Belgian Cancer Registry (Kankerregister 2010) and from a study by Hippisley-Cox et al. (Hippisley-Cox *et al.* 2007) to account for the relative risk of developing colon cancer in individuals with mental disorders. The risk of developing colon cancer varied between 0.004% and 0.597%.

Table 2 Age- and gender- dependent probabilities (%) for developing diabetes, stroke, coronary heart disease or colon cancer and associated mortality rate(%)

	Diabetes				Coronary Heart Disease					Stroke					Colon cancer					
								mortality rate					mortality rate							
	incidence		mortality rate		incidence		1st year	follow up		incidence		1st year	follow up		incidence		mortality rate		overall mortality	
age (years)	men	women	men	women	men	women		men	women	men	women		men	women	men	women	men	women	men	women
20-24	0.033	0.027	0.290	0.078	0.009	0.010	31.070	8.835	8.680	0.014	0.011	37.000	0.414	0.148	0.004	0.004	14.089	14.089	0.235	0.078
25-29	0.052	0.042	0.315	0.107	0.022	0.017	31.070	8.835	8.680	0.022	0.017	37.000	0.449	0.203	0.008	0.008	14.089	14.089	0.251	0.105
30-34	0.088	0.072	0.326	0.119	0.049	0.027	31.070	8.835	8.680	0.033	0.026	37.000	0.466	0.227	0.012	0.012	14.089	14.089	0.255	0.116
35-39	0.152	0.123	0.463	0.198	0.102	0.046	31.070	8.835	8.680	0.049	0.038	37.000	0.662	0.377	0.032	0.032	14.089	14.089	0.346	0.189
40-44	0.256	0.209	0.638	0.310	0.198	0.080	31.070	8.835	8.680	0.073	0.058	37.000	0.912	0.588	0.037	0.037	14.089	14.089	0.438	0.282
45-49	0.414	0.337	1.083	0.510	0.354	0.137	31.070	8.835	8.680	0.110	0.086	37.000	1.547	0.969	0.085	0.085	14.089	14.089	0.705	0.454
50-55	0.628	0.510	1.821	0.838	0.419	0.166	31.070	8.835	8.680	0.165	0.130	37.000	1.943	1.188	0.164	0.164	14.089	14.089	1.147	0.743
56-59	0.879	0.714	2.920	1.200	0.646	0.275	31.070	8.835	8.680	0.250	0.197	37.000	3.116	1.702	0.256	0.256	14.089	14.089	1.788	1.044
60-64	1.112	0.904	4.481	1.848	0.904	0.423	31.070	8.835	8.680	0.368	0.290	37.000	4.782	2.621	0.373	0.373	14.089	14.089	2.653	1.513
65-69	1.311	1.065	6.353	2.574	1.198	0.631	31.070	8.835	8.680	0.559	0.440	37.000	6.779	3.651	0.597	0.597	14.089	14.089	3.759	2.088

Mortality probabilities

The age- and gender-dependent mortality probabilities for the diseases included into the model were either calculated by multiplying average national mortality probabilities (Nationaal Instituut voor Statistiek 2010) with the mortality increase associated with a certain disease or they were obtained from the literature. Ubink-Veltmaat et al. (Ubink-Veltmaat *et al.* 2003) found a 40% mortality increase in people with diabetes. A twofold mortality increase exists among stroke patients compared with the general population (Intego 2010). For CHD, Moholdt et al. (Moholdt *et al.* 2008) reported an annual mortality probability of 8.98% for men and 8.68% for women. Yearly mortality in colon cancer patients was found to be 14.09% (Gatta 2006). The results of several studies showed that individuals with MD are at an increased risk of dying of the diseases included into the Markov model (Brown *et al.* 2010, Hippisley-Cox *et al.* 2007, Laursen *et al.* 2007, Osborn *et al.* 2007a, Truyers *et al.* 2011) (table 2). In the Markov model, the mortality probabilities for the general population were multiplied with those relative risk factors.

Effect of the health promotion intervention

The probability that the health promotion intervention resulted in a significant BMI change between an intervention and control group was derived from the effectiveness study of the research project. A small difference of 0.20 kg/m² between the intervention and control group was found following the 10-week health promotion intervention. The results of previous research suggested that a reduction of 1 BMI unit resulted in a decreased risk of developing diabetes (Schienkiewitz *et al.* 2006), CHD (McGee 2005), stroke (Kurth *et al.* 2002, Rosengren *et al.* 2003), and colon cancer (Renehan *et al.* 2008). Based on this evidence, the risk reductions applied in the Markov model were calculated (table 3).

Table 3 Original data and adjusted reductions used in the model

Health state	Relative risk reduction 1 kg/m² BMI decrease (%)		Risk reductions applied in the Markov model (%)		Reference
	men	women	men	women	
CHD	4.7	5.7	0.94	1.14	1
Stroke	6.0	8.5	1.20	1.70	2,3
Diabetes	13.0	11.0	2.60	2.20	4
Colon cancer	5.2	2.0	1.04	0.40	5

CHD, coronary heart disease

Cost data input

Disease costs

A public payer perspective was considered, including only direct medical costs. For CHD and stroke, first year costs and follow-up costs were taken separately into account as the cost for an individual suffering from a newly diagnosed CVD is different from the cost for those already suffering longer from CVD (Annemans *et al.* 2010, Lamotte *et al.* 2003). The overall cost of diabetes was calculated accounting for the proportion of diabetic patients with no complications, microvascular complications, macrovascular complications, and those with both microvascular and macrovascular complications and the costs associated with these complications (Williams *et al.* 2002). Research on the economical consequences of colon cancer suggests that both the first year following the diagnosis and the last year (end of life) are associated with the highest costs (Van Gelder 2009). So, for colon cancer, an equal cost per year was assumed. No costs were attached to the "dead" state, since the costs of fatal events were already accounted for in the relevant disease states. An overview of the costs included into the Markov model are listed in table 4. Future costs were discounted at 3% as suggested by the Belgian Health Care Knowledge Centre (Cleemput *et al.* 2006).

Table 4 Costs and utilities used for the Markov decision-analytic modeling - base case

Parameter	Base case		Reference
	men	women	
Cost data input (€)			
CHD first year (cost/year)	4386		1,2,3
CHD subsequent years (cost/year)	1183		1,3
Stroke first year (cost/year)	13319		1
Stroke subsequent years (cost/year)	4756		1
Diabetes (cost/year)	3312		4
Colon cancer (cost/year)	7988		5
Intervention cost first year	35		
Intervention cost year 2-5	21		
Utilities			
At risk	0.71		6
CHD	0.47		7
CHD1	0.56		7
Stroke	0.50		7
Stroke1	0.50		7
Diabetes	0.63		7
Colon cancer	0.64		7
Colon cancer1	0.64		7

1, (Annemans *et al.* 2007); 2, (Lamotte *et al.* 2003); 3, (Annemans *et al.* 2010); 4, (Williams *et al.* 2002); 5, (Van Gelder 2009); 6, (Saarni *et al.* 2010); 7, (De Smedt D. *et al.* 2012)

Intervention costs

The intervention costs per participant included the use of a pedometer (13.70€), staff cost (20.57€), administrative costs (0.48€), and the intervention manual cost (0.25€). An effective duration of five years was considered for the pedometers. For this reason, the pedometer cost was taken into account in the Markov model every five year. The total duration time of the intervention program, the number of participating sheltered housing organizations, and the time investment (hourly wages) of the mental health nurses involved in the program were taken into account to calculate the staff cost per participant. The manual cost included the cost per participant of the manual developed for the staff supervising the intervention. The administrative costs included copies with exercises for use in the group-based sessions.

Health-related quality of life

The baseline utility, i.e. the utility for individuals with mental disorders without a history of diabetes, CHD, stroke or colon cancer was set at 0.71 (Saarni *et al.* 2010). The utilities related to the other disease states were derived from a health economic evaluation of a community-based physical activity intervention (De Smedt D. *et al.* 2012). QALYs were calculated by multiplying the utilities with the number of life years an individual is living with a disease included into the model. Future QALYs were discounted at 1.5% as required by the Belgian Health Care Knowledge Centre (Cleemput *et al.* 2006). An overview of the utilities used in the Markov model can be found in table 4.

Scenario and one-way sensitivity analysis

Health economic evaluations are characterized by some degree of uncertainty, imprecision, or methodological considerations (Drummond *et al.* 2005). To handle this uncertainty, scenario analysis and one-way sensitivity analysis was performed. In the scenario analysis, three alternative modeling assumptions were assessed. In a first scenario, full compliance with the health promotion program was assumed. For this analysis, the mean change in BMI of only those participants who completed the intervention was used as input parameter. In a second scenario, the effects on the costs and health effects of offering the program twice a year were analyzed. In the last scenario, it was assumed that the decrease in BMI in the intervention group was associated with a n increase in health-related quality of life. This assumption was based on the findings of a previous health economic evaluation of exercise and the prevention of a number of somatic diseases (Annemans *et al.* 2007). In that study, a utility loss of 0.021 was accounted for per unit BMI increase. Based on these results, we assumed a utility gain of 0.021 per unit BMI decrease. Using one-way sensitivity analysis made it possible to assess the effects of key parameters on the ICER, by varying them

separately. The following parameters were varied: intervention cost, intervention effect, disease costs, and relative risk reductions of the diseases related to a BMI decrease.

RESULTS

Base case

An average QALY amount of 10.81 and 11.48 with a cost of 4,215€ and 4,283€ for respectively men and women was found for the treatment as usual (control) group. The implementation of the health promotion intervention targeting physical activity and healthy eating resulted in a limited QALY improvement of 0.006 in men and 0.005 in women. The total discounted costs of the intervention were 4,483€ in men and 4,575€ in women. This resulted in a delta cost between intervention and no intervention of 268€ and 292€ in respectively men and women. An ICER of 44,693€/QALY in men and 63,060€/QALY in women was found. Based on a cost-effectiveness threshold of 30,000 €/QALY, it can be concluded that the health promotion program in its current form in both men and women was not cost-effective.

