Evaluation of health promotion programmes in severe mental illness: theory and practice

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Abstract

Health promotion programmes for patients with severe mental illness (HPP) are not uniformly evaluated. We discuss the evaluation of HPP in theory and practice, as a prerequisite for future uniform evaluation.

We explored the expected outcome and mechanism of HPP in the current literature. Based on this theoretical exploration we selected measures assessing the expected outcome and mechanism in current practice. The individual properties of these measures were described.

Based on our theoretical exploration the outcome of HPP can be expressed in several aspects of health. Health can be improved through several mechanisms. In the current evaluation of HPP only some of the expected outcomes were evaluated. The measures used for evaluation were not all representative for the constructs they should assess.

Important aspects of HPP are currently not evaluated, based on a comparison between our theoretical exploration of expected outcome and mechanism and current practice. Additionally, not all measures in use are suitable for evaluation of HPP. Therefore, development and identification of suitable measures is necessary. Our framework offers valuable directions for the development of such measures and the future evaluation of HPP. Copyright © 2014 John Wiley & Sons, Ltd.

Introduction

The somatic health status of people with severe mental illness (SMI) is worse when compared to the somatic health status of the general population, and this divergence

has increased over the last decades (De Hert *et al.*, 2011b; Saha *et al.*, 2007). This reduced somatic health tendency has multiple interlinked causes, which are potentially reversible (De Hert *et al.*, 2011b; Robson and Gray, 2007;

Wildgust and Beary, 2010). Mental health care providers have initiated various health promotion programmes for patients with SMI (HPP) (O'Brien *et al.*, 2013) to improve the somatic health (Happell *et al.*, 2012; O'Brien *et al.*, 2013; Tranter *et al.*, 2012; van Hasselt *et al.*, 2013). Improving somatic health leads to a potential improvement of experienced well-being as well (Kwekkeboom and van Weert, 2008).

Randomized studies of HPP have evaluated the results effects of health education, exercise, smoking cessation and changes in the health care organization (van Hasselt *et al.*, 2013). Although the anticipated outcomes of these HPP overlap, these programmes are not evaluated uniformly. The evaluations were performed with various different measures and they evaluated many different aspects of these HPP. The diversity in evaluation methods hampers comparisons between programmes, in particular on effectiveness, and therefore evidence-based choices on implementation of HPP cannot be made (van Hasselt *et al.*, 2013). For future comparisons of HPP it is necessary to evaluate uniformly.

As a prerequisite for future uniform evaluation this exploratory overview aims to describe and discuss the evaluation of HPP in theory and practice. Firstly, we developed a theoretical exploration of all expected outcomes and mechanisms of HPP. Secondly, we assessed the properties of measures currently used for evaluation of HPP.

Methods

For clarity we start with defining the terms we use in this manuscript in Table 1.

Theoretical exploration of potential outcome and mechanism of HPP

To enable exploration of the expected *outcome* of HPP, we defined improved health as the ultimate outcome of HPP.

Improved health can be achieved either by preserving a health status that would have deteriorated without intervention or by improving current and future health states. In order to detect improvement, an understanding of the situation without intervention is necessary. Therefore we start by developing a conceptual framework of reduced health in patients with SMI. Any change in this development of reduced health can subsequently be labelled as outcome.

A Medline search was performed searching for overviews on potentially modifiable causes of physical illness and/or reduced somatic health in patients with SMI influencing healthy life expectancy. The search terms included: mental disorder, health status and physical. Based on the findings, additional searches were performed aimed at other diseases related to a specific SMI risk factor, or other risk factors specific for diseases in SMI. This information was condensed to form a *conceptual framework* describing determinants of disease related to outcome of HPP.

Evaluation of a *mechanism* in HPP is only sensible, if it is theoretically plausible to get an outcome through that specific mechanism. We conceptualized several potential mechanisms of interventions, from the types of interventions identified in our systematic review (van Hasselt *et al.*, 2013). The theoretical exploration of mechanism consists of an exploration of the evidence that these specific mechanisms are related to a specific outcome. Therefore, a second Medline search was performed to explore the theoretical plausibility of these mechanisms. The search terms included: a description of the mechanism (e.g. smoking) and the likely outcome (e.g. cardiovascular disease, diabetes mellitus).

