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Towards a comprehensive routine outcome monitoring program for people with psychotic disorders: The Pharmacotherapy Monitoring and Outcome Survey (PHAMOUS)

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ABSTRACT

Background: Patients with psychotic disorders are at risk of developing mental health and social problems, and physical disorders. To monitor and treat these problems when indicated, an annual routine outcome monitoring program, Pharmacotherapy Monitoring and Outcome Survey (PHAMOUS), was developed. This paper presents the background and content of PHAMOUS, implementation of PHAMOUS, characteristics of the patients screened in 2015, and the outcome of patients with three annual screenings between 2011 and 2015.
Methods: PHAMOUS was implemented in four mental health institutions in the Northern Netherlands in 2006. During the PHAMOUS screening, patients are assessed on socio-demographics, psychiatric symptoms, medication, physical parameters, lifestyle, (psycho)social functioning and quality of life, using internationally validated instruments.
Results: In 2015, 1955 patients with psychotic disorders were enrolled in the PHAMOUS screening. The majority (72%) was receiving mental healthcare for ten years or longer. A small group was hospitalized (10%) in the past year. Half of the patients were in symptomatic remission. Less than 10% had a paid job. More than half of the patients fulfilled the criteria for metabolic syndrome (54%). The subsample with three annual screenings from 2011 to 2015 ($N = 1230$) was stable, except the increasing prevalence of high glucose levels and satisfaction with social relationships (Cochran's $Q = 16.33$, $p = .001$ resp. $Q = 14.79$, $p = .001$).
Conclusion: The annual PHAMOUS screening enables to follow the mental, physical and social health problems of patients, which offers a good basis for shared-decision making with regard to updating the annual treatment plan, next to a wealth of data for scientific research.

1. Introduction

People suffering from severe mental illnesses (SMI) may profit much from a systematic, regular evaluation of their health, as these patients often fail to adequately present their problems, leading to high numbers of unmet needs in mental, physical and psychosocial care (Bellack, 2004; Drake et al., 2000; Patterson and Leeuwenkamp, 2008; Kern et al., 2009). Furthermore, in this population, unhealthy lifestyle factors, such as poor dietary habits, sedentary lifestyle and smoking (de Leon and Diaz, 2005; Vancampfort et al., 2010; De Hert et al., 2009; De Hert

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et al., 2011) considerably increase the cardiovascular risk-factors, such as overweight, diabetes, higher cholesterol levels and hypertension (McEvoy et al., 2005; Hasnain et al., 2010; Mitchell et al., 2013), with subsequent cardiovascular problems and high mortality rates (De Hert et al., 2009; De Hert et al., 2011; Vancampfort et al., 2010; Galletly et al., 2012). Also, the frequently reported cannabis use (Peralta and Cuesta, 1992; Hall and Degenhardt, 2000; Richardson, 2010) contributes to the psychotic symptoms (van Os et al., 2009). In addition, people with psychotic disorders, have an increased risk of comorbid mental disorders (e.g. depressive symptoms (Lako et al., 2012a)) and, equally important, the majority of this population has large psychosocial problems.

In the Northern Netherlands, in the early 2000s several pilot studies were conducted on monitoring the physical health of people using antipsychotics, urged by the emergence of metabolic disturbances due to second generation antipsychotics. For the detection of diabetes, hypertension and metabolic syndrome, regular (at least once a year) measurements of Hb1Ac, blood pressure and waist circumference were introduced.

In order to improve the quality of care for patients with psychotic disorders and other SMI, in 2006, the Pharmacotherapy Monitoring and Outcome Survey (PHAMOUS) was started, implementing a comprehensive ROM-program in four large mental healthcare organizations in the Northern Netherlands. PHAMOUS serves to map the physical, mental and social conditions of these patients, next to the effects of sustained medication intake.

A comprehensive ROM-assessment can be successful in the following domains (Delespaul, 2015): (i) clinical process: continually optimize treatment decisions using repeated assessments; (ii) managerial: to generate management information to optimize strategic choices for the care systems; (iii) accountability: to improve transparency and generate information for external accountability; (iv) science: to provide data to study (course of) mental illness, symptom severity and care needs, and to assess the outcome of real-life implementation of (evidence-based) treatment protocols.

In this paper, we will describe the design (protocol and instruments) and implementation of the actual PHAMOUS screening. Also, the demographic, physical and mental health characteristics of the cohort (2015) will be presented, as well as a three year follow-up of patients with screenings between 2011 and 2015. Next, we will evaluate PHAMOUS in its present form. Finally, future directions, possibilities and challenges will be addressed.

