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Original article

Contribution of family social support to the metabolic control of people with diabetes mellitus: A randomized controlled clinical trial

Lilian Cristiane Gomes [a,*], Anna Claudia Martins Coelho [a], Danielle dos Santos Gomides [a], Maria Cristina Foss-Freitas [b], Milton César Foss [b], Ana Emilia Pace [c]

[a] Fundamental Nursing Graduate Program, EERP/USP, Ribeirão Preto, São Paulo, Brazil
[b] Department of Medical Clinics of the School of Medicine, Ribeirão Preto/USP, Ribeirão Preto, São Paulo, Brazil
[c] Department of General Nursing and Specialist at EERP/USP, Ribeirão Preto, São Paulo, Brazil

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ABSTRACT

Aim: This randomized controlled clinical trial aimed to evaluate the contribution of family social support to the clinical/metabolic control of people with type 2 diabetes mellitus.
Background: Diabetes mellitus is a chronic disease that requires continuous care in order for individuals to reach glycemic control, the primordial goal of treatment. Family social support is essential to the development of care skills and their maintenance. However, there are few studies that investigate the contribution of family social support to diabetes control.
Methods: The study was developed between June 2011 and May 2013, and included 164 people who were randomized using simple randomization. The intervention group differed from the control group in that it included a family caregiver, who was recognized by the patient as a source of social support. The educational interventions received by people with diabetes mellitus were used as the basis of the education provided through telephone calls to patients' family members and caregivers, and their purpose was to encourage dialogue between the patients and their relatives about the topics related to diabetes.
Results: Regarding the clinical impact, the results showed that there was a greater reduction in blood pressure and glycated hemoglobin in the intervention group than in the control group, showing a positive effect on the control of the disease.
Conclusions: Families should be incorporated into the care of people with diabetes mellitus and especially in health care programs, in particular those that can promote different forms of social support to strengthen the bond between family members.

1. Introduction

Type 2 diabetes mellitus (T2DM) is a chronic disease of particular importance not only because of the increase in its prevalence but also because when poorly controlled, it is associated with other consequent morbidities, including cardiovascular, renal, ophthalmic, and neurological diseases; these comorbidities can result in physical disability and premature death (Francisco et al., 2010; Lessa, 2004). Brazil, which was ranked eighth among the top ten countries with the highest number of T2DM cases in the world (4.6 million) in 2000, is expected to be ranked sixth in 2030, with an estimated 8.9 million people diagnosed with the disease (Wild, Roglic, Green, Sicree, & King, 2004).

Due to the chronic nature of the disease, persons with T2DM require long-term monitoring to maintain their care and glycemic control; this control is the main focus of treatment, which primarily aims to prevent and/or delay the serious chronic complications of the disease (Sociedade Brasileira de Diabetes, 2016). The need for behavioral changes and the incorporation of new technologies into treatment can be challenging for persons with T2DM and their family and may require new skills for maintaining care. Accordingly, health education is considered essential to the treatment of T2DM (Francisco et al., 2010) because of its contribution to preventing acute events and to reducing the risk of

Abbreviations: T2DM, Type 2 diabetes mellitus; HbA1c, glycated hemoglobin; BMI, body mass index; WC, waist circumference; DM, diabetes mellitus; SS, social support; H0, null hypothesis; AH, alternate hypothesis; T0, before the start of the intervention (baseline); T6, six months after the start of the intervention; T12, three months after the end of the intervention; ICF, Informed Consent Form; SCT, Social Cognitive Theory; IG, intervention group; CG, control group; SD, standard deviation; SBP, systolic blood pressure; DBP, diastolic blood pressure; FPG, fasting plasma glucose; CI, confidence interval; LLCI, lower limit of the confidence interval; ULCI, upper limit of the confidence interval; UKPDS, United Kingdom Prospective Diabetes Study; T1DM, Type 1 diabetes mellitus.

* Corresponding author at: Rua João Carlos Farah, 340, Jardim Agenor de Lima, CEP: 37.800-000, Guaxupé, MG, Brazil.
E-mail addresses: liliancg@unifeg.edu.br (L.C. Gomes), annaclaudiacoelho@yahoo.com.br (A.C.M. Coelho), danielle_gomides@hotmail.com (D.S. Gomides), crisfoss@fmrp.usp.br (M.C. Foss-Freitas), mcfoss@fmrp.usp.br (M.C. Foss), aepace@eerp.usp.br (A.E. Pace).