Scenario analysis of alternative model assumptions

Applying the scenario of full compliance with the health promotion intervention resulted in a cost-effective intervention in men (22,810 €/QALY), and borderline cost-effective in women (33,147 €/QALY). Offering the scenario twice a year did not result in a cost-effective intervention in men (40,148 €/QALY) and in women (56,860 €/QALY). The health promotion program became cost-effective if we assumed an increase in health-related quality of life as a result of the BMI decrease (men: 4,127 €/QALY; women: 4,311 €/QALY). An overview of the different scenario cost-effectiveness results is listed in the tables 5a and 5b.

Table 5a Scenario analysis: effects on cost/QALY in men

	Control		Intervention				
	QALYs	**Cost (€)**	**QALYs**	**Cost (€)**	**Δ QALY**	**Δ Cost (€)**	**ICER (€/QALY)**
Base case	10.810	4,215	10.816	4,483	0.006	268	44,693
Scenario 1	10.810	4,215	10.820	4,441	0.010	226	22,810
Scenario 2	10.810	4,215	10.822	4,697	0.012	483	91,236
Scenario 3	10.810	4,215	10.875	4,483	0.065	268	4,127

scenario 1, full compliance with the program; scenario 2, offering the program twice a year;
scenario 3, increase in quality of life as a result of the BMI-decrease in the intervention group

Table 5b Scenario analysis: effects on cost/QALY in women

	Control		Intervention				
	QALYs	Cost (€)	QALYs	Cost (€)	Δ QALY	Δ Cost (€)	ICER (€/QALY)
Base case	11.484	4,283	11.490	4,575	0.005	292	63,060
Scenario 1	11.484	4,283	11.492	4,537	0.008	254	33,147
Scenario 2	11.484	4,283	11.494	4,811	0.009	527	126,684
Scenario 3	11.484	4,283	11.552	4,575	0.068	292	4,311

scenario 1, full compliance with the program; scenario 2, offering the program twice a year;
scenario 3, increase in quality of life as a result of the BMI-decrease in the intervention group
ICER, Incremental Cost-Effectiveness Ratio

One-way sensitivity analysis

One-way sensitivity analyses were performed to evaluate the effect of the uncertainty of several parameters on the ICER. The results of the one-way sensitivity analyses are shown using Tornado diagrams (Figure 2 and 3). From these figures it can be concluded that the model is most sensitive to the intervention effect and to the intervention cost for the years in which the pedometer cost was not taken into account. Varying the other input parameters of the model had less influence on the results.

Figure 2 One-way sensitivity analysis: effects on cost/QALY in men

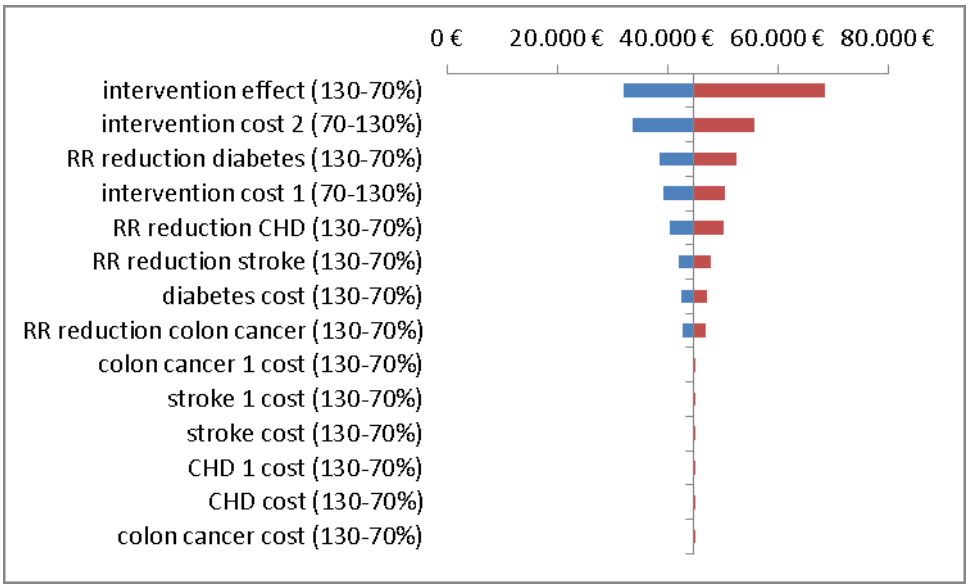
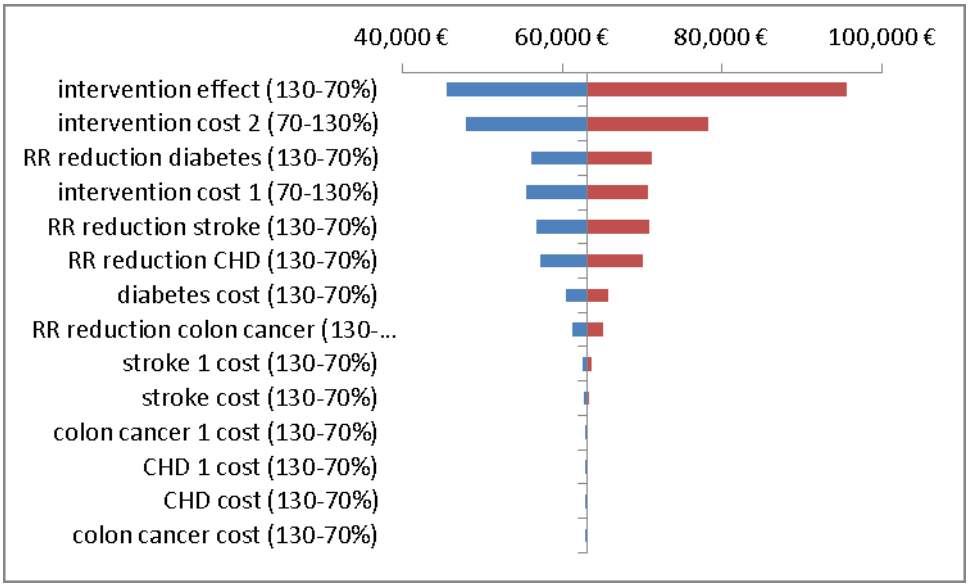


Figure 3 One-way sensitivity analysis: effects on cost/QALY in women



DISCUSSION

The aim of the study was to evaluate the cost-effectiveness of a health promotion intervention targeting physical activity and healthy eating in individuals with mental disorders living in sheltered housing in the Flanders region (Belgium). This occurred by using a Markov decision-analytic health economic model providing information on the costs and the health benefits related to the health promotion program. The use of modeling, which allows real-life situations to be represented in a mathematical or statistical manner, has gained wide acceptance in the field of health economic evaluation. The most frequent approach is Markov modeling, in which data from different sources can be combined and projections of the results over time can be made (Drummond *et al.* 2005).

The base case calculation showed that the intervention was not cost-effective in both men and women. Scenario analysis assuming an increase in health-related quality of life as a result of the BMI decrease showed that the program became cost-effective in men and in women. Assuming full compliance with the program resulted in a cost-effective and borderline cost-effective intervention in men and women respectively. The cost-effectiveness results were most sensitive to the input parameters 'intervention effect' and 'intervention cost' (for the years in which the pedometer cost was not taken into account) as demonstrated with one –way sensitivity analysis. An ICER of 44,693€/QALY in men and 63,060€/QALY in women was found based on the base case calculations. Assuming a cost-effectiveness threshold of 30,000€/QALY as recommended by the Belgian Health Care Knowledge Centre (Cleemput *et al.* 2008), it could be concluded that the health promotion

intervention was not cost-effective. A possible explanation for this result may be that a BMI change of 0.20 kg/m², drawn from the effectiveness study, was used to calculate the risk reduction of the diseases included into the Markov model. This resulted in limited risk reduction rates for diabetes, CHD, stroke and colon cancer in the intervention group compared with the control group.

Evaluation studies assessing the effectiveness of health promotion programs targeting physical activity and healthy eating in individuals with mental disorders are required to obtain knowledge on which interventions work best and are thus most effective. Evidence on the effectiveness alone of such programs is yet insufficient for policy making. There is a growing need on health economic research in health care. This is largely caused by increasing budget constraints and rising demands for evidence-based health care spending (Drummond *et al.* 2005). So, health systems are facing the problem how to set priorities in the allocation of health care resources to medical or public health interventions (Littlejohns *et al.* 2012). Knowledge on this can be obtained by performing economic evaluations of for example health promotion programs providing payers and governments with better insights how to spend the available resources in the most efficient way. In mental health care, health economic research predominantly focused on cost-effectiveness analyses of psychopharmacological drugs (Hanrahan *et al.* 2006, Polsky *et al.* 2006) and mental health promotion and mental disorder prevention (Zechmeister *et al.* 2008). Nevertheless the need for health economic evaluations of health promotion interventions targeting physical activity and healthy eating in mental health care was already addressed (Evans *et al.* 2005, Menza *et al.* 2004), there is a lack of such evaluation studies (Verhaeghe *et al.* 2011).

It is important to bear in mind that health economic evaluations are characterized by some degree of uncertainty, imprecision, or methodological considerations (Drummond *et al.* 2005). In the current study, scenario analysis and one-way sensitivity analysis was performed to identify critical methodological assumptions and areas of uncertainty. In scenario analysis, a series of scenarios is constructed to evaluate their impact on the cost-effectiveness results, while one-way sensitivity analysis makes it possible to assess the effects of key parameters on the Markov model outputs (i.e. the ICER), by varying them separately. Applying the scenario in which an increase in health-related quality of life as a result of the BMI decrease was assumed, resulted in a cost-effective intervention in both men and women. This result must however been cautiously interpreted. Research on the effects of weight loss on health-related quality of life in people with mental disorders is scarce providing no conclusive evidence that weight loss is associated with an increase in health-related quality of life (Verhaeghe *et al.* 2011). This is similar with the results of a study on exercise and quality of life in a general population sample of postmenopausal women. No significant differences in

health-related quality of life, measured using the SF-36 questionnaire, were found between the individuals who lost weight and those who did not following a 6-month exercise intervention (Martin *et al.* 2009). The scenario assuming 100% compliance with the health promotion program showed a cost-effective result in men, and a borderline cost-effective result in women. It can however be discussed to what extent 100% compliance is achievable in populations with mental disorders. Previous qualitative research identified a number of barriers such as the mental disorder itself or side effects of psychotropic drug use hampering the participation of individuals with mental disorders in health promotion programs (McDevitt *et al.* 2006).

