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Original article

"Living together with dementia": Training programme for family caregivers – A study protocol

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ABSTRACT

Introduction: Due the increase incidence of Dementia, the creation, implementation and evaluation of the effectiveness of training programmes for family caregivers of people with dementia living at home should be a goal of health professionals. The aim of this paper is to describe the randomised control trial protocol that will assess the effectiveness of the training programme for family caregivers who care for people with dementia at home "Living together with Dementia".
Methods: Randomised control trial. Family caregivers of people with dementia in early and moderate stages will be recruited through a neurology appointment at the São João Hospital Centre, Porto-Portugal. The inclusion criteria employed will be as follows: to be the main caregiver of the person with dementia; to be literate; the care target has dementia in early or moderate stage; the person with dementia does not suffer from any other severe mental pathology. Caregivers will be randomised and assigned to control and experimental groups. 3 assessment moments will take place: initial, after the intervention and a follow up of 3 to 6 months. The assessment instruments include a survey containing sociodemographic data, Caregiver Burden Scale, Caregiver Assessment Satisfaction Index and Caregiver Assessment Difficulties Index. The participants of the experimental group will be submitted to a 7-week individual psychoeducational programme. The study was approved by the Health Ethics Committee of the São João Hospital Centre in September 2015.
Discussion: This programme might prove an asset to family caregivers of people with dementia living at home, since it pinpoints understanding and preparation of their role. It also facilitates the intervention of health professional, as it features as a guideline for their performance with this target population.

Introduction

In the present sociodemographic context, dementia assumes itself as an emerging Public Health problem, and the involvement of family members in the assisting plan is increasing.[1] Training family members who undertake the responsibility of caring for people with dementia who remain at home is paramount, so these acquire knowledge and skills to cope with the disease and its evolution.

In the early and moderate stages of the pathology, psychological and behavioural alterations are a main overload factor for family caregivers, since these lack strategies to manage these changes. So as to address this need, an increasing greater number of countries have been developing training programmes designed to assist family caregivers of people with dementia living at home. These sort of intervention are beneficial for the person with dementia, for the caregiver and for the health service, since institutionalisation is delayed.[2]

Diverse interventions with family caregivers of people with dementia are to be found in literature, such as family and personal counselling, psychoeducation, emotional support groups, skill training programmes, multiple component programmes,

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psychotherapy programmes, cognitive and behavioural programmes, and "technology" based interventions, among others.[3] However, training a caregiver entails providing knowledge and skill, in which psychoeducation appears to be the most efficient type of intervention, due to the consistency of the results when it comes to the increase of the competences of the family caregivers and both overload and depression reduction.[4,5]

An integrative review including training programmes for family caregivers of people with dementia has proved it necessary to systematise programmes according to the stage of dementia, so as to facilitate the comparison of results, the verification of efficiency levels and the assessment of health gains induced by their application, given the fact that this is the only possibility to assess their quality.[6] The review established also that training programmes for family caregivers of people with dementia living at home produce positive results for participants; notwithstanding, results need to be deepened and validated. The conceptual characteristics of these programmes require improved definition, as for instance via focus groups or Delphi studies, as well as by proving their effectiveness, e.g., by using controlled experimental studies with more significant samples.[6]

In Portugal a gap of training programmes for family caregivers of people with dementia living at home is felt, which substantiates the present study. The programme "Living together with Dementia" has been created with resource to an integrative revision of literature,[6] a focus group[7] and a Delphi study. It is a psychoeducational study featuring individual sessions, aiming at the training of the family caregiver of people with dementia living at home.

So as to validate the programme, a randomised controlled pilot study is taking place, whose protocol is presented in this study. The goals of the pilot study are as follows:

- To assess the effectiveness of the programme "Living together with dementia" when compared to the ordinary nursing care provided to these caregivers;
- To assess overload, satisfaction and difficulties of the family caregivers after participating in the programme.

The hypothesis that we endeavour to prove is that the family caregivers who integrate the experimental group and participate in the "Living together with dementia" programme will present lower overload levels, greater satisfaction levels and less difficulties associated with the caregiver role than the control group participants.

Methods

Study design

The "Living together with dementia" programme has been designed as a randomised control trial with follow up (4 months, after the end of the intervention). All procedures are in accordance with consolidated standards of reporting trials (CONSORT)[8] presented in Fig. 1.

Setting

The study will take place at the São João Hospital Centre, EPE, Porto-Portugal, at the neurology outpatient consultation, namely, the dementia consultation.

Participants

Inclusion criteria

The following inclusion criteria should be met to allow family caregivers to be eligible to participate in the "Living together with dementia" programme: (a) To be the main caregiver of the person with dementia in early or moderate stages; (b) to be literate; (c) to be motivated to participate in the programme; and (d) to reside in Porto.

Exclusion criteria

Family caregivers were excluded if: (a) the target population of care does not have dementia in early or moderate stage; and (b) the person with dementia suffers from other severe mental pathology.

Recruitment/randomisation

For a 6-month period (from October 2015 to March 2016), the family caregivers were recruited subsequent to the neurology outpatient consultation, namely the dementia group of the São João Hospital Centre – EPE – Porto. The neurologists attending the dementia consultation (auxiliary researchers) have identified the caregivers who met the inclusion criteria and requested their permission to be afterwards reached per telephone, in order to provide information about the study and to accept or not to take part in it. The telephone contact that took place afterwards has been performed by one of the auxiliary researchers. The family caregivers who accepted to participate in the study have been classified in a random numeric listing, and had a participation code assigned (from FC1 to FC27). The allocation has been performed by the drawing of lots of numbered slips of paper performed by the research supervisors. The first 12 caregivers whose numbers have been drawn integrated the experimental group. Helsinki Declaration[9] ethical principles have been considered throughout the entire process.

Ethical considerations

The study and its protocol were accepted by the Health Ethical Commission of the São João Hospital Centre in September 2015. The study is registered in www.clinicaltrials.org with ID number NCT 03015428. All family caregivers who will participate in the study signed a free, prior and informed consent required for a health institution.

Interventions

Conventional care

The family caregivers who integrate the control group will have access to standard health care in the health institution where the study is taking place, such as a neurology appointment every 6 months and the possibility of solving any queries about the pathology, care provision and therapeutic regime with the healthcare professionals' team (doctor, nurse, social worker, psychologist). The participants of the control group will be assessed in the beginning of the study (T1), 7 weeks after (T2) and in a 4-month follow up (T3).

"Living together with dementia" programme

The family caregivers who integrate the experimental group will be submitted to the "Living Together with Dementia" programme, an individual psychoeducational programme, developed and applied by mental health and psychiatry specialist nurses which aims at training the family caregiver who undertakes the care of people with dementia living at home. This is a 7-week programme, composed by 7 individual sessions with a one weekly session load and an average duration of 60 min each and 2 group sessions with all the caregivers present with an average duration

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