Selection and discussion of currently used measures

We present an explorative overview of the properties of measures assessing outcome and mechanism currently

Table 1. Definitions of terms, in order of appearance in the manuscript

Term	Description
Outcome	The consequences of the intervention; that which “comes out” of it (Øvretveit, 1998).
Conceptual framework	A model of interlinked concepts that together provide a comprehensive understanding of a phenomenon or phenomena (Jabareen, 2009).
Mechanism	The expected factor or process that causes the outcome, similar to the likely process of change (Craig <i>et al.</i> , 2008).
Target	The part or whole of a person which the intervention aims to effect (Øvretveit, 1998).
Mechanism measure	A measure to assess whether a specific mechanism took place in the target person.
Outcome measure	A measure of an important expected effect of the intervention on the target person (Øvretveit, 1998).
Domain	A group of measures assessing similar constructs.

used in HPP evaluation. The selection of measures was based on our previous systematic review (van Hasselt *et al.*, 2013). This systematic review was focused on the evaluation of randomized interventions directed toward improving somatic health for patients with SMI. Twenty-two original studies were included, the different interventions were grouped based on their descriptions in types. The outcome measures used were grouped in domains based on comparable measures. Next to the evaluation of outcome and mechanism, domains evaluating costs, psychiatric symptoms and process factors were described.

For this exploration of mechanism and outcome measures, a Medline search was performed on the characteristics of all the included outcome measures. This search focused on their ability to measure the elements they were designed to measure, suitability for use in patients with SMI and ability and if necessary evidence on responsiveness, as well as the ability to be used as parameters to distinguish differences in outcome over time. The search terms included: the name of the measure, validity, responsiveness, mental disorders.

Results

Theoretical exploration of potential outcome

Based on the current evidence for modifiable risks on potentially modifiable causes of physical illness and/or reduced somatic health in patients with SMI we developed a cross table of information describing risk factors and health states (Table 2). Based on this cross table we designed our conceptual framework for outcome (Figure 1). This was constructed as a structural model, presenting the course of development of reduced somatic health in patients with SMI. The different types of lines are related to the different risk factors. Changes in this development can be marked as outcome. Even though determinants such as tobacco smoking are not exclusive for SMI patients, the addition of these on top of their specific vulnerability and side effects of medication is exclusive for these patients. Cardio metabolic diseases are main causes of death in populations with SMI (De Hert *et al.*, 2011b). Therefore, the importance of cardio metabolic risk factors is stressed with their central position in the structural framework. This position emphasizes the possibility to assess this important intermediate stage between health and disease. As this framework describes the development of reduced somatic health, positive health effects of medication are not included.

Theoretical exploration of potential mechanism

Based on our systematic review, the following types of mechanisms were used in randomized HPP: exercise,

improving diet, smoking cessation or reduction, early detection and treatment of disease and change in health care provision. Per type of mechanism, a brief description is presented regarding the potential influence on health status in the following sections.

Exercise

Physical activity has a beneficial effect on the primary and secondary prevention of cardiovascular disease, diabetes mellitus and osteoporosis (Warburton *et al.*, 2006a). With or without weight loss exercise has a beneficial effect on risk factors for cardiovascular disease: diastolic blood pressure, triglycerides, high-density lipoprotein (HDL) and glucose (Kesaniemi *et al.*, 2001; Shaw *et al.*, 2006). It is still unclear whether physical activity as such leads to changes in health or physical fitness is the mediating factor. Physical fitness and physical activity are both independently related to cardiovascular mortality (Myers *et al.*, 2004). For weight loss, through any method, there is a positive correlation between the magnitude of sustained weight loss and the long-term improvement in all components of the metabolic syndrome (Ferland and Eckel, 2011). Furthermore, weight loss reduces the risk of developing diabetes mellitus (DM). For patients with type 2 DM, the regulation of blood glucose levels improved with weight loss (Aucott *et al.*, 2004).

Improving diet

Changing diet can induce health benefits, including the benefits of weight loss. Apart from weight loss, the risk of developing cardiovascular disease decreases by changing the patient's diet by either reducing the levels of, for instance, fat and sodium or increasing the intake of products like fruit and vegetables (Brunner *et al.*, 2007).

Smoking cessation or reduction

Smoking cessation reduces the incidence of cardiovascular and coronary heart disease (Wu and Sin, 2011). Smoking cessation diminishes the loss of pulmonary capacity in patients with mild to moderate chronic obstructive pulmonary disease (COPD). Furthermore, it reduces the risk of COPD progression as well as the risk for lung cancer and cardiovascular disease (Godtfredsen and Prescott, 2011). Smoking cessation can also lead to reduced risks in periodontal health in comparison to persistent smokers (Warnakulasuriya *et al.*, 2010). Among individuals who smoked 15 or more cigarettes per day, smoking reduction reduces the risk of lung cancer and cardiovascular risk factors (Eliasson *et al.*, 2001; Godtfredsen *et al.*, 2005).