Some limitations and considerations of the current study need to be addressed. First, in the Markov model, it was assumed that the 10-week health promotion intervention was repeated every year maintaining the same BMI change. Studies evaluating the long-term effects of health promotion programs targeting physical activity and healthy eating on BMI change in people with mental disorders is yet lacking (Faulkner *et al.* 2003, Verhaeghe *et al.* 2011). Second, the disease transition and mortality probabilities were retrieved from the literature and national available data. For some transition probabilities, national data were absent, so data from other countries was used. This may have resulted in an underestimation or overestimation of some transition or mortality probabilities. Third, the utilities used in the Markov model also may be under- or overestimated. A utility of 0.71 found by Saarni et al. (Saarni *et al.* 2010) in a sample of schizophrenia and major depressive disorder patients was used for the "healthy state" utility. We are aware that different utilities for populations with other psychiatric diagnoses are possible. For example, a mean utility (measured by the EQ-5D) of 0.50 was found in a population of individuals with borderline personality disorder (van Asselt *et al.* 2009). Nevertheless, about two-thirds of the study population included in the effectiveness study consisted of individuals diagnosed with schizophrenia or mood disorders. In this sense, the use of a utility of 0.71 is to our opinion a reasonable reflection of the reality. It is also important to note that utility weights may vary according to the different measurement instruments being used. For example, Lamers et al. (Lamers *et al.* 2006) compared the use of the EQ-5D and the SF-6D in a sample of mental disorder patients. In that study, the use of the EQ-5D resulted in larger health gains and consequent lower cost-utility ratios compared with the use of the SF-6D. For the several diseases states, no data on health-related quality of life in populations with mental disorders was found. So, these utilities were derived from a cost-effectiveness study of an exercise intervention in a general population sample in Belgium (De Smedt D. *et al.* 2012), probably resulting in an underestimation or overestimation of the utilities included into the Markov model.

As far as known to the authors, this is the first study assessing the cost-effectiveness of a health promotion intervention targeting physical activity and healthy eating in individuals with mental disorders. Further research is required to explore the minimum level of effectiveness that would be needed for an intervention to be cost-effective. Further health economic evaluation studies of health promotion targeting physical activity and healthy eating in mental health care is required accounting for other study conditions such as individually-based programs and/or programs delivered in inpatient settings.

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CHAPTER 8

General discussion

1. INTRODUCTION

In this part of the thesis, the main findings of the research project are summarized and a reflection and discussion of the findings is provided. This is followed by a discussion of some methodological considerations, strengths and limitations of the project and the relevance of the results to public health. The chapter ends with some directions for future research.

The overall aim of the research project was to examine the effectiveness and cost-effectiveness of a health promotion intervention targeting physical activity and healthy eating in individuals with mental disorders living in sheltered housing in the Flanders region (Belgium).

The project was initiated based on two important observations. First, the results of several studies showed higher prevalence rates of overweight and obesity in people with mental disorders compared with the general population (Filik *et al.* 2006, Mackin *et al.* 2007). The high burden of these conditions is, at least partially, associated with unhealthy lifestyle behavior including lack of regular physical activity and more unhealthy eating habits compared with the general population (Osborn *et al.* 2007, Roick *et al.* 2007). It is well known that obesity is a substantial risk factor for the development of several somatic diseases including cardiovascular disease, type 2 diabetes, and certain cancers (World Health Organization 2004). To minimize the risk of obesity, health promotion interventions targeting physical activity and healthy eating should be integrated into the daily care of individuals with mental disorders. In the general population, the effectiveness of lifestyle interventions including supervised exercise, sessions targeting healthy lifestyle behavior, or diet counseling has already been demonstrated (Eriksson *et al.* 2006, Lombard *et al.* 2010). In mental health care, research on health promotion has only recently received attention by researchers and the effectiveness of health promotion targeting physical activity and healthy eating is not yet fully established (Lowe and Lubos 2008).

A second observation was that there is a growing need on health economic research in health care. This is largely due to increasing budget constraints and therefore rising demands for evidence-based and cost-effective health spending (Drummond *et al.* 2005). In the general population, cost-effectiveness studies of health promotion interventions aiming at physical activity and healthy nutrition yield no conclusive evidence (Brunner *et al.* 2001, Muller-Riemenschneider *et al.* 2009), while in mental health care, there is a lack of such studies (Zechmeister *et al.* 2008). Based on these two observations, the PhD project started with a systematic review (Verhaeghe *et al.* 2011a)

evaluating published studies examining the effectiveness and/or cost-effectiveness of lifestyle interventions targeting physical activity and healthy eating in individuals with mental disorders.

In a second part of the research project, a literature review evaluating the perceptions of patients and mental health nurses of health promotion targeting physical activity and healthy eating was performed (Verhaeghe *et al.* 2011b). This was followed by a qualitative study examining the factors influencing the integration of physical activity and healthy eating into the daily care of individuals living in sheltered housing and to gain insight into the relationships and complexities of these factors. (Verhaeghe *et al.* 2013). Health promotion interventions for individuals with mental disorders are even more complex than such interventions in the general population because these programs have to be adapted to and offered beside other treatment aspects, such as psychiatric and psychological treatment. In addition, underlying conditions such as the absence of motivation or side effects of psychotropic drug use (McDevitt *et al.* 2006) raise more issues related to trial participation, compliance with the program and interactions with other treatment aspects. A better understanding of the concerns of patients and mental health nurses regarding the implementation of health promotion programs in mental health care would result in the development of programs that better meet the patients' and nurses' needs.

The knowledge obtained from part one and two was used in the third part of the research project. In this part, an adapted version of the "Health promotion on well-balanced eating and healthy physical activity" (Flemish Institute of Health Promotion and Disease Prevention 2007) was implemented in sheltered housing in the Flanders region (Belgium). Both the effectiveness and cost-effectiveness of the intervention were examined.

2. MAIN FINDINGS

2.1. Effectiveness and cost-effectiveness of health promotion targeting physical activity and healthy eating in people with mental disorders: a systematic review

Fourteen primary studies and three systematic reviews were included in the review. The results of the primary studies showed that small improvements in body weight and BMI were possible through psycho-educational and/or behavioral interventions targeting physical activity, exercise and healthy eating. The difference in weight change between intervention and control groups was significant in nine of fourteen studies. Changes in BMI between intervention and control groups were found to be significant in eight studies.

Effects on health-related quality of life were examined in five studies. Small improvements were, although not always statistically significant, observed. No studies evaluating the cost-effectiveness of health promotion interventions targeting physical activity, exercise and healthy eating in a psychiatric patient population were found.

2.2. Perceptions of mental health nurses and patients about health promotion in mental health care: a literature review

The findings of the review suggested that patients and mental health nurses are aware of the physical and mental health benefits of healthy lifestyle behavior. In general, both patients and nurses were positive towards the potential of integrating health promotion into the daily care. Several barriers hindering the integration of healthy lifestyle behavior were however identified by both patients and nurses. Support from the mental health nurse appeared to be an element of concern for patients to change unhealthy lifestyle behavior.

2.3. Qualitative study: Perceptions of patients and mental health nurses of health promotion

The study population included individuals with mental disorders living in sheltered housing in the Flanders region (Belgium) and mental health nurses working in these settings. The findings of the focus groups with mental health nurses and individual interviews with patients resulted in a better understanding of the factors influencing the integration of health promotion activities into the daily care of people living in sheltered housing. Although physical and mental health benefits of regular

physical activity, exercise and healthy eating were reported, several barriers to integrate more healthy lifestyle behavior into the daily life were described by both patients and nurses.

Support from the mental health nurses to change unhealthy lifestyle behavior was identified by the participating patients as a substantial need. Lack of time was yet identified by the nurses as an important barrier to integrate health promotion activities into their daily work. This was primarily caused by the wide variety of problems (e.g. psychological, relational, administrative, financial) residents in sheltered housing were suffering from. In all three focus groups, there was agreement that stability on these domains of care was considered necessary to focus on lifestyle issues. Some mental health nurses also described that their own views and attitudes towards physical activity and healthy eating influenced the way in which they integrate health promotion counseling in their work.

The majority of the nurses participating in the focus groups reported that they felt more comfortable focusing on the mental health problems of the patients, rather than addressing health promotion issues. A majority of the interviewed patients expressed being interested in preferably group-based health promotion activities because this enabled support from others and social contacts.

2.4. Effectiveness of a health promotion intervention targeting physical activity and healthy eating

The baseline data of our prospective intervention study showed a high prevalence of several risk factors for the development of important somatic diseases including cardiovascular disease and type 2 diabetes. The results of the research part assessing the effectiveness of the health promotion intervention showed that, from baseline to the end of the intervention period at ten weeks, significant changes in the outcomes body weight, BMI, waist circumference, and fat mass were possible. From baseline to the end of the intervention period at ten weeks, the changes in the primary outcomes were more promising in those participants who completed the intervention.

No significant differences between the intervention and the control group in changes in the secondary outcomes from baseline to the end of the intervention (at ten weeks) were observed, except for the pedometer-determined steps/day. The mean number of daily steps increased in the intervention group, while it even decreased in the control group. No significant differences between the two study groups were observed in changes in the outcomes health-related quality of life, psychiatric symptom severity, eating habits, and self-reported physical activity levels.

2.5. Cost-effectiveness of the health promotion intervention

By using a decision-analytic health economic model of the Markov type, the cost-effectiveness of the health promotion intervention was evaluated. The base case cost-effectiveness analysis resulted in an incremental cost-effectiveness ratio of 44693€/QALY in men, and 63060€/QALY in women. Scenario analysis assuming an increase in health-related quality of life as a result of the BMI decrease resulted in a cost-effective intervention in both men and women. The intervention also became cost-effective in men, but not in women in the scenario assuming full compliance with the program. The results of the one-way sensitivity analysis identified that the model was most sensitive to the intervention effect and to the intervention cost for the years in which the pedometer cost was not taken into account.

