



Original article

A randomized trial to assess the efficacy of a psychoeducational intervention on caregiver burden in schizophrenia



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ABSTRACT

Background: Patient's relatives usually care for patients with schizophrenia, and as informal caregivers they experience negative consequences. The aim of the EDUCA-III trial is to test the efficacy of a psychoeducational intervention program (PIP) versus standard care to reduce the caregiver burden at post-intervention (4 months), and at follow-up (8 months).

Method: A two-arm, evaluator blind, multicentre, randomized controlled trial. The PIP group had 12 weekly group sessions. The control intervention group had the usual support and standard care. Primary outcomes were change scores since baseline on the Zarit Burden Interview (ZBI) and the Involvement Evaluation Questionnaire (IEQ).

Results: One hundred and nine caregivers were randomized to PIP and 114 to control condition from 23 research sites. The decrease of ZBI scores was significantly higher on the PIP arm at 4 months (mean difference [MD] = -4.33; 95% CI -7.96, -0.71), and at 8 months (MD = -4.46; 95% CI -7.79, -1.13). There were no significant decreases in the IEQ scores (MD at 4 months = -2.80; 95% CI -6.27, 0.67; MD at 8 months = -2.85; 95% CI -6.51, 0.81).

Conclusions: The PIP condition seems to reduce caregiver burden.

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1. Introduction

Schizophrenia is an incapacitating, long-lasting psychiatric disorder which has serious consequences for both the patient and caregivers [1]. During the asylum period, families were usually excluded from care. However, the process of deinstitutionalization and the development of community psychiatry in the 1960s and 1970s changed the pattern of care of many severe psychiatric patients, placing in the family the burden of care. Usually a family

member, known as the primary or main caregiver, assumed most of the care [2].

This main caregiver become responsible of the patient care, helping them to solve tasks related with different areas of care; for instance his/her physical and emotional support (i.e. adherence to treatment), socio-economic aspects (i.e. social integration, occupational issues), or activities of daily life (ADLs) [3].

Caring for a person with schizophrenia can lead to substantial physical and psychological burden, including negative physical and emotional effects as well as costs in terms of time and use of economical resources [4]. This complex situation has been defined as “caregiver burden”: a negative psychological state experienced by informal caregivers produced by physical, psychological/emotional, social, economic difficulties derived from the care of patients [5,6].

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Although positive experiences also appear [7], between 83 to 95% of relatives or friends of patients with schizophrenia might experience significant burden that may reduce the quality of care provided, endangering both patients and caregivers alike [8,9]. It is therefore important that a comprehensive treatment of schizophrenia include interventions intended for reducing the negative impact of the illness on caregivers. However, with some exceptions [10], most research supporting the efficacy of family interventions has focused on patient outcomes, and only marginally has considered the situation of the caregiver as an adequate target for intervention [11]. Accordingly, the NICE guideline highlights lack of evidence on interventions specifically targeting caregiver burden in schizophrenia [12]. The EDUCA-III trial, presented here, is a multicentre randomized controlled trial designed to assess the effect of a psychoeducational intervention program (PIP) on caregiver's burden and other relevant mental health outcomes. The PIP was administered in a group format and focused on the didactically and skilful communication of key information to the caregiver within the framework of a cognitive-behavioural approach [13].

1.1. Aims of the trial

To assess the efficacy of a PIP versus standard care on the reduction of caregiver burden at the end of trial (4 months since baseline), and to assess the maintenance of the therapeutic effect at follow-up (8 months since baseline).

2. Methods

2.1. Hypothesis and design

The main hypothesis of the trial was that caregivers allocated to a PIP would present lower subjective burden at postintervention endpoint (4 months), and at further follow-up (8 months) than caregivers allocated to control condition. A secondary hypothesis was that caregivers allocated to PIP would also present better mental health according to self-reported indicators at endpoint and follow-up than caregivers allocated to control condition.

The design was a two-arm, evaluator blind, international, multicentre, randomized controlled trial. All research sites had 2 investigators: one trained in the application of the PIP, and other-blinded to the allocated intervention—who assessed the caregiver outcomes. Throughout the trial, a central research committee oversaw the correct management of trial procedures and adherence to protocol. The trial protocol was approved by appropriate Institutional Review Boards of Spain and Portugal (Ethical and Scientific Research Committees of Navarra, Spain; and Sisters Hospitallers, Portugal). All participants (caregivers and patients) signed an informed consent form prior to randomization and trial inclusion.

2.2. Participants, inclusion and exclusion criteria

Dyads of patients diagnosed with schizophrenia or schizoaffective disorder (DSM-IV criteria) and family primary caregivers were recruited from 21 outpatient psychiatric centres in Spain and from 3 outpatient psychiatric centres in Portugal.

Persons caring for a relative were eligible for the trial if they met the following inclusion criteria:

- males or females (18+ years) currently caring for a relative with a diagnosis of schizophrenia or schizoaffective disorder;
- the caregiver should not be professionally paid (i.e., he/she should be an informal caregiver) and spend a minimum of 4 h/week caring for the patient;

- the patient should have been diagnosed at least 2 years before trial recruitment and was receiving appropriate outpatient clinical care.

The following were considered exclusion criteria:

- caregivers without time to attend the weekly sessions of PIP training;
- caregivers currently receiving, or having recently received (last year), any standardized psychoeducational intervention similar to the one administered in the trial;
- the patient cared for had an hospitalization in the month before randomization, or was on residential care;
- the patient presented mental retardation, dementia or any other organic cognitive disorder.

On the other hand, the following criteria for ending the trial before completion were established:

- caregiver decision;
- change from outpatient to inpatient status or residential care for the patient being cared for;
- patient being discharged from the original health care service;
- protocol deviations as assessed by the central research committee.

2.3. Interventions

The caregivers allocated to the control group received the usual support from the outpatient psychiatric service where the patients were treated, and had periodical interviews and information about the situation and clinical course of the patient. The caregivers allocated to the intervention group received the same usual support plus the PIP. The PIP was developed by a group of psychiatric, psychologist and mental health experts with practical knowledge in patient and caregiver interventions. It is based on the principles of the psychoeducational program developed in REACH-II study [14] for dementia caregivers, subsequently adapted to the characteristics of caregivers of people with schizophrenia. Underlying the PIP is a behavioural-cognitive approach to provide caregivers with education, skills to manage troublesome behaviors, social support, cognitive strategies for reframing negative emotional responses, and strategies for enhancing healthy behaviors and managing stress. The PIP was administered over 12 weekly group sessions lasting 90–120 mins each. To avoid fatigue or inattention there was a time-break of 15 mins at the middle of each session.

On the PIP sessions the caregiver received standardized information about the clinical course of schizophrenia and was trained on cognitive and behavioural skills. These included general caregiving abilities, communication skills, the ability to seek and enjoy pleasant events, to seek support, as well as relaxation techniques. The PIP required active participation from caregivers (i.e. role playing, applying new skills to conflict, etcetera). It applied cognitive-behavioural techniques focused on identifying and challenging negative beliefs and developing a new style to deal with caregiving demands. All sessions had the same formal structure:

- an introduction to review the progress of the homework tasks;
- information about the topic to be dealt with;
- exercises to practice the new knowledge or skills. The PIP was applied by mental health professionals (psychologist or psychiatrist) trained in the program by the same researchers who developed it. We provided a manual for the therapist and a

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