Table 2. References for conceptual framework for outcome

	Side effects of medication	SMI related vulnerability	Diet	Tobacco smoking	Exercise
Cardio metabolic risk	Robson and Gray, 2007; Goff <i>et al.</i> , 2005	Robson and Gray, 2007	Robson and Gray, 2007; de Hert <i>et al.</i> , 2011b	Robson and Gray, 2007; Goff <i>et al.</i> , 2005	Robson and Gray, 2007
Sexual dysfunction	Robson and Gray, 2007; de Hert <i>et al.</i> , 2011b; Malik, 2007	de Hert <i>et al.</i> , 2011b; Malik, 2007	—	—	—
Extrapyramidal symptoms (EPS)	Sadock <i>et al.</i> , 2009	—	—	—	—
Gastroesophageal GE	Mookhoek <i>et al.</i> , 2005	—	—	Mookhoek <i>et al.</i> , 2005	—
Dental/oral	Robson and Gray, 2007; de Hert <i>et al.</i> , 2011b	—	—	—	—
Diabetes mellitus (DM) type 2	Robson and Gray, 2007; Goff <i>et al.</i> , 2005	de Hert <i>et al.</i> , 2011b; Goff <i>et al.</i> , 2005	de Hert <i>et al.</i> , 2011b	de Hert <i>et al.</i> , 2011b Chang, 2012	de Hert <i>et al.</i> , 2011b
Cardiovascular disease (CVD)	de Hert <i>et al.</i> , 2011b	de Hert <i>et al.</i> , 2011b	de Hert <i>et al.</i> , 2011b	de Hert <i>et al.</i> , 2011b	de Hert <i>et al.</i> , 2011b
Osteoporosis	Crews and Howes, 2012	—	Crews and Howes, 2012	Crews and Howes, 2012	Crews and Howes, 2012
Impaired lung function	—	—	—	Robson and Gray, 2007; de Hert <i>et al.</i> , 2011b	Garcia-Aymerich <i>et al.</i> , 2007

Figure 1. Conceptual framework for outcome.

Early detection

Early detection is used to improve healthy life expectancy by detecting asymptomatic precursor states of the disease. However, this holds true only when true preventive treatment of these complications is possible. Presenting an overview of the effects of early detection of each disease was not possible. Therefore, we limited ourselves to the early detection and treatment of DM, osteoporosis, hypercholesterolemia and hypertension. The effect of DM screening and following intensive treatment to reduce HbA1c as a treatment strategy for all individuals is currently debated (Koshizaka *et al.*, 2012). What remains is that screening and early treatment leads to reduction of potentially lethal complications in those whose diabetes is detected early and to the detection of a group of patients at high risk for developing diabetes (Rahman *et al.*, 2012). Osteoporosis screening can potentially reduce fractures and related morbidity and mortality. The effect of screening has been assessed for groups at risk for developing osteoporosis. Early detection had no effects on fracture and related morbidity (Laliberte *et al.*, 2011). Reducing cholesterol can reduce the five-year incidence of major coronary events, coronary revascularization, and stroke (Cholesterol Treatment Trialists' (CTT) Collaborators, 2012). The reduction of cardiac incidents is even greater in persons with a history of coronary heart disease, than in persons without a disease history (Baigent *et al.*, 2005). Lowering blood

pressure leads to a reduction of stroke and coronary heart disease when used as primary and secondary prevention (Chalmers and Chapman, 2001; Law *et al.*, 2003).

Health care organization changes

Organizational changes to improve the health care system focus mainly on coordination of care for individual patients, improving inter professional communication within one department or communication between departments of health care. In our selection of randomized studies no evaluation of health screening was present. Coordination of care or enhancing a multi-disciplinary team with a specialist, e.g. a pharmacist, has been studied in patients with multi-morbidity. The limited results, mainly in elderly, suggest that these interventions have mixed effects but show a tendency to improve prescribing and medication adherence (Smith *et al.*, 2012). The evidence for implementing multi-disciplinary meetings or multi-disciplinary educational programmes is scarce and based on very different health care settings. No conclusions can be drawn yet on this subject (Reeves *et al.*, 2008; Zwarenstein *et al.*, 2009). Shared care is based on an increased collaboration of primary and specialist care. The evidence of shared care is based on short-term follow-up and relatively few studies. Up until now, only improved prescribing is a consistent outcome of these studies (Smith *et al.*, 2007).