3. DISCUSSION OF THE FINDINGS

The promising results found in the review about the effectiveness of health promotion interventions must yet been cautiously interpreted as the studies included in the review were frequently limited in terms of small sample sizes, short intervention periods and absence of long-term follow up. These methodological considerations were congruent with those of previous reviews about the evaluation of health promotion interventions in mental health care (Faulkner et al. 2003, Lowe and Lubos 2008). Lowe and Lubos (Lowe and Lubos 2008) also highlighted the need of standardized outcome measures such as percentage of weight loss and measurement of the waist circumference.

Based on the results of our review, it was concluded that further research evaluating both the effectiveness and cost-effectiveness of health promotion programs targeting physical activity and healthy eating in people with mental disorders is required. It was also concluded that qualitative research examining the perceptions of patients and mental health nurses regarding health promotion in mental health care is likely to be relevant. The knowledge obtained from such research can be useful in the development and implementation of lifestyle interventions in mental health care.

In the review of perceptions of mental health nurses and patients of health promotion, studies assessing the perceptions of a broad spectrum of patients (for example inpatients or outpatients) were eligible for inclusion. The question was raised if research examining the perceptions of individuals living in sheltered housing would lead to different results. For example, are the barriers hampering the integration of healthy lifestyle behavior targeting physical activity and healthy eating

found in the review congruent with barriers that are likely to be relevant for individuals living in sheltered housing? In only one study included in the review, results specifically related to eating habits were reported (Shiner *et al.* 2008). The participants in that study described that prompting by a primary care physician or mental health provider was a common reason for changing eating habits and exercise. They also reported that successful adaptation of healthy dietary practices was related to the provision of simple messages from the mental health nurses (for example: suggestions on replacing unhealthy foods with healthier alternatives).

The barriers identified from the focus groups and individual interviews in our study such as lack of motivation related to the mental disorder, psychotropic drug use and the absence of support were similar with the findings of previous studies (McDevitt *et al.* 2006, Ussher *et al.* 2007, Verhaeghe *et al.* 2011b). Research on barriers to physical activity in the general population identified lack of time as an important obstacle to engage in exercise (Trost *et al.* 2002). This is contrary to the findings of our study were lack of time was not reported as a barrier by the interviewed patients. Despite these barriers, a majority of the interviewed patients expressed being interested in health promotion activities. A preference for group-based activities existed because this enabled support from others and social contacts. This is congruent with the findings of previous research identifying group support both from other members as from staff as an important advantage of group-based health promotion activities (Pelletier *et al.* 2005). Although the interviewed patients preferred group-based programs, individual interventions may also play a critical role in behavior change (Richardson *et al.* 2005). The course of the mental illness may be a reason for the implementation of individually-based interventions. Indeed, this may influence the way in which patients are able to understand that for example obesity increases the risk of diabetes. In this sense, it may be necessary that nurses have to adapt the way in which they provide support (Hultsjo and Hjelm 2012).

The majority of the nurses who participated to the focus groups perceived themselves inadequately trained to practice health promotion. This is similar with the findings of a systematic review of primary care providers' perceptions of physical activity counseling practices. Lack of knowledge or training was identified as an important barrier to such practices (Hebert *et al.* 2012). Nurse educational programs must therefore teach nurses how to recognize the potential for health promotion opportunities, as well as how to develop and plan for health promotion so that it becomes a recognized part of treatment (Casey 2007).

Another important finding of the focus groups was that own views and attitudes of the mental health nurses towards healthy lifestyle behavior were likely to influence how physical activity and healthy

eating issues were discussed with their patients. Similar findings were reported by Hultsjo & Hjelm (Hultsjo and Hjelm 2012). In that study, the experiences of community mental health professionals supporting prevention of type 2 diabetes in psychotic patients were examined. It was found that staff who were more interested in health reported that they focused more on providing healthy lifestyle support to their patients. This is also congruent with the results of previous research of health habits of physicians and their counseling practices on exercise (Frank *et al.* 2003) and nutrition (Frank *et al.* 2002). It is thus possible that some differences existed in the way the health promotion program was delivered to the participants. For example, nurses being themselves engaged in exercise activities or being more interested in healthy cooking may possibly have delivered the sessions in a more enthusiastic way. The nurses in the intervention group were also instructed to provide individual support to the participants. Again, differences in the way the support was delivered were possible. As far as known, no studies examining the influence of the views and attitudes of health professionals delivering a health promotion intervention on effect size of for example weight loss in mental health care exist. To minimize the risk of bias due to differences in the way the intervention was delivered, all sheltered housing organizations in the intervention group were visited by the same member of the research team. The aim of the visit was to instruct the nurses who would be involved in the group-based sessions. During the training, they were instructed how to deliver the sessions, how to use the manual and how to organize the walking sessions. The nurses were also instructed how to provide individual support to the participants.

Although the possibility of bias as described above, the choice to involve the mental health nurses in the delivery of the intervention was a well considered choice, based on the findings of the individual interviews with the patients. They considered the mental health nurses as the most appropriate individuals to provide healthy lifestyle related support. This is important because the specific context of sheltered housing strongly influences the patient – mental health nurse relationship. This relationship is different from that in inpatient settings in a sense that the nurse is entering into the private living environment of the patient. The institutional background of the psychiatric inpatient facility, providing a certain authority to the nurse, is absent (Sheltered Housing Federation 2004). So, in sheltered housing, confidence of the patient in the mental health nurse is probably even more important than in other settings. Mental health nurses can play a critical role in behavior change through the frequent contact with and support of the patient. Moreover, barriers related to the mental disorder can be more appropriately addressed (Richardson *et al.* 2005). Supporting the patient to make healthier lifestyle choices is yet not exclusively the responsibility of the mental health nurse. Other (mental) health professionals including psychiatrists, psychologists, general

practitioners, occupational therapists also have their role in supporting the patient in making healthy lifestyle choices.

Several risk factors for the development of important somatic diseases were found to be common in the study population. Using the BMI-classification of the World Health Organization (World Health Organisation 2012), 80% of the study population was classified as being overweight. Forty-seven per cent of the total sample was even in the obese category, compared with 47% overweight and 14% obesity in the general population in Belgium (Van der Heyden *et al.* 2010). It is important to highlight that 68% of the participants in the intervention group were on second generation antipsychotic drug prescription. It is well known that several of these drugs cause to some extent weight gain (Henderson *et al.* 2000, Parsons *et al.* 2009), but they have shown to be effective in controlling mental disorder symptoms (Awad and Voruganti 2004, Lieberman *et al.* 2001). Smoking prevalence also exceeded that of the general population in Belgium. Among the study participants, 61% were daily smokers compared with 21% in the Belgian general population (Van der Heyden *et al.* 2010).

The changes in the primary outcomes were rather small but this may be explained by the relatively short intervention duration of ten weeks. Nevertheless, previous research suggested that improvements in body weight after an intervention period of (more or less) similar duration were possible (Ball *et al.* 2001, Mauri *et al.* 2008, Wu *et al.* 2008). For example, in the study by Mauri et al. (Mauri *et al.* 2008), a mean weight loss of 3.6 kg was found following a 12-week intervention period in a sample of psychiatric patients on antipsychotic treatment. As already mentioned, a number of barriers was identified from the interviews and focus groups (Verhaeghe *et al.* 2013). So, it was assumed that an intervention duration exceeding a 10-week period would be too demanding for both participants and nurses.

From baseline to the end of the intervention period (at ten weeks) and from baseline to the end of the study (at 36 weeks), respectively about 20% and 40% of the individuals were lost to follow up. For this reason, it was examined if differences between the participants with only baseline data and those with additional follow-up data existed for the variables sex, age, body weight, BMI, waist circumference, and fat mass at baseline. Mean age in the individuals in the intervention group with only baseline data was significantly lower compared with those with baseline data and data at ten weeks (40.2 vs. 47.6 years, p=0.001) and those with baseline data and data at the end of the study (43.4 vs. 48.0 years, p=0.010). In the control group, the mean baseline body weight and BMI were significantly higher in the individuals with only baseline data compared with those for whom baseline data and data at the end of the intervention period (at ten weeks) were available (weight: 94.4 vs.

83.0 kg, p=0.010;BMI: 32.4 vs. 28.8 kg/m², p=0.018). An additional analysis was performed to examine whether these differences may have influenced the results on weight change found in our study. It was examined if a correlation existed between baseline weight and weight change. The results indicated that no significant correlation existed between the baseline weight and weight change of the participants in the control group (r=0.17, p=0.163). It can thus be assumed that the differences in baseline weight and BMI between the participants in the control group with only baseline data and those with baseline and follow-up data did not largely influence the results found in our study. A possible explanation is that those individuals with a higher baseline weight and BMI were less likely to attend the second measurement because of a lack of motivation or resignation because the first measurement was too confronting. The dropout rates observed in our study are similar with those found in a sample of schizophrenia patients following a 14-week behavioral weight loss program. (Brar et al 2005) In the intervention group, 35% of the individuals were lost to follow up, while in the control group the drop out rate was 24%.

The changes in the primary outcomes were more promising in the participants who completed the program. This result must yet been cautiously interpreted because almost half of the individuals in the intervention group did not complete the health promotion program. The most common reason to withdraw from the study was no further motivation or interest to participate. This is in accordance with the views of the mental health nurses who participated in the focus groups. They saw lack of motivation as an important barrier for psychiatric patients to engage in health promotion activities (Verhaeghe *et al.* 2013). Nevertheless, relatively positive attitudes towards the integration of health promotion activities in sheltered housing were reported by the patients who participated in the individual interviews (Verhaeghe *et al.* 2013). This is congruent with the findings of previous research by McDevitt et al. (McDevitt *et al.* 2006) on perceptions of individuals with mental disorders regarding health promotion. In that study, exercise was seen as positive and desirable with benefits for both the physical and mental health.

