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Research report

Feasibility of a psychoeducational family intervention for people with bipolar I disorder and their relatives: Results from an Italian real-world multicentre study

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ABSTRACT

Background: Despite several guidelines recommend the use of psychoeducational family interventions (PFIs) as add-on in the treatment of patients with bipolar I disorder, their implementation on a large scale remains limited. The aim of the present study is to identify obstacles for the feasibility of PFIs in routine care.

Methods: This was a multicentre, real-world, controlled, outpatient trial, carried out in 11 randomly recruited Italian mental health centres. Two mental health professionals from each center attended a modular training course on PFI and provided the intervention. Difficulties and benefits experienced by mental health professionals in implementing the intervention were assessed through the Family Intervention Schedule (FIS-R), which was administered six times.

Results: Sixteen out of the 22 recruited professionals completed the training and administered the PFI to 70 patients with bipolar I disorder and their relatives. The retention rate of families receiving the intervention was 93%. Mental health professionals reported high levels of organizational difficulties, several benefits in their daily clinical work and low levels of intervention-related difficulties. The most important organizational obstacles were related to the need to integrate the intervention with other work responsibilities and to the lack of time to carry out the intervention. These difficulties did not decrease over time. Intervention-related difficulties were rated as less problematic since the first time assessment and tended to improve over time.

Limitations: Low number of recruited professionals; use of a not previously validated assessment instrument.

Conclusions: PFIs are feasible in routine care for the treatment of patients with bipolar I disorder and their relatives, and main obstacles are related to the organization/structure of mental health centres, and not to the characteristics of the intervention itself.

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1. Introduction

It is now well documented that bipolar disorder has a significant impact on relatives living with the patient (Pompili et al., 2014). Family members often report financial difficulties, impairment in marital and parenting roles, restriction in social and leisure activities, but also mental health problems such as sleep disturbances, anxiety and depressive feelings (Beentjes et al., 2012).

In the last few decades, a number of family interventions have been proposed aiming at supporting relatives of mentally ill persons (Reinares et al., 2014; Fiorillo et al., 2013; Luciano et al., 2012a; Carrà et al., 2007). All these interventions share a number of characteristics that are consistent with the growing recovery approach in the mental health field, being community-based, emphasizing the achievement of personal goals, working on instilling hope, and focusing on improving natural supports (Glynn et al., 2006).

Several trials have shown improved outcomes among patients with bipolar disorder, as well as their relatives in terms of wellbeing, when family supportive interventions are provided (Fiorillo et al., 2014; Candini et al., 2013; Geddes and Miklowitz, 2013; Reinares et al., 2010; Colom et al., 2009; Justo et al., 2007; Sajatovic et al., 2004). In particular, psychoeducational family interventions (PFIs) have proved to be effective in: (a) increasing patients' and relatives' knowledge about the disorder, by improving patients' affective symptoms and adherence to treatment (Poole et al., 2015); (b) reducing relapses and hospitalizations (Lyman et al., 2014; Parikh et al., 2012); and (c) decreasing family burden (Fiorillo et al., 2014; Jonsson et al.; 2011). Based on this evidence, several authors (Geddes and Miklowitz, 2013) and international guidelines (NICE, 2013; Goodwin, 2009) suggest to provide PFIs along with pharmacological treatment for an optimal management of people with bipolar disorders.

However, despite their efficacy, PFIs are not routinely provided in community mental health centres, for a variety of reasons which are related to professionals, to barriers in mental health services delivery, and to patients and relatives (Cohen et al., 2008; Glynn et al., 2006; Dixon et al., 2001). In particular, the lack of financial resources, the insufficient staff/patients ratios, heavy workloads, the paucity of training opportunities, and the overstructured nature of the intervention are reported among the key factors hampering the large-scale dissemination of psychoeducational family interventions (Gold et al., 2006; McFarlane et al., 2001). On the other hand, users' and relatives' difficulties include worries about stigmatization, previous negative experiences with mental health services and misconceptions about the efficacy of the intervention itself (Murray-Swank et al., 2007). Moreover, relatives often have other competing family responsibilities, and therefore travel distance, time commitment, and emotional demand have been reported among factors that reduce their availability to be involved in the intervention (Sherman, 2006).

The feasibility of a psychosocial intervention should be regarded as the result of the impact of barriers and facilitators (i.e., logistical issues, availability of caregivers to attend the sessions, educational level of participants, financial resources) and of the acceptability of the intervention (i.e., participants' satisfaction, appropriateness of the intervention to local socio-cultural contexts) (Brooke-Sumner et al., 2015). Studies exploring these factors in routine clinical practice are sparse and yield inconsistent findings (Bird et al., 2014).

The study herein presented was carried out as part of a multicenter, national, study, funded by the Italian Ministry of Health, aiming to: (1) assess the efficacy of a psychoeducational family intervention on clinical status and social functioning of patients with bipolar I disorder, as well as on relatives' social functioning; (2) identify the obstacles for its feasibility in routine care. Data relevant to the first aim have been reported elsewhere (Fiorillo et al., 2014); in this paper, we report results concerning the feasibility of the intervention.

2. Methods

Eleven Italian, randomly selected, mental health centres were invited to take part in the study. All of them agreed to participate.

The experimental intervention was based on the psychoeducational family intervention model originally developed by Falloon (1985) for schizophrenia management, and by Miklowitz and Goldstein (1997) for bipolar I disorder. Our research group has adapted this approach to Italian non-tertiary settings and sociocultural background (Luciano et al., 2012b).

In each centre, two mental health professionals were invited to participate in the study and were trained on the psychoeducational intervention following a structured program including: (a) three monthly sessions of two and a half days (20 h per session); (b) one session carried out at each site with the aim to inform all professionals on the purposes and the methodology of the study; (c) five supervision sessions, lasting one day and a half each; (d) regular phone and e-mail supervision over the study period; (e) a five-day training course on the assessment tools before the beginning of the intervention, during which mental health professionals' inter-rater reliability on questionnaires and interviews used for the study was tested. At each supervision meeting, and regularly every month by phone call or e-mail, implementation and clinical problems occurring in providing the intervention were carefully reviewed.

Difficulties and benefits experienced by mental health professionals were recorded by a revised version of the Family Intervention Schedule (FIS-R), previously developed in a large, multicentre, EU-funded study, assessing dissemination of family psychoeducational intervention for people with schizophrenia (Magliano et al., 2005). The FIS was administered at T0 (after recruitment of families), T1,T2, T3, T4, and T5 (after 3, 6, 9, 12, and 15 months, respectively).

Each centre was expected to consecutively recruit 16 families of patients with a DSM-IV-TR diagnosis of bipolar I disorder (APA, 2002), which were allocated to the experimental or the control group. Full details of the study methodology are reported in Fiorillo et al. (2014).

The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. The protocol was submitted to, and approved by, the relevant ethical and review boards. The trial received public funding from the Italian Ministry of Health (Number: 9556/2009).

3. Assessment instruments

The FIS-R is a self-administered instrument consisting of 33 items, subdivided in three subscales: (1) benefits of the intervention (e.g., feeling more confident in one's work; feeling more satisfied in one's work; knowledge of users' family context; communication with service' users; relationship with service' users families; support to families; positive clinical results); (2) organizational difficulties (e.g., integrating the intervention with other workloads; burden of work; lack of support by the administration; having to work beyond one's usual working hours; difficulties in engaging families; etc.); (3) approach-related difficulties (e.g., difficulties in performing specific sessions of the intervention such as those on individual assessment, in defining personal goals or those on the communication skills and problem-solving