Selection of domains

Five domains for outcome evaluation and five domains for mechanism evaluation assessed elements of the conceptual framework (Tables 3 and 4). The domains evaluating outcome assessed cardio-metabolic risk factors and side-effects of medication. Furthermore general functioning, general health and quality of life (QoL) were also classified as outcome evaluation because they were presented as concepts directly relating to health. The domains evaluating mechanism assessed; diet, exercise and tobacco smoking. Furthermore, adherence to professional guidelines and self-efficacy were also classified as mechanism evaluation because they were possible facilitators of all mechanisms of the framework.

Properties of outcome measures

Cardio-metabolic risk factors

The outcome measures in this domain can be subdivided into different types: grouped risk factors and single outcome measures. Grouped risk factors were defined as an individual risk estimation based on a selection of cardio-metabolic risk factors. National Cholesterol Education Programme (NCEP) ATP III predicts less accurate cardiovascular morbidity and mortality than the Framingham risk score and fasting glucose is at least as good as the metabolic syndrome in predicting diabetes mellitus (Reaven, 2011). Evidence shows that Framingham underestimates the risk of cardio-metabolic morbidity and mortality, especially in the group of patients with severe mental illness (De Hert *et al.*, 2009). For the estimation of body fat body mass index (BMI) is a good estimation of the amount, but gives no information on its localization. Waist circumference, as a proxy for visceral fat, enables a more accurate individual risk estimation than only BMI. There is no evidence that waist-hip ratio or skin fold measurement is more accurate than waist circumference for risk estimation (Snijder *et al.*, 2006). Waist circumference is strongly related to other cardiovascular risk factors (van Dijk *et al.*, 2012). Finally, there is no clear basis for the cut-off point, "Increase in body weight of >7%" after the start of a treatment (Jayaram *et al.*, 2006).

For the other single cardio-metabolic risk factors, when presenting blood pressure, it is often not clear whether investigators measured this only once or multiple times during a session and which assessment is reported. National Institute for Health and Clinical Excellence (NICE) guidelines recommend for the diagnosis of hypertension to perform ambulatory or home blood pressure assessment after an incidental measurement of 140/90 mmHG (National

Institute for Health and Clinical Excellence, NICE, 2011). To assess the cardiovascular risk total cholesterol, as well as HDL cholesterol should be measured according to current NICE guidelines. For screening on insulin resistance, related to an increased cardiovascular risk and risk on diabetes, it is stated that there is no "best" test. Fasting glucose does not identify patients with impaired glucose tolerance, an important risk factor for diabetes and cardiovascular disease. HbA1c is presented as the best option. An additional advantage of HbA1c is that it can be used to monitor treatment response (Waugh *et al.*, 2007).

Side-effects of medication

Extrapyramidal symptoms consist of a cluster of symptoms including parkinsonism, dystonia, dyskinesia and akathisia. To our knowledge, no studies have been done on the responsiveness of observed extra pyramidal symptom scales. The AIMS scale has been widely used to assess dyskinesia (Dean *et al.*, 2006). For robust information a combination of instrumental measurement and a clinical rating is advised, especially in long-term trials (Dean *et al.*, 2004; Loonen and van Prang, 2007).

General functioning

The domain of general functioning was conceptualized as those outcome measures that are related to the impairments or possibilities in the ability to and real execution of various tasks of day-to-day living. Global assessment of functioning (GAF) ratings made by an individual rater can be used to measure changes and outcomes at the group level (Soderberg *et al.*, 2005).

Quality of life (QoL)

QoL is conceptualized by us as a domain of outcome measures that assess the impact of diseases and symptoms on the experienced possibility to live your life in health according to the World Health Organization (WHO) criterion of health as a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity. The SF-36, MANSA and QoLI were validated in patients with SMI (Bjorkman and Svensson, 2005; Coons *et al.*, 2000; Norholm and Bech, 2007). Also the WHOQoL B was validated in patients with SMI and this scale was shown to be responsive to changes over time (Kao *et al.*, 2011; Mas-Exposito *et al.*, 2011). These outcome measures are all generally used and accepted to represent QoL.