From the end of the program to the end of the study, the decreases of the primary outcomes in the intervention group disappeared, except for the outcome fat mass. Muscle mass is more dense and heavier than the body fat that is lost, explaining why body weight may not rapidly change (Ballor and Keesey 1991, Thompson *et al.* 1982). In the intervention group, the mean number of pedometer-determined steps/day increased from baseline to the end of the intervention period at ten weeks. A possible explanation for the further decrease in fat mass, but not in body weight in the intervention group is that these individuals continued to exercise during the follow up period. No data were however available to confirm or reject this hypothesis.

At baseline, the mean number of pedometer-determined steps/day was 6872 and 7215 in the intervention and control group respectively. This is significantly lower than the mean number of 9596 steps/day found in a sample of the general population in the towns of Ghent and Aalst in the Flanders region in Belgium (De Cocker *et al.* 2007). Mean age in that sample was slightly higher compared with that of our study population (48.7 vs. 46.3 years) and consisted of 47% men, compared with 61% in the sheltered housing sample. Based on the classification of Tudor-Locke (Tudor-Locke and Bassett, Jr. 2004) of pedometer-determined steps/day, 60% of the study population was identified as sedentary (<5000 steps/day) or low active (5000-7499 steps/day). In the intervention group, the promising results of the pedometer-determined steps/day must be carefully interpreted. Almost half of the participants did not register their daily steps during the second registration period. It is thus likely that only the motivated participants registered their steps during the second registration period resulting in an overestimation of the effect size. It is also important to report that exercise was a part of the intervention as, during the 10-week intervention period, weekly supervised 30-minutes walking sessions were organized. In the intervention group, the pedometer was used as a measurement tool and as a motivational tool. The participants were informed by the mental health nurse (during the first group-based session) that they were allowed to keep the pedometer during the intervention period. They were also informed that those who would complete the program (= attended at least eight of ten sessions) were allowed to keep the pedometer at the end of the study as a reward. In the control group, the pedometers were only used as a measurement tool. After each registration period of one week, the pedometers were collected by the nurses.

The study population was also characterized by poor eating habits at baseline. Unhealthy eating behavior is however not limited to psychiatric patient populations. Indeed, the daily intake of fruit and vegetables was found to be lower in a sample of the Belgian general population (Vandevijvere *et al.* 2009) as compared with the “Recommended Dietary Allowances (RDA)” (Vanhauwaert *et al.* 2007). But in our study population the daily fruit and vegetables intake was even lower compared with this general population sample (fruit, 91 vs. 118g; vegetables, 103 vs. 138g). The daily intake of nutrient-poor, energy-dense foods including soft drinks and sweets in the study population exceeded that of the general population in Belgium (445 vs. 266g).

In our study, a trend was found in the intervention group for a positive relation between the duration of stay in sheltered housing and the amount of weight loss. Individuals already staying longer in sheltered housing lost more weight. A possible explanation for this trend may be derived from the results of the focus groups with the mental health nurses. There was agreement among those nurses

that the likelihood to successfully change unhealthy lifestyle behavior increases as individuals are staying longer in sheltered housing. It was argued that in those individuals more stability exists on other domains of care resulting in increased opportunities for lifestyle counseling (Verhaeghe *et al.* 2013).

No significant differences between the two study groups in the secondary outcomes were found, except for the pedometer-determined steps/day. This may be explained by the short time period of ten weeks between the two measurement moments. Forsberg et al. (Forsberg *et al.* 2010) examined the effects of a health promotion intervention among psychiatric patients living in supported housing in Sweden. From baseline to the end of the study at 12 months, no changes in health-related quality of life (assessed by using the SF-36 Health Survey) nor psychiatric symptoms (assessed by using the SCL-90-R) were found between the intervention and control group nor within both groups.
Assuming a cost-effectiveness threshold of 30000€/QALY in Belgium, it could be concluded that the health promotion program was not cost-effective in the base case. The risk reductions of the diseases included in the model were calculated using a BMI change of 0.20 kg/m², drawn from the effectiveness study. Using this rather small amount of BMI change may be a possible explanation of the cost-effectiveness results in the base case.

There is growing need on health economic research in health care. This is largely caused by increasing budget constraints and rising demands for evidence-based health spending (Drummond *et al.* 2005). Health systems are facing the problem how to set priorities in the allocation of health care resources to medical or public health interventions (Littlejohns *et al.* 2012). Evidence on the effectiveness alone of a new drug, medical device or intervention is insufficient for policy making. In mental health care, health economic research predominantly focused on health economic evaluations of psychopharmacological drugs (Hanrahan *et al.* 2006, Polsky *et al.* 2006) and on mental health promotion and mental disorder prevention (Zechmeister *et al.* 2008). Although the need for health economic evaluations of health promotion interventions in mental health care was already addressed (Evans *et al.* 2005, Menza *et al.* 2004), such evaluation studies are lacking (Verhaeghe *et al.* 2011a). Health economic assessment of health promotion programs has a substantial social value. Prevention has an economic cost, but it may also save money in improved healthy life expectancy because diseases and complications can be avoided. The prevention or treatment of obesity is of extreme importance as these conditions are risk factors for the development of several diseases including cardiovascular disease, type 2 diabetes, certain cancers… (World Health Organization 2004). This results in considerable direct and indirect health care costs

(Konnopka *et al.* 2011, Trogdon *et al.* 2008) and reduced health-related quality of life (Tarride *et al.* 2012).

4. METHODOLOGICAL CONSIDERATIONS, LIMITATIONS AND STRENGHTS OF THE RESEARCH PROJECT

4.1. Perceptions of patients and mental health nurses of health promotion

The aim of qualitative research is to describe and explain individuals' experiences, behaviors, interactions, and social contexts using in-depth interviews, focus groups, or participant observation (Pope and Mays 1995). By interviewing patients and mental health nurses in our study, it was assumed that this would contribute to the development and implementation of a health promotion intervention that was effective and satisfactory to the study population of individuals living in sheltered housing. A limited understanding of health promotion is a significant barrier to effective nursing-related health promotion in mental health care. The main challenge for nursing is how to effectively integrate and apply health promotion principles into practice. This requires an understanding of how an individual's health is influenced by social, cultural, political and economic conditions (Whitehead 2009). Qualitative findings are assumed to be useful in the development of complex interventions by identifying and addressing barriers and facilitators to implementing the intervention in a way that better meet the needs of patients and staff (Corrigan *et al.* 2006). In this sense, qualitative methods can be complementary to quantitative methods by providing a description and understanding of meanings, experiences and views of the participants (Pope and Mays 1995). This was also the main reason that, for the review of perceptions of patients and mental health nurses, only studies with a qualitative design were eligible for inclusion.

A purposive sampling strategy was used to select the mental health nurses and patients to participate in the focus groups and individual interviews. In this type of sampling, the participants are chosen according to the project's goals to gain insight and understanding by hearing from the respondents in depth (Morgan 1998). It was the aim to interview patients with healthy lifestyle behavior targeting physical activity and eating habits as well as patients with more unhealthy lifestyle behavior. For this reason, the mental health nurses were involved in the recruitment process of the patients to participate in the interviews. They were asked to recruit patients accounting for lifestyle behavior (inclusion of both patients with healthy and unhealthy lifestyle behavior), sex, psychiatric diagnosis and age.

A common limitation of qualitative research is the impracticality of using large, representative samples to collect data. As a consequence, it is questionable whether the results of such research can be generalized to wider populations (Horberg *et al.* 2004). Contrary, the purpose of this type of research is yet not to generalize to larger populations but to gain insight and understanding by hearing from people in depth (Morgan DL 1998, Pope and Mays 1995). In our study, the results of the interviews and the focus groups resulted in an improved understanding of the factors influencing the integration of health promotion activities targeting physical activity and healthy eating in individuals living in sheltered housing. This knowledge was useful in the development and implementation of the health promotion intervention examined in our research project.

4.2. Effectiveness of a health promotion intervention targeting physical activity and healthy eating

Randomized controlled trials (RCTs) provide the most reliable evidence for assessing the effectiveness of a treatment (Sibbald and Roland 1998). The key advantage of an RCT is the minimization of both known and unknown confounders by the random allocation of individuals (Tansella *et al.* 2006). The design of evaluation studies of public health interventions, like health promotion programs, poses however several problems and they require multiple, flexible, and community driven strategies (Rychetnik *et al.* 2002). In some cases, individual randomization is not possible or desirable because it may cause contamination bias when participants in the control group may receive certain aspects of the intervention if they are in proximity to individuals in the intervention group (Christie *et al.* 2009, Taljaard *et al.* 2009). This can be solved through the randomization of groups of individuals to the intervention or control group. This is known as a cluster or group or community RCT (Christie *et al.* 2009, Puffer *et al.* 2003). In our research project, the choice for a cluster randomized controlled design was based upon the risk that participants in the intervention and control group could live together in the same sheltered housing organization. This would definitively have caused contamination bias.

A substantial risk of non-participation on the sheltered housing organization level was assumed based on the findings of the focus groups identifying lack of time due to the high workload in the daily care of patients as a common barrier for mental health nurses to engage in health promotion activities (Verhaeghe *et al.* 2013). It was also assumed that organizations being assigned to a non-preferred study arm could be disappointed, which may in turn have reduced their willingness to participate in the study (Howard and Thornicroft 2006, Macias *et al.* 2009). Therefore, a preference design was chosen. In this design, subjects are allowed to select the intervention assignment.

Preference designs are useful when strong preferences among potential participants threaten either the ability to recruit an adequate sample size of representative participants or when such preferences threaten individuals' acceptance of treatment assignment (TenHave *et al.* 2003).

The study population consisted of individuals with mental disorders independent from their psychiatric diagnosis. From the literature, it was clear that the burden of overweight and obesity is affecting psychiatric patients with a wide variety of mental health disorders including schizophrenia, mood disorders, and anxiety disorders (Davidson *et al.* 2001, Dickerson *et al.* 2006, Mackin *et al.* 2007). Consequently, health promotion targeting physical activity and healthy eating is likely to be important for this population irrespective of their diagnosis. In addition, the study was conducted in sheltered housing which is aimed at individuals with "severe and persistent psychiatric difficulties" (Sheltered Housing Federation 2004). The selection of individuals limited to a certain type of psychiatric diagnosis would definitively have caused both practical and ethical considerations.

