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Physical health promotion in patients with functional psychoses receiving community psychiatric services: Results of the PHYSICO-DSM-VR study

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ABSTRACT

Objectives: Psychotic patients have poorer health behaviours, including poor diets and sedentary lifestyles increasing their risk for obesity, diabetes, hypertension, and dyslipidaemia, and tend to have a shorter life expectancy as compared to nonpsychiatric populations. Lifestyle intervention programmes that target modifiable risk factors in such patients have produced uneven results. The objective was to evaluate the efficacy of a package of health promotion strategies to improve diet and physical exercise in psychotic patients. Our hypothesis was that a pre- to post-treatment improvement in physical activity and dietary habits would occur in the group receiving intervention.
Method: This randomised controlled trial was carried out in four psychiatric services. The intervention included psychoeducation sessions on diet and physical activity and regular participation in walking groups (experimental group). The control group received routine treatment. The primary outcome was an improvement of at least one World Health Organization recommendation on diet and exercise.
Results: Of a total of 326 subjects recruited, 169 were randomly assigned to the experimental group and 157 to the control group. An improvement in one or more World Health Organization criteria over baseline was observed in 25.4% of experimental group subjects and in 12.2% of control group subjects (odds ratio 2.46, 95% confidence interval 1.22–4.97; $p = 0.01$).
Conclusions: A statistically significant proportion of the sample achieved post-treatment improvement in lifestyle habits, especially as regarded increased physical activity. A post-intervention reduction in lifestyle variability was also noted. Interventions directly addressing dietary habits may be desirable in psychotic patients.

1. Introduction

Psychiatric patients, especially those with severe mental illness, suffer from a variety of physical health conditions that often go underrecognised and undertreated. It is only in recent years that the scientific community has acknowledged this widespread problem (see Leucht et al., 2007, for a thorough examination of the issue in schizophrenic patients). Generally, schizophrenic patients are noted to have greater physical morbidity (Leucht et al., 2007) and mortality (standardised mortality ratio [SMR] 151, 95% confidence interval [CI] 148–154) as compared to the general population, with approximately 60% of the excess mortality due to natural causes and the remaining 40% resulting mainly from suicides and accidents (Bradshaw et al., 2005; Brown, 1997). The situation is complicated by self-neglect related to mental illness, stigma by health professionals, and disparities in health care access.

Among the non-modifiable risk factors for poor physical health are gender, age, family history, socioeconomic status, and side effects of antipsychotic medications (e. g., cardiovascular side effects). The modifiable risk factors include metabolic syndrome, diabetes, obesity, smoking, psychiatric symptoms, and unhealthy lifestyles (Heald, 2010). The combination of a higher prevalence of and inadequate attention to modifiable risk factors increases the risk of cardiovascular disease (CVD) and other diseases for this population (Allison et al., 2009; De Hert et al., 2011). A similar situation in an Italian sample has also been reported (Berti et al., unpublished results).

These risk factors can be prevented and related conditions treated with pharmacological and non-pharmacological approaches. Pharmacological interventions involve a discriminating choice of antipsychotic medication and pharmacological therapies for the treatment of diabetes and its comorbidities (American Diabetes Association, ADA, 2004) or bupropion for smoking cessation or reduction, for example (Tsoi et al., 2010). Whenever possible, pharmacological treatment combined with

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lifestyle interventions is recommended. Non-pharmacological interventions entail primarily monitoring physical health (see specific guidelines like those of the ADA, 2004; Barnett et al., 2007; Marder et al., 2004) and delivering lifestyle interventions to help patients develop healthier lifestyles and to reduce risk factors.

Several systematic reviews on physical health promotion (in particular, weight management) in psychiatry have shown that it is, indeed, possible to implement successful health promotion strategies in psychiatric settings (Álvarez-Jiménez et al., 2008; Bonfioli et al., 2012; Caemmerer et al., 2012; Faulkner et al., 2007). Faulkner et al. (2007) reported that the role of physical inactivity and poor diet as independent risk factors for CVD infers the need for non-pharmacological or lifestyle intervention regardless of weight loss per se. However, much of the literature is flawed by the lack of large-scale and methodologically appropriate randomised controlled trials and, generally, by the heterogeneity of interventions, targets of intervention, outcome measures and methods used (Bradshaw et al., 2005).

To fill this gap, we designed a health promotion intervention based on a previous pilot study (Chioffi et al., 2008) and an epidemiological study on the prevalence of physical comorbidity and poor health behaviour in psychotic patients (Berti et al., unpublished results). In the present study we evaluated the efficacy of the intervention. Our main hypothesis was that a post-intervention improvement in diet and physical activity behaviours would occur in people with functional psychoses, as compared to those receiving routine treatment.