Table 3. Outcome evaluation, domains and measures

Domain	Subdomain	Included measures	Short description
Cardio-metabolic risk factors	Grouped	Framingham	Risk score is based on age, blood pressure, diabetes, smoking, cholesterol and HDL to predict cardiovascular risk (Druss <i>et al.</i> , 2010)
		NCEP ATP III	Criteria for the assessment of cardiometabolic risk based on obesity, triglycerides, HDL cholesterol, blood pressure and impaired fasting glucose (Druss <i>et al.</i> , 2010).
	Obesity	BMI	Body mass index, relation between weight and height (Snijder <i>et al.</i> , 2006).
		Skinfold	Assesses body fat by determining the thickness of a specific skin fold (Snijder <i>et al.</i> , 2006).
		Percentage weight increase	Weight increase as a percentage of base line weight (Snijder <i>et al.</i> , 2006).
		Waist circumference	Measure of the waist circumference (Snijder <i>et al.</i> , 2006).
		Waist-hip ratio	Ratio between waist and hip-circumference (Snijder <i>et al.</i> , 2006).
	Hypertension	Sphygmomanometric blood pressure	Sphygmomanometric assessment of systolic and diastolic blood pressure.
	Lipids	HDL ratio	The ratio of HDL to LDL cholesterol.
		Lipid profile	Assessment of cholesterol and HDL, LDL and triglycerides.
Side-effects of medication		Total cholesterol	Total cholesterol serum level.
		HbA1c	Assess the glycosylated haemoglobin which reflects elevated blood glucose levels during the preceding weeks (Waugh <i>et al.</i> , 2007).
	Insulin resistance	Fasting glucose	Assesses the glucose in an eight hour fasting state (Waugh <i>et al.</i> , 2007).
		AIMS	Abnormal Involuntary Movement Scale assesses dyskinesia by means of seven items, rated on a severity scale which assess abnormal movements in various anatomical locations (Gharabawi <i>et al.</i> , 2005).
		Webster scale	A clinical rating scale in which each of the following parkinsonian signs are rated for severity (Webster, 1968); bradykinesia of hands, rigidity, posture, gait, upper-extremity swing, tremor, fades, speech and self-care.
		1-item rating scale	Rating on a Likert scale of current physical health.
	General health	Basic health screening	Basic health screening questionnaire
		SF-36	Quantifies health in eight health concepts, which can be summarized to physical and mental health and well-being (Ware and Sharebourne, 1992).
		SCL-90	Assesses multiple domains of psychiatric symptoms and it includes items on physical health. SCL 90 is aimed at measuring distress related to these symptoms (Olsen <i>et al.</i> , 2004).
		MANSA	MANSA contains 16 questions, investigating objective quality of life and satisfaction with life as a whole, job, financial situation, friendships, leisure activities, accommodation, personal safety, people that the person lives with, family and health. Satisfaction is rated on a seven-point scale (Bjorkman and Svensson, 2005).

(Continues)

Table 3. (Continued)

Domain	Subdomain	Included measures	Short description
General functioning		SF-36 QoL	SF-36 quantifies health in eight health concepts, which can be summarized to physical and mental health and well-being (Ware and Sherbourne, 1992). Lehman quality of life (QoL) interview, a structured self-report interview, on patients' ratings of their QoL. The interview provides a broad based assessment of the objective and subjective QoL in several life areas, including living situation, family relations, social relations, daily activities, finances, safety and legal problems, work and school and health (Lehman <i>et al.</i> , 1993).
		WHOQoL B	Consists of a self-report list of 26 items on four domains; physical health, psychological, social relations and environment (Skevington <i>et al.</i> , 2004)
		GAF	Global assessment of functioning from DSM is a 0–100 score filled out by a clinician on the patient's overall level of functioning at a particular point in time (Soderberg <i>et al.</i> , 2005)

General health

The domain general health has been conceptualized by us as an overall estimate of health and disease. As such it can be hypothesized as a complex measure of variable symptoms and specific disease states. SF-36 and SCL-90 are rating scales that cover multiple health aspects, and are described by some authors as outcome measures of general health. For the “1-item rating” and the “basic health screening” no information was present on representativeness for the concept general health and their validity. All currently used general health scales are based on self-assessment of the severity and impact of the disease state. Therefore these outcome measures are a relative value of the experienced burden for an individual at a certain time point. This use of individual assessment of burden of diseases generates an overlap with self-rated QoL outcome measures. Although they overlap, general health should be regarded as a different outcome domain than QoL (Hewitt, 2007). Therefore the currently used outcome measures do not assess our construct of general health.