2. Methods

2.1. Implementation of the PHAMOUS screening

All participating organizations in PHAMOUS (Lentis Mental Health Institution, GGZ Friesland Mental Health Institution, GGZ Drenthe Mental Health Institution, and the University Center for Psychiatry of the University Medical Center Groningen) are collaborating in the Rob Giel Research center (RGOc). Since 2010, the RGOc facilitates RoQua (Routine Outcome & Quality Assessment), a safe and reliable software application that can be integrated in electronic patient file systems, allowing to systematically collect clinical data in combination with 'routine outcome' data (for details see van der Krieke et al., 2013).

The aforementioned institutions deliver a broad spectrum of specialized mental healthcare, serving a catchment area of 1.7 million inhabitants in 2015 (Statistics Netherlands). PHAMOUS includes specific questionnaires, interviews, laboratory testing and physical evaluations to assess psychiatric symptomatology, physical and social problems, and quality of life of patients with psychotic disorders. Once a year, the contents of the protocol are updated by a board, consisting of members of all institutions participating in PHAMOUS. A report, composed in RoQua, summarizes the screening results and is, in line with the shared decision making model, discussed with the patient. Subsequently, patient and clinician formulate a treatment plan for the forthcoming year (see also van der Krieke et al., 2013). The report of the relevant outcomes is sent to the general practitioner (GP), highlighting specific problems and needs (e.g. anomalous outcome on laboratory tests, interviews and questionnaires) and proposing changes in the treatment plan to be performed either by the mental health professionals or the GP. In accordance with the declaration of Helsinki, patients are informed that aggregated and anonymized data may be used for healthcare optimization and scientific research to improve treatment and guidance.

2.2. Study population

All patients fulfilling the DSM-IV criteria for schizophrenia, schizoaffective disorder or other psychotic disorders, aged 18 years and older, are intended to be included in PHAMOUS. No exclusion criteria are used for the PHAMOUS screening.

2.3. Screening and training procedure

Trained research nurses carry out the PHAMOUS screening. Booster sessions are organized regularly to optimize consensus and discuss any problems. In view of turnover of staff and to improve reliability of the measurements, all above-mentioned training procedures are continually, at least yearly, repeated. In each center, a research coordinator is appointed as a contact person assuring the quality, troubleshooting and implementation of PHAMOUS. Duration of the screening per patient, including preparation and administration by the research nurse, is between three and four hours, depending on the condition of the patient.

2.4. Measurements

The yearly PHAMOUS screening consists of measures in the following domains.

Sociodemographic characteristics. Age, gender, living situation, education and daily activities are assessed during the interview with the research nurse.

Psychiatric characteristics. Main diagnosis and comorbidity according to DSM-IV (American Psychiatric Association, 2000), age at onset of first psychotic episode and age at first mental healthcare contact are assessed during the interview. Also, the severity of psychotic symptoms during the past week is assessed with the consensus remission items (Andreasen et al., 2005) of the Positive and Negative Syndrome Scale for Schizophrenia (PANSS; Kay et al., 1987) The mean score of eight items (delusions, conceptual disorganization and hallucinations, blunted affect, social withdrawal and lack of spontaneity, unusual thought content and mannerisms and posturing) was calculated. Symptomatic remission was determined, based on whether patients had a score of three or lower on all eight remission items.

Antipsychotic medication and side effects. The patient brings medication prescriptions at the interview. Types of (antipsychotic) medication (ATC code; Anatomical Therapeutic Chemical classification system, oral or depot, dose, date of starting/stopping) are registered. Haloperidol equivalents of antipsychotic medication were calculated based on the recommendations of Gardner et al. (2010). Present extrapyramidal side effects are assessed by the research nurse by rating presence of akathisia, acute dystonia, tardive dyskinesia, and parkinsonism (scoring options: absent, minor, moderate, severe).

Desired and undesired treatment effects of antipsychotics are evaluated with the brief self-report version of the Subjects' Response to Antipsychotics questionnaire, the SRA-34 (Lako et al., 2013). Mean sum scores of desired effects and of undesired effects were calculated.

Physical characteristics. The following parameters are assessed: the research nurse asks for present somatic diseases (diabetes, cardiovascular diseases, osteoporosis, thyroid abnormalities, hypercholesterolemia and epilepsy); weight and height are measured (to calculate the Body

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