On the sheltered housing level, approximately 60% of the organizations in the Flanders region agreed to participate in the study. On the individual level, only about 20% of the individuals living in these settings were willing to enter into the study. The generalizability of the findings to wider populations of people with mental disorders can thus be discussed. For this reason, a number of characteristics of the study population were compared with the "Minimum Psychiatric Data (MPD)" provided by the Belgian Federal Ministry of Public Health (Federal Public Service Health 2012). All Belgian mental health care facilities including sheltered housing are required to register a set of data. These data are entered into the MPD database and consist of demographic and socioeconomic patient characteristics, psychiatric diagnosis, and treatment data. The duration of stay in sheltered housing and the proportion of individuals diagnosed with schizophrenia, substance misuse, and personality disorder were comparable with the data of the MPD database. Our study population however consisted of a higher proportion of women, the mean age was slightly lower and a higher proportion of mood disorder patients was included.

The study population was characterized by relatively high drop out rates. Missing outcome data are a common problem in clinical trials (Wood *et al.* 2004). A possible approach to deal with this is to only include the participants without missing data into the analyses. This may yet result in a reduction of power and biased estimates (Altman 2009).Contrary, in an intention-to-treat analysis, all randomized individuals are included into the analysis in their assigned group, regardless from whether they received the treatment or intervention or withdrew from the treatment or intervention (Fisher *et al.* 1990, Hollis and Campbell 1999). The analysis of the primary outcomes (body weight, BMI, waist

circumference, and fat mass) in our study was performed on an intention-to-treat basis. For those participants for whom only baseline data were available, the missing data were replaced (=imputation) by the mean change in the different primary outcomes from baseline to respectively the second and third measurement moment in the control group. Given the high drop out percentages in the study population and hence the number of imputations that had to be applied (about 20% from baseline to the end of the intervention at ten weeks and about 40% from baseline to the end of the study), it is likely that this approach resulted in an underestimation of the results. This may have indeed attenuated the results in the intervention group because, for those participants with only baseline data available, the mean increase in the primary outcomes observed in the control group, was used as imputation.

Despite the poor compliance and persistence, the results of the effectiveness study demonstrated that small although statistically significant improvements in body weight, BMI, waist circumference, and fat mass were possible following a health promotion intervention targeting physical activity and healthy eating. Yet, and as expected, the results were more pronounced in those individuals who completed the program. This is promising given the number of barriers identified through the interviews and focus groups and the high percentage of participants who were on second generation antipsychotic drug prescription. Another strength of the research project was that it used an innovative design. As far as known, this was the first study examining the effectiveness of a health promotion intervention using a cluster preference randomized controlled design. The research project also contributed to the lack of health economic evaluation research of health promotion interventions targeting physical activity and healthy eating in mental health care.

4.3. Cost-effectiveness of the health promotion intervention

Some limitations and methodological considerations of the health economic evaluation study need to be addressed. In the Markov model, a repeated implementation of the 10-week program once a year was assumed maintaining the same BMI change of 0.20 kg/m². Studies evaluating the long-term effects on BMI of health promotion interventions targeting physical activity and healthy eating in people with mental disorders are yet lacking (Faulkner *et al.* 2003, Verhaeghe *et al.* 2011a). The disease transition probabilities and mortality probabilities were retrieved from the literature and national available data. For certain transition probabilities, national data were however missing. In these cases data from other countries was used. This may yet resulted in an underestimation or overestimation of some disease or mortality probabilities included in our model. Individuals with mental disorders are at an increased risk of developing the diseases included in the model or dying

from these diseases. A strength of the current Markov model is that these increased relative risks were accounted for in the calculation of the disease and mortality transition probabilities.

Health economic evaluations are characterized by some degree of uncertainty, imprecision, or methodological considerations. One possible way to handle uncertainty is scenario analysis. In this type of analysis, a series of scenarios is constructed to evaluate its impact on the cost-effectiveness results (Drummond *et al.* 2005). In the current study, the effects on the results of three alternative modeling assumptions were evaluated through scenario analysis. Offering the health promotion program twice a year did not result in a cost-effective intervention. The scenario analysis assuming an increase in health-related quality of life as a result of the BMI decrease resulted in a cost-effective intervention in both men and women. The scenario assuming 100% compliance with the program showed a cost-effective result in men but not in women. It can however be discussed to what extent a (close to) 100% compliance is achievable in populations with mental disorders, and at what cost. The scenario analysis provided insight in which input parameters of the model were most uncertain. Based on the results of this scenario analysis, it could be assumed that performing a probabilistic sensitivity analysis would only confirm the fact that the base case result would be a not cost-effective one.

Health-related quality of life measures were retrieved from the literature. About two-thirds of our study population consisted of schizophrenia patients or mood disorder patients (Verhaeghe *et al.* 2012). For this reason, a utility of 0.71 found by Saarni et al. (Saarni *et al.* 2010) was used in our Markov model for the “healthy” state. We are aware that different utilities for other psychiatric diagnosis exist. For example, a mean EQ-5D utility of 0.50 was found in a sample of individuals with borderline personality disorder (van Asselt *et al.* 2009). For the several disease states, no studies assessing the health-related quality of life in populations with mental disorders with one of the included diseases in the model were found. So, utilities were derived from a cost-effectiveness study in a general population sample (De Smedt D. *et al.* 2012), probably resulting in an overestimation of the utilities used in the Markov model. These uncertainties around the health-related quality of life in individuals with mental disorders can be mapped by performing sensitivity analyses.

As far as known, this was the first study performing a health economic evaluation of a health promotion intervention targeting physical activity and healthy eating in individuals with mental disorders.

5. PRACTICAL IMPLICATIONS – RELEVANCE TO PUBLIC HEALTH

It was clear from the literature that people with mental disorders are at a greater risk of being overweight or obese. These conditions contribute to the high prevalence of considerable somatic diseases such as cardiovascular disease and type 2 diabetes. Cardiovascular disease is an important cause of the high premature mortality rates in this population. Despite this vulnerable health conditions, this population is less likely having their physical illnesses diagnosed and managed effectively. Barriers to somatic healthcare include patient-related elements (poor treatment compliance, treatment refusal), the nature of the mental disorder (social isolation, physical symptoms unreported or masked because of high pain tolerance in some patients associated with antipsychotic drug use), physicians' attention principally focused on the psychiatric problems and physical complaints regarded as psychosomatic symptoms (Fleischhacker *et al.* 2008, Lambert *et al.* 2003, Phelan *et al.* 2001). Regular monitoring of the physical health, especially for those at risk for the development of cardiovascular disease or diabetes, is required. This can be performed by the psychiatrist in collaboration with the mental health nurse, but also the involvement of primary care providers such as the general practitioner appears to be appropriate.

Physical activity and healthy eating are important issues in the primary and secondary prevention of several somatic diseases such as cardiovascular disease and diabetes (Warburton *et al.* 2006, Willett and Stampfer 2013). Health promotion activities targeting physical activity and healthy eating should be integrated into the daily care of individuals with mental disorders. This is necessary because of the high burden of excessive weight gain contributing to medical complications and increased mortality, diminished health-related quality of life and increased health care costs. A median stay in sheltered housing of about four years was found in the study population. This makes sheltered housing an appropriate setting to support individuals with mental disorders to engage in more healthy lifestyle behavior on the long-term. Sheltered housing organizations are also appropriate settings to integrate healthy lifestyle support into their treatment supply as the main goal of sheltered housing is the psychiatric rehabilitation of the patient. In the rehabilitation process, patients receive support to develop the emotional, social and intellectual skills needed to live, learn and work in the community with the least amount of support (Anthony *et al.* 2002). This may comprise several domains of care including psychological, domestically or leisure time support, but also healthy lifestyle behavior support.

In sheltered housing, the weekly meeting between the patient and the mental health nurse is a convenient moment to discuss healthy lifestyle issues. This will increase the likelihood that lifestyle support becomes an integral part of the treatment. A contradiction was however identified between the patients' expressed need of support from the mental health nurse to change unhealthy lifestyle behavior and lack of time reported by the nurses as an important barrier to integrate healthy lifestyle counseling into their daily work. Mental health nurses may nevertheless play a critical role in stimulating patients to live a more healthy lifestyle as they are considered by the patients as their counselors. Lack of time was also the main reason for five of the eight sheltered housing organizations who returned the response form reporting that they were not willing to participate. The other reason for non-participation, reported by the remaining three organizations, was that they had recently participated to another study.

Another element of concern was that mental health nurses felt more secure addressing the mental health problems of their patients rather than focusing on health promotion issues. Hence, there appears to be a lack of recognition of healthy lifestyle counseling as a regular part of treatment. Below, some suggestions are described that may contribute to considering lifestyle counseling as a regular component of treatment in sheltered housing. First, it is recommended to include health promotion into the sheltered housing (and/or other mental health care facilities) policy so that it becomes a recognized part of the treatment. Second, specific training for mental health nurses how to address lifestyle issues is necessary to make them more comfortable to include this into the daily care. A third possible pathway is providing a remuneration directly related to achieved results on quality indicators. This mechanism is known as 'pay-for-performance' (Van Herck *et al.* 2010). In the context of sheltered housing, a financial incentive could be foreseen for the integration of health promotion activities into the daily care of patients.

On the one hand it is recommended to organize periodical supervised exercise sessions (for example: walking sessions or accompanying patients to the gym) or healthy eating sessions. On the other hand, as lack of time is an important barrier perceived by nurses working in sheltered housing, patients should also be motivated to engage in routine daily physical activities such as going to the shop on foot or by bike. Some sheltered housing organizations are making an appeal on volunteers (for example: providing household support for patients). Sheltered housing organizations should investigate if it is an option to involve volunteers in for example supervised exercise or healthy cooking activities.