Properties of mechanism measures

Exercise

We conceptualized mechanism measures of exercise as measures assessing actual exercise or constructs strongly related to exercise. The ability to measure “responsiveness”, the change in exercise level over time was tested for physical

activity recall tests in a systematic review including the tests used for interventions to improve somatic health in SMI. The authors concluded that only two of the 85 questionnaires were analysed for responsiveness, these two tested questionnaires had poor responsiveness. Furthermore, for all questionnaires the information on content validity was essentially lacking (van Poppel *et al.*, 2010). Even results of diverse questionnaires on prevalence of exercise in minutes cannot be compared (Brown *et al.*, 2004).

Physical fitness measurements can evaluate aerobic fitness, anaerobic fitness and musculoskeletal fitness. Unfortunately, it is unclear how these different types of fitness are related to health (Warburton *et al.*, 2006b). Research has been primarily focused on the relation between aerobic fitness and mortality. Furthermore, there is no clear relation between strength measures and cardiovascular mortality. Therefore we will limit ourselves to aerobic fitness evaluation. An improvement of aerobic fitness is associated with reduction in total mortality and cardiovascular risk (Lee *et al.*, 2011). The gold standard for measuring aerobic physical fitness is a graded exercise test during which oxygen consumption (VO₂), carbon dioxide production, and pulmonary ventilation are measured (Mossberg and Fortini, 2012). The required equipment for this evaluation limits the large scale use of this measurement. Aerobic fitness intensity, can also be expressed in metabolic equivalents (MET), this is strongly related to all causes of mortality (Kodama *et al.*, 2009). These MET values can be calculated from different ergometer and treadmill protocols (Kodama

Table 4. Mechanism evaluation, domains and measures

Domain	Included measures	Short description
Diet	DINE Mizes	Assesses daily fat and fibre intake (Roe <i>et al.</i> , 1994). A 24-item self-report instrument designed to assess cognitions associated with anorexia nervosa (Osman <i>et al.</i> , 2001).
Exercise	Borg Exercise recall tests Exercise tolerance tests pedometer Strength	Generally used measure to evaluate exertion at a certain exercise. Different tests were used to assess the retrospective assessment of exercise: the 13-item patient activation questionnaire, the active Australia questionnaire, Baecke questionnaire, the behavioural risk factor surveillance on physical activity, the Blair seven-day physical activity recall and the GODIN questionnaire on exercise There are tests directly assessing the exercise tolerance for walking or cycling; the incremental shuttle walk test, the estimated maximal oxygen consumption, the graded exercise tolerance test (<i>inter alia</i> Franz test). The outcomes reported from these tests differ from heart rate/exercise intensity in watts to maximal capacity (VO ₂ max). Electronic device used to assess the daily activity. Tests were used assessing strength–maximal dynamic strength and maximal sit up endurance.
Tobacco smoking	Biological smoking markers Nicotine dependence Smoking abstinence	Biological markers of tobacco smoking cessation (point prevalence abstinence) were used; exhaled CO and cotinin measures in saliva. Nicotine dependence was assessed with the Fagerstrom test for nicotine dependence and the Shiffman Jarvik nicotine withdrawal scale, 11 item readiness and motivation to quit smoking 12 months abstinence and continuous abstinence were assessed next to time to relapse after cessation, reduction of >50% of amount of smoking.
Adherence to professional guidelines	Eligible versus obtained services Quality indicators	The proportion between eligible versus obtained services in healthcare Quality indicators for preventive medicine, advised services for this high risk population. These quality indicators were derived from a guideline for the general public (DiGuseppi <i>et al.</i> , 1996) advising screening for amongst others cardiovascular health and metabolic health.
Self-efficacy	Health-related self-efficacy Self-efficacy for exercise	Assessment of health-related self-efficacy Assessment of self-efficacy for exercise

et al., 2009). Using MET values outcomes can be presented showing the achieved peak intensity of fitness, or prolonged duration of fitness at a certain intensity. It should be noted, however, that possibly the standard set of MET values for specific exercise should be adapted when used for the population of patients with SMI with more obesity and comorbidity (Woolf-May and Ferrett, 2008). The Borg exercise scale can also be used to assess the moment of maximal exercise, but is not an assessment of physical capacity *per se* (Lear *et al.*, 1999). Pedometers are small devices used to assess the amount of steps taken in daily activity and sports. Pedometer scores have been related to

cardiovascular fitness and weak to moderate associations were found with exercise tolerance tests (Tudor-Locke *et al.*, 2002).