2. Methods

2.1. Research design

This multicentre randomised controlled trial compared pre- to post-treatment changes in dietary habits and physical activity in psychotic patients participating in a health promotion intervention versus patients receiving routine care in community psychiatric services.

2.2. Participants

The study was carried out at four community psychiatric services (CPSs), Department of Mental Health of ULSS 20 (Unità Locale Socio-Sanitaria 20, Verona, Italy), from April 2012 to January 2014. Approval was obtained from the ethics committees of ULSS 20 and the AOUI of Verona (Azienda Ospedaliera Universitaria Integrata di Verona).

Eligible participants were identified from the local psychiatric case register (Amaddeo et al., 1997) or referred by psychiatrists. Inclusion criteria were: 1) diagnosis of affective or non-affective functional psychosis according to the World Health Organization (WHO) International Statistical Classification of Diseases and Related Health Problems, 10th Revision (World Health Organization, 2007; codes F20-22, F24-F25, F28-F31, F23.3, F33.3); 2) age 18–65 years; 3) one or more contacts with one of the CPSs involved in the 3 months preceding the beginning of recruitment; 4) no moderate or severe intellectual disability; 5) no organic brain disorders; 6) ability to grant consent to inclusion; 7) not receiving individual treatment related to diet and physical exercise; 8) ability to participate in the programme's physical activities; 9) not fulfilling two WHO criteria listed in Subsection 2.4 below. Written informed consent was obtained from all subjects participating in the study.

2.3. Intervention

The experimental group (EG) received a health promotion intervention package and the control group (CG) received routine treatment for their psychiatric disorder. The intervention package (6 months duration) comprised:

- seven one-hour health education group sessions (two on physical activity and five on nutrition) delivered by two trainers and two dieticians over the course of 6 months
- weekly one-hour group walking sessions under the guidance of an expert trainer
- prompting by telephone or in person to promote adherence

2.4. Outcome measures and assessment

The primary outcome was two WHO recommendations on diet and exercise (World Health Organization, 2004): 1) Take 5: at least five servings of fruit and/or vegetables a day (400–500 g daily); and 2) engaging in moderate physical activity (like brisk walking) for at least 30 min on at least 5 days a week. Improvement over baseline in at least one WHO recommendation at the final assessment was defined as a successful lifestyle change.

Psychiatric diagnosis according to the Schedule for Clinical Assessment in Neuropsychiatry (SCAN-IGC; Wing et al., 1990) was confirmed at baseline. Sociodemographic data were categorized using the Client Sociodemographic and Service Receipt Inventory (CSSRI-EU; Chisholm et al., 2000). Levels of physical activity and dietary habits were assessed at baseline and follow-up via the Progressi delle Aziende Sanitarie per la Salute in Italia (PASSI; Istituto Superiore di Sanità, 2005) questionnaire. The PASSI questionnaire investigates physical activity and eating habits and was used in a previous Italian epidemiological study on monitoring of health habits and illness risk. Details on the kind of information the questionnaire investigates are given in Subsection 3.2 below.

2.5. Statistical analyses

We hypothesised that a differential improvement between study arms in 10% of patients who fulfilled at least one additional WHO recommendation (diet or exercise) would indicate that the intervention was successful in achieving its aims. Based on a two-sample proportion test (chi^2) with alpha set to 5% and power to 80%, 141 participants per arm were required. Accounting for an expected 30% attrition rate, the number of participants to be recruited was fixed at 100 for each of the four study centres.

Four sequence lists were generated, stratified by sex and age group (age 18–45 and age 46–65 years), with a 1:1 allocation ratio. The lists were generated using a randomly permuted blocks method (block size was fixed to three) to ensure that the sub-samples were balanced (Ryan, 2008). The allocation sequences were generated by an independent individual not involved in the study and stored in computer files. Chi-square and independent *t*-tests, where appropriate, were applied to demographics and medical information to assess sample homogeneity at baseline.

Intention-to-treat principle was applied as the primary analysis, followed by a per protocol to complement. Missing values were imputed according to two different criteria and taking into account the last available assessment. When the fifth assessment was present, it was copied into the missing evaluation. Otherwise, it was assumed that the missing data from both arms followed the trend as “control arm” (12% of patients improved). The single imputation technique, based on the missing at random assumption, was performed taking age and sex into consideration.

In order to check for treatment effects on the primary outcome, and accounting for the multicentre structure of the sample, logistic regression was performed using the Huber-White estimator of variance (Brennan, 2014). This was preferred to a multilevel approach, after checking the homogeneity of variance across the centres by intraclass correlation coefficient (ICC < 1%). Two-way ANOVA was applied to compare differences in session attendance by sex and age groups. All analyses were performed using Stata 14.1 (Stata Corp LLC, College Station, TX, USA).

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