The development and implementation of health promotion programs in populations with mental disorders is more demanding compared with the development and implementation of such programs in the general population. In mental health care, health promotion activities have to be adapted to and offered beside other treatment aspects. So, it was assumed that asking the patients and mental health nurses about health promotion would result in an improved understanding of the factors influencing the likelihood of successfully implementing health promotion programs in sheltered housing. The information obtained from this research part was indeed useful in the design and implementation of the health promotion intervention, but may also be meaningful for future health promotion programs in populations with mental disorders. The "Health promotion on well-balanced eating and healthy physical activity" program (Flemish Institute of Health Promotion and Disease Prevention 2007) served as basis for the health promotion program used for the research project. Some adjustments to that program were made to better meet the needs and interests of the study population of individuals with mental disorders. The adjustments were principally based upon the results of the individual interviews with the patients and focus groups with the mental health nurses. This resulted in a manual that is easy to replicate in future health promotion programs targeting physical activity and healthy eating for other psychiatric populations.

Lifestyle modification should also not be restricted to those individuals being overweight or obese. Individuals with a BMI within the "healthy" range may also have unhealthy eating habits or lack of regular physical activity. Education on healthy lifestyle behavior should especially be started from the moment a patient is on psychopharmacological drug prescription as these drugs are known to cause weight gain.

Beside the statistical significance of the results it is also important to consider the clinical relevance of the results. According to the UK Department of Health (Department of Health 2006) reductions in body weight of five per cent or more are considered to greatly reduce the risks of physical health problems. At the end of the intervention period, only 5.5% of the participants in the intervention group reached this target. In those who completed the intervention, 10.7% lost at least five per cent of their baseline body weight. Another 13% lost between four and five per cent. Thirteen per cent of the individuals in the intervention group lost at least 1 BMI-unit from baseline to the end of the intervention at ten weeks. The results of several studies suggest that the reduction of 1 BMI unit results in a significant decrease of the risk for the development of coronary heart disease (McGee 2005) , stroke (Kurth *et al.* 2002, Rosengren *et al.* 2003)and type 2 diabetes (Schienkiewitz *et al.* 2006).

6. FUTURE RESEARCH

A main consideration of the current research project were the participation rate and drop out rates. A participation rate of about 20% was obtained at the individual level and at the end of the study, 40% of the individuals in both the intervention and control group were lost to follow up. The main reason for withdraw from the study was the absence of further motivation to participate. A number of barriers to engage in health promotion activities was identified from the interviews with patients and focus groups with mental health nurses. Further research on how to overcome these barriers is required. This may include for example research on rewards to motivate patients to participate and persist in such programs.

Further research examining the perceptions of patients, mental health nurses and other health professionals involved in the care for psychiatric patients in other mental health care facilities is required. This will enable to compare the findings of the current research project for similarities and differences. This is important as the development and implementation of health promotion programs may possibly has to be adapted to the specific mental health care setting context.

The study demonstrated that small but significant improvements in body weight, BMI, waist circumference and fat mass were possible in a population of people with mental disorders following a psycho-educational, behavioral and exercise group-based intervention. Additional controlled trials with longer duration are necessary to determine the long-term effects of maintained health promotional efforts. These studies will have to deal with the barriers identified in the current research project to minimize the risk of losing participants during the study period. In this sense, research on the optimal “intervention dose” in terms of acceptability, effectiveness and cost-effectiveness of the intervention is required. This is also necessary to examine if changes in outcomes such as physical activity, eating habits, health-related quality of life, and psychiatric symptom severity occur in trials with longer duration. The current study consisted of a group-based intervention, although individually-based programs may also be important for behavior change. Individual counseling may also be appropriate due to the course of the mental illness. Although the value of group support was identified by the interviewed patients, participation in group-based interventions may be too confronting for some individuals. Therefore, it is useful to also evaluate the effectiveness and cost-effectiveness of individually-tailored interventions targeting physical activity and healthy eating.

Further analyses of the cost-effectiveness study including one-way sensitivity analysis and probabilistic sensitivity analysis varying the crucial parameters is necessary to investigate the impact on the results of the cost-effectiveness analysis. Further research evaluating the costs and benefits of health promotion interventions in mental health care can result in more efficient health care spending.

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SUMMARY

In the last decades, overweight (Body Mass Index 25-29.9 kg/m²) and obesity (Body Mass Index ≥30 kg/m²) have become a serious global public health problem. Excessive weight gain is an important risk factor for the development of several somatic diseases such as coronary heart disease, stroke, type 2 diabetes, and certain cancers. Obesity results in increased health care costs and reduced health-related quality of life. There is conclusive evidence that the prevalence of obesity is even higher in individuals with mental disorders than in the general population. Important risk factors for the high prevalence of obesity in this population include side effects of especially second generation antipsychotic drugs causing weight gain and unhealthy lifestyle behavior including lack of regular physical activity and unhealthy eating habits. In this sense, lifestyle modification through regular physical activity and more healthy eating behavior is a valid pathway to reduce the substantial burden of excessive weight gain in people with mental disorders. However, this issue received only since recently attention by researchers. There is thus a need for studies evaluating the effectiveness of health promotion interventions targeting physical activity and healthy eating in this population. In addition to knowing what works and in what context, information on the costs and benefits of such interventions is required.

A first aim of this PhD research was to evaluate the literature about the effectiveness and cost-effectiveness of health promotion targeting physical activity and healthy eating in individuals with mental disorders. Based on the results of a systematic review, it could be concluded that robust evidence on the effectiveness of such interventions was scarce. Trials were frequently limited in terms of small sample sizes, short intervention periods and absence of long-term follow up. No studies evaluating the cost-effectiveness of health promotion interventions in mental health care were found.

A second objective of the PhD research was to examine the perceptions about health promotion in individuals with mental disorders and in mental health nurses to gain insight into the factors influencing the integration of healthy lifestyle behavior into the daily care of this population. First, a review was conducted revealing that the literature concerning this topic principally consisted of qualitative studies using interviews and focus groups. Positive perceptions of both patients and nurses towards health promotion were found in literature, but several barriers hampering the integration of healthy lifestyle behavior into the daily care of people with mental disorders were identified. These barriers included for example lack of motivation, side effects of psychotropic drug use, and absence of support. In a second phase, individual interviews with patients and focus groups with mental health nurses were conducted to gain insight into the factors influencing the integration

of physical activity and healthy eating in the specific context of sheltered housing. Although physical and mental health benefits were reported, several barriers to integrate healthy lifestyle behavior into the daily life of this population were described by both patients and nurses. Important barriers reported by the patients included for example lack of energy associated with the mental disorder, side effects of psychotropic drug use, and hospitalization. Lack of time and the absence of patients' motivation were identified by the nurses as substantial barriers. Support from the mental health nurse was considered important by the participating patients to change unhealthy lifestyle behavior. The information derived from this part of the research project was useful in the development and implementation of the health promotion program.

The third objective of the PhD research was to examine the effectiveness and cost-effectiveness of a health promotion intervention targeting physical activity and healthy eating in sheltered housing in the Flanders region (Belgium). For this study, an innovative design consisting of a cluster preference randomized controlled design was used. The sheltered housing organizations had the possibility to choose their preferred study arm (intervention or control group) or were randomly assigned to one of the two groups when they expressed no preference. Twenty-five organizations agreed to participate. In a 10-week period, the participants in the intervention group (n=201) received the health promotion intervention above the treatment as usual, while the individuals in the control group (n=83) received only treatment as usual. The program consisted of ten group-based psycho educational and behavioral sessions including discussions on physical activity and healthy eating. In the same 10-week period, a weekly 30-minutes walking was organized. The effectiveness study showed small although significant improvements in the primary outcomes body weight, body mass index, waist circumference, and fat mass following the 10-week intervention. The decreases in these outcomes however disappeared during a six-month follow up period, except for the outcome fat mass. From baseline to the end of the intervention period (at ten weeks), the decreases in the primary outcomes were even more promising in those participants who completed the intervention. In the intervention group, a trend was found for a positive relation between duration of stay in sheltered housing and weight loss. Individuals already staying longer in sheltered housing lost more weight. No significant differences between the intervention group and the control group in changes in health-related quality of life, psychiatric symptom severity, eating habits, and physical activity were found, except for the pedometer-determined steps/day. This result must be cautiously interpreted because almost half of the participants did not register their daily steps during the second registration period.

The results of the cost-effectiveness evaluation suggested that the program was not cost-effective, but scenario analysis and one-way sensitivity analysis was applied to assess the impact on the results.

A first scenario, in which the program would be offered twice a year, did also not result in a cost-effective intervention. In a second scenario, 100% compliance with the program was assumed. This resulted in a cost-effective program in men, and a borderline not cost-effective program in women. Applying the scenario in which an increase in health-related quality of life as a result of the decrease in BMI was assumed, resulted in a cost-effective intervention in both men and women.

The thesis ends with a reflection of the main findings against the existing literature, some methodological considerations, limitations and strengths of the research project, the relevance to public health and some directions for future research.

In conclusion the relevance to public health of the research project and directions for future research are provided. The vulnerable somatic health of individuals with mental disorders requires a regular monitoring of the physical health, especially for those at risk for the development of considerable somatic diseases including cardiovascular disease and type 2 diabetes. Health promotion targeting physical activity and healthy eating should be integrated into the daily care of individuals with mental disorders. Further research is required to examine the effectiveness and cost-effectiveness of such programs in other settings such as for example inpatient settings or under other conditions such as group-based versus individually-based interventions and/or programs with longer duration. Further research evaluating the costs and benefits of health promotion interventions in mental health care will provide payers and governments with better insights how to spend the available resources in the most efficient way.