Diet

We conceptualized mechanism measures of diet as measures assessing actual diet or constructs strongly related to diet choices and habits. In evaluating dietary intake it is preferable to use biomarkers (Brunner *et al.*, 2007) but these are complicated to use in day-to-day practice. To our knowledge, there are no studies on the validity of using food frequency questionnaires or registration of diet

for 24 hours for people with SMI, therefore no advice on future use is possible. Cognitions related to weight and diet can be assumed to influence diet, but no clear evidence is present to support this. Therefore, cognitions should not be used as single outcome for diet, because their relation with the actual diet and thus their relation with influence on somatic health is not evident.

Tobacco smoking

We conceptualized mechanism evaluation of tobacco smoking as measures assessing actual tobacco smoking or constructs strongly related to tobacco smoking. It should be noted that smoking cessation is the final endpoint of different phases in a trajectory starting with motivation to quit. Effects of interventions leading to progression in this trajectory are missed if the focus is only on abstinence. Therefore, intention to quit, nicotine dependence, withdrawal symptoms and smoking rate are useful measures to analyse effects caused by the intervention possibly leading to future smoking cessation (Baker *et al.*, 2011). Because these measures cannot yet predict future smoking cessation and therefore health benefits, they should not be used as a single outcome. Further interpretation of their value as implementation measures is beyond the scope of this article.

The prolonged abstinence is based on biological markers; exhaled carbon monoxide (CO) is less specific for measuring tobacco exposure than urine cotinine (Benowitz, 1999). Prolonged abstinence can also be assessed based on self-reports. These measures are moderately interconvertible (Hughes *et al.*, 2010). It is not yet clear which measure is valid to use for assessment of reduction of smoking and health effects (Hatsukami *et al.*, 2006).

Self-efficacy

We conceptualized this domain as measures assessing self-efficacy as a facilitator for the mechanisms that lead to improved somatic health. Based on social cognitive theory, judgements of self-efficacy expectation play major roles in determining whether to perform a specific behaviour in short and long term (Resnick and Jenkins, 2000). Although measures of self-efficacy are predictors of current physical activity, studies show that interventions directed toward improving self-efficacy for exercise did improve the exercise rate. However, also measures of self-efficacy remained unchanged (Lee *et al.*, 2008). No evidence was found on the influence on health related self-efficacy and mechanism evaluation. Therefore, self-efficacy cannot be treated as mechanism evaluation.

Adherence to professional guidelines

We conceptualized this domain as measures assessing the amount and/or type of care that was delivered related to the amount and type advised by professional guidelines. The measure adherence to preventive services can be seen as a facilitator to the mechanisms that lead to improved somatic health. Adherence to preventive services is a facilitator for different mechanisms because it supports and controls the start or continuation on an individual level of specific prevention. It is clearly a facilitator of early detection and reducing cardio-metabolic risk factors, but possibly also for diet, exercise and smoking cessation because advice on life style changes is part of the preventive advice by the guideline. It is unclear what the exact relation is between percentage of increase in preventive services obtained related to changes in health outcome. Furthermore, currently guidelines are available for (preventive) health care for patients with SMI, indicators could, additionally, be derived from these guidelines.

Conclusion

Important elements of HPP are currently not evaluated, based on a comparison of our exploration of expected outcome and mechanism based on theory and the measures used in current practice. Our conceptual frameworks shows that the development of reduced somatic health of patients with SMI goes through multiple interrelated and intertwined pathways. In the current evaluation of outcome of HPP only some of the outcomes of the structural model were assessed. The evaluation of mechanism is only performed for a part of the potential mechanisms described in our theoretical exploration. The evaluation of outcome and mechanism was only partly performed using representative measures for these constructs.

To evaluate outcome of HPP the outcome measures of BMI, blood pressure, total and HDL cholesterol, and HbA1c are representative of the single cardio-metabolic risk factors. Furthermore, only some extrapyramidal symptoms were assessed as side-effects. The evaluation was limited to parkinsonism and tardive dyskinesia, acathisia was not included. However the responsiveness remains unknown for the measures used for parkinsonism and tardive dyskinesia. There are a number of outcome measures available for assessing QoL and the GAF ratings. The elements sexual dysfunction, dental and oral disease, osteoporosis, gastro-oesophageal reflux and impaired lung function were shown to be important aspects influencing healthy life expectancy in our conceptual framework, but were never evaluated. No suitable instrument is available

for general health, however it is a promising construct to assess on an overall scale the amount of morbidity and mortality risks.

Mechanism evaluation was performed for exercise, diet and tobacco smoking which are potentially plausible mechanisms based on our framework. Exercise should ideally be expressed in MET values. For the mechanism of improving diet, currently no instrument is representative. Smoking cessation should be based on biological markers. Added to this, information on intention to quit and dependence should also be collected. Additionally, self-efficacy and adherence to professional guidelines and self-efficacy were assessed. Improving self-efficacy can facilitate different mechanisms, but currently no evidence is present to support the use of this domain to assess the mechanism that is facilitated. Adherence to professional guidelines is linked with health care organization changes and early detection of disease in our framework that can have beneficial effects potentially, but the evidence is not yet present. For the domain adherence to professional guidelines, it is not clear what should be considered as clinically relevant increases.

Strength and limitations

Our study is the first to present an appraisal of the theory and current practice of HPP evaluation. This manuscript emphasizes the need for future research to develop and validate measures for the evaluation of outcome and mechanism of HPP, especially for those domains currently without suitable measures. It was outside the scope of this paper to evaluate measures that were not used in studies on HPP. In the literature, the development from risk factor to somatic disease is descriptively organized either by risk factor or by disease, for the sake of clarity (De Hert *et al.*, 2011a; Robson and Gray, 2007). But, a single disease may be caused by multiple, often interrelated factors that all contribute to the final risk for developing that disease, and a single factor may cause multiple diseases. Our framework clearly depicts that for multiple reasons people with SMI are specifically more vulnerable for cardio-metabolic diseases due to an additional effect of risk factors in this group. We included only potentially modifiable risk factors, for instance reduced exercise, but for research non-modifiable risk factors should also be included as confounders. Our conceptual framework should have also included the influences on healthy life expectancy, but this was not possible because information on QoL for these health states in patients with SMI is lacking. Most studies on QoL have only

been performed in patients with schizophrenia. Different outcome measures were used to assess the current QoL, and mostly only the influence of a single somatic condition on QoL. A relation has been shown between reduced QoL and cardio-metabolic risk factors, sexual dysfunction, extra pyramidal symptoms and diabetes (Bebbington *et al.*, 2009; Bobes *et al.*, 2007; Briggs *et al.*, 2008; Meyer *et al.*, 2005; Olfson *et al.*, 2005; Strassnig *et al.*, 2003). Although, we have attempted to give a good overview, it is of course only possible to assess the most important causes and diseases in patients with SMI. Moreover, we found no systematic appraisal of evidence on the properties of certain measures.

Meaning of the study and future studies

Our findings on insufficient and lacking measures for HPP evaluation means that the currently available evidence on improving health in patients with SMI is not all based on meaningful evaluations. Parallel to the need to improve somatic health in patients with SMI there is a need for research on methodology and effectiveness of HPP. A priority in research should be given to a cardio metabolic risk assessment for this population. It is striking that currently no grouped risk score is available for an overall assessment of risk for patients with SMI. It is advisable to follow the recommendation by a European expert group to use the relative risk based on smoking, total cholesterol and systolic blood pressure to estimate cardiovascular risk until a specific risk assessment is developed (De Hert *et al.*, 2011a).

The interpretation of QoL values as an effect evaluation of HPP should be interpreted carefully. The valuation of QoL of patients with SMI, and hypothesis on expected changes in QoL after interventions may differ from that in the general population. The sometimes counterintuitive high perception on QoL by patients with SMI also reflects an adaptation to their malicious circumstances. Conversely, interventions that promote positive change, may produce transient decreases in life satisfaction in response to change and the renewed awareness that their lives could be better (Lehman *et al.*, 1993).

Our theoretical exploration can be used for clinical purposes and research. In the clinical setting information from the determinants of health of an individual patient can be related to the possible disease states he/she can develop and which should be prevented. In developing future interventions, the mechanism should be based on theoretical evidence as represented in our theoretical exploration and the evaluation should be performed with

meaningful measure. In research it can be used to identify confounders that may influence outcomes.

Deduction

It is theoretically plausible through different mechanisms to improve the somatic health of patients with SMI. Currently, the evaluation of mechanism and outcome is insufficient in HPP. Moreover, not all outcome measures currently in use to assess effect and mechanism are representative for these constructs. There is a great need to improve the somatic health of patients with SMI. Therefore, the development of suitable outcome measures to properly

evaluate the characteristics of interventions to improve somatic health deserve highest priority. Our theoretical exploration may offer valuable directions for the selection and development of these outcome measures.

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Declaration of interest statement

The authors have no competing interests.

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