SAMENVATTING

Overgewicht (Body Mass Index 25-29.9 kg/m²) en obesitas (Body Mass Index ≥30 kg/m²) zijn in de jongste decennia tot een wereldwijd probleem geëvolueerd. Overmatige gewichtstoename is een belangrijke risicofactor voor het ontstaan van verschillende somatische aandoeningen zoals coronaire hartaandoeningen, beroerte, type 2 diabetes en bepaalde vormen van kanker. Obesitas leidt tot een toename van de kosten voor gezondheidszorg en een verminderde kwaliteit van leven. Er is doorslaggevend bewijs dat de prevalentie van obesitas zelfs nog hoger is bij personen met een psychiatrische problematiek dan bij de algemene bevolking. Gewichtstoename als nevenwerking van het gebruik van tweede generatie antipsychotica en een ongezonde levensstijl op het vlak van lichaamsbeweging en voedingsgewoonten zijn belangrijke risicofactoren voor de hoge prevalentie van obesitas in deze populatie. Het verminderen van de problematiek van overmatige gewichtstoename bij personen met een psychiatrische problematiek door middel van het wijzigen van de ongezonde levensstijl op het vlak van lichaamsbeweging en voedingsgewoonten is dan ook een aanbevolen aanpak. Vanuit de onderzoekswereld wordt echter nog maar recent aandacht aan dit onderwerp geschonken. Er is nood aan studies die de effectiviteit van gezondheidspromotie interventies op het vlak van lichaamsbeweging en gezonde voedingsgewoonten bij deze populatie evalueren. Het is hierbij ook belangrijk om kennis te verwerven inzake de kosten en gezondheidswinst van dergelijke interventies.

Een eerste doelstelling van het doctoraatsonderzoek was het evalueren van de literatuur inzake de effectiviteit en kosteneffectiviteit van gezondheidspromotie interventies inzake lichaamsbeweging en gezonde voedingsgewoonten bij personen met een psychiatrische problematiek. Op basis van de resultaten van de literatuurstudie kon worden besloten dat afdoend bewijs inzake de effectiviteit van dergelijke interventies zeldzaam was. Studies waren vaak beperkt in termen van kleine studiepopulaties, korte interventieperiodes en een gebrek aan lange termijn follow up. Er werden geen studies gevonden die de kosteneffectiviteit van gezondheidspromotie interventies in de geestelijke gezondheidszorg evalueerden.

Een tweede doelstelling van het doctoraatsonderzoek was het nagaan van de ervaringen van personen met een psychiatrische problematiek en psychiatrisch verpleegkundigen inzake gezondheidspromotie, om zo inzicht te krijgen in de factoren die de integratie van een gezonde levensstijl in de dagelijkse zorg voor deze populatie beïnvloeden. Vooreerst werd een literatuurstudie uitgevoerd waaruit bleek dat de literatuur inzake dit onderwerp vooral uit kwalitatief onderzoek (interviews en groepsgesprekken) bestond. Er werden zowel bij patiënten als bij psychiatrisch

verpleegkundigen positieve ervaringen ten aanzien van gezondheidspromotie geïdentificeerd, maar ook verschillende hindernissen die de integratie van een gezonde levensstijl in de zorg voor personen met een psychiatrische problematiek belemmeren. Deze hindernissen waren bijvoorbeeld een gebrek aan motivatie, nevenwerkingen van psychofarmaca en een gebrek aan ondersteuning. In een tweede fase werden individuele interviews met patiënten en groepsgesprekken met psychiatrisch verpleegkundigen gehouden om inzicht te krijgen in de factoren die de integratie van een gezonde levensstijl in de specifieke context van beschut wonen beïnvloeden. Ondanks het feit dat verschillende fysieke en mentale voordelen voor de gezondheid werden geïdentificeerd, werden ook verschillende hindernissen door zowel patiënten als verpleegkundigen gerapporteerd. Gebrek aan energie ten gevolge van de psychiatrische problematiek, nevenwerkingen van psychofarmaca en hospitalisatie werden als belangrijke hindernissen door de patiënten ervaren. Gebrek aan tijd en de afwezigheid van motivatie bij patiënten werden door de verpleegkundigen als belangrijke hindernissen geïdentificeerd. Ondersteuning door verpleegkundigen werd door de patiënten als belangrijk ervaren om hun ongezonde levensstijl te wijzigen. De informatie die in dit deel van het onderzoek werd verkregen was relevant en nuttig bij de ontwikkeling en implementatie van de gezondheidspromotie interventie.

De derde doelstelling van het doctoraatsonderzoek was het nagaan van de effectiviteit en kosteneffectiviteit van een gezondheidspromotie interventie inzake lichaamsbeweging en gezonde voedingsgewoonten in initiatieven voor beschut wonen in Vlaanderen (België). Voor deze studie werd gebruik gemaakt van een innovatief studie design, met name een “cluster preference randomized controlled” design. De initiatieven voor beschut wonen hadden de mogelijkheid om de studie arm (interventie of controle groep) van hun voorkeur te kiezen. Indien ze geen voorkeur hadden werd ze “ad random” toegewezen aan één van de twee studiegroepen. 25 Organisaties waren bereid tot deelname aan de studie. De deelnemers in de interventiegroep (n=201) kregen, naast hun gewone behandeling en begeleiding, gedurende 10 weken de gezondheidspromotie interventie, terwijl de deelnemers in de controlegroep (n=83) enkel de gewone behandeling en begeleiding kregen. De interventie bestond uit 10 groepsgerichte psycho-educationele en gedragsgerichte sessies inzake lichaamsbeweging en voedingsgewoonten. Gedurende dezelfde 10 weken werd ook een wekelijkse wandeltocht van 30 minuten georganiseerd. Uit de resultaten van de studie inzake de effectiviteit van de interventie bleek dat beperkte, doch significante, dalingen in de primaire uitkomsten lichaamsgewicht, body mass index, buikomtrek en vet massa werden vastgesteld. Met uitzondering van de uitkomst vet massa bleken de dalingen in deze uitkomsten na een follow up van 6 maand echter verdwenen te zijn. Van bij de start tot het einde van de interventie (na 10 weken) was de daling in de primaire uitkomsten beter bij de deelnemers die het programma

hadden voltooid. In de interventiegroep was een trend waarneembaar voor een positieve relatie tussen de lengte van het verblijf in beschut wonen en de mate van gewichtsdaling. Bewoners die reeds langer in beschut wonen verbleven verloren meer lichaamsgewicht. Met uitzondering van het aantal stappen per dag (gemeten door middel van stappentellers) werden geen significante verschillen tussen de interventie- en controlegroep in wijzigingen in de kwaliteit van leven, ernst van de psychiatrische problematiek, voedingsgewoonten en lichaamsbeweging gevonden. De resultaten van de stappentellers moeten echter met de nodige voorzichtigheid worden geïnterpreteerd omdat ongeveer de helft van het aantal deelnemers hun stappen in de tweede registratieperiode niet opnieuw hadden geregistreerd.

Uit de resultaten van de kosteneffectiviteit studie bleek dat de interventie niet kosteneffectief was, maar scenario analyses en sensitiviteitsanalyses werden uitgevoerd om de impact op de resultaten te beoordelen. Een eerste scenario waarin het programma tweemaal per jaar zou worden aangeboden bleek ook niet kosteneffectief te zijn. In een tweede scenario werd 100% naleving van het programma verondersteld. Dit resulteerde in een kosteneffectief programma voor mannen, maar niet voor vrouwen. De toepassing van het scenario waarin een directe toename van de kwaliteit van leven werd verondersteld als gevolg van een BMI-daling resulteerde in een kosteneffectieve interventie bij zowel mannen als vrouwen.

De thesis eindigt met een reflectie van de belangrijkste resultaten ten opzichte van de literatuur, een aantal methodologische bedenkingen, beperkingen en sterktes van het onderzoeksproject, de relevantie voor de volksgezondheid en een aantal aanbevelingen voor verder onderzoek.

Tot besluit geven we de relevantie van het onderzoek en een aantal aanbevelingen voor verder onderzoek weer. Gezien de kwetsbare somatische gezondheid van personen met een psychiatrische problematiek is opvolging van de fysieke gezondheidstoestand noodzakelijk. Dit is zeker belangrijk voor diegene met een verhoogd risico op hart- en vaataandoeningen en type 2 diabetes. Gezondheidspromotie op het vlak van lichaamsbeweging en voedingsgewoonten dient te worden geïntegreerd in de dagelijkse zorg voor personen met een psychiatrische problematiek. Verder onderzoek inzake de effectiviteit en kosteneffectiviteit van dergelijke programma's in andere settings zoals intramurale voorzieningen en onder andere omstandigheden zoals groeps- versus individueel gerichte interventies en programma's met een langere duurtijd is noodzakelijk. Verder onderzoek waarbij de kosten en gezondheidswinst van gezondheidspromotie interventies in de geestelijke gezondheidszorg wordt geëvalueerd zal bijdragen tot betere inzichten voor verzekeraars en overheden inzake het besteden van de beschikbare budgetten op de meest efficiënte wijze.

APPENDICES

Appendix 1 Registration document pedometers

REGISTRATIEFORMULIER "PEDOMETERS" **REGISTRATIEPERIODE 2** **ID-nummer deelnemer** ☐☐☐☐☐

Datum	/ /	/ /	/ /	/ /	/ /	/ /	/ /
uur waarop pedometer 's morgens werd aangedaan		☐					
uur waarop pedometer 's avonds werd uitgedaan							
totaal aantal stappen vandaag							
hebt u de pedometer overdag uitgedaan?	O ja / O nee	O ja / O nee	O ja / O nee	O ja / O nee	O ja / O nee	O ja / O nee	O ja / O nee
indien ja, hoelang?	minuten	minuten	minuten	minuten	minuten	minuten	minuten
deed u vandaag een sport- of bewegingsactiviteit?	O ja / O nee	O ja / O nee	O ja / O nee	O ja / O nee	O ja / O nee	O ja / O nee	O ja / O nee
Indien ja, welke?							
Hoelang deed u die sportactviteit?							
hoeveel minuten hebt u vandaag gefietst?	minuten	minuten	minuten	minuten	minuten	minuten	minuten

Appendix 2 example of the online dietary assessment tool

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Nick Verhaeghe
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Nick Verhaeghe was born on January 13th, 1973. He finished secondary school at the 'Onze-Lieve-Vrouwe College' in Bruges in 1991. He started his 'Nursing studies, social nursing' in 1992. After finishing his nursing studies, he started working in a retreat home. From 1998 until 2008, he worked in a sheltered housing facility in mental health care. In 2001, he started his university education 'Health care management and policy sciences' at Ghent University. In 2005, he obtained his MSc degree.

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