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chronic morbidities during the disease course (American Diabetes Association, 2016).

Health education comprises a set of planned activities that aim to improve people's knowledge and skills to maintain health, improve engagement in healthy behaviors, and promote changes in attitudes and perceptions about disease to facilitate adjustment to new situations of daily living (Chrvala, Sherr, & Lipman, 2016; Hoving, Visser, Mullen, & van den Borne, 2010). Health education is also considered a strategy that can be used to help persons take responsibility for self-care, function autonomously and become motivated to use their own knowledge and skills in problem solving (Bagnasco et al., 2014; Haas et al., 2012).

Previous studies have demonstrated the benefits that educational interventions can have on glycemic control in people with T2DM, especially interventions that combine behavioral, cognitive and affective aspects in a collaborative approach and include regular reinforcements for participants (Chrvala et al., 2016; Cooper, Booth, Fear, & Gill, 2001; Eakin et al., 2014; Klein, Jackson, Street, Whitacre, & Klein, 2013; Lynch, Liebman, Ventrelle, Avery, & Richardson, 2014; Minet, Møller, Vach, Wagner, & Henriksen, 2010; Norris, Engelgau, & Narayan, 2001; Norris, Lau, Smith, Schmid, & Engelgau, 2002a; Norris et al., 2002b). However, these same studies have differed regarding the frequency of contact with the educator, the follow-up time (Chrvala et al., 2016; Cooper et al., 2001; Eakin et al., 2014; Klein et al., 2013; Lynch et al., 2014; Minet et al., 2010), the sample size (Eakin et al., 2014; Lynch et al., 2014; Minet et al., 2010) and the effects of the intervention on other clinical parameters, such as blood pressure (Cooper et al., 2001; Lynch et al., 2014; Norris et al., 2002b), lipid profile and body weight (Eakin et al., 2014; Lynch et al., 2014; Norris et al., 2001; Norris et al., 2002a).

Other studies have noted that the most effective interventions for reducing glycated hemoglobin (HbA1c) were those that focused on the patients (Chrvala et al., 2016; Windrum, García-Goñi, & Coad, 2016) and were based on the empowerment of individuals (providing motivation for self-awareness, assessing problems, establishing personal goals and monitoring the achievement of goals) (Chen, Wang, Lin, Hsu, & Chen, 2015), as well as those that included typical elements of the subjects' culture (culturally adapted education) (Bhurji, Javer, Gasevic, & Khan, 2016). Culturally tailored educational interventions have also resulted in a significant reduction in body mass index (BMI) and waist circumference (WC) and a slight improvement in blood pressure and lipid profile (Bhurji et al., 2016).

Furthermore, it should be noted that chronic disease management occurs in a context that includes health professionals, social network members and the physical environment. Understanding the social context has important implications for the planning of interventions that aim to improve people's health and well-being (Gallant, 2003). In particular, social support (SS) is considered a facilitator of diabetes mellitus (DM) self-care (Cardoso, Queirós, & Ribeiro, 2015) because it is an interpersonal process that is centered on the exchange of information (Finfgeld-Connett, 2005) in which one has the perception or belief of being connected to and feeling loved and esteemed by others (Martins, 2005).

Systematic reviews have shown that families are one of the main sources of SS for adults with DM (Rintala, Jaatinen, Paavilainen, & Astedt-Kurki, 2013; Strom & Egede, 2012) and that families actively participate in the health care of adults and elders (Gallant, 2003). Care is most often provided by a family member when patients do have blood relatives, not only because of their existing relationship but also because this responsibility is culturally assigned (Cattani & Girardon-Perlini, 2004). SS can be considered a personal dimension of family relationships, i.e., to occur as a result of these relationships (Pedro, Rocha, & Nascimento, 2008), regardless of family structure.

Although the literature shows that educational interventions developed together with family carers of people with DM may contribute to the management of the disease, few studies have examined the effects of family SS on metabolic control in adults with DM (Rintala et al., 2013). In addition, the gaps and inconsistencies between studies, which have been conducted in different population samples, require further research to better understand the true influence of SS on disease-related outcomes (Strom & Egede, 2012), preferably using randomized controlled trials.

Based on the background presented, this study proposed to investigate whether the inclusion of family SS in an education program for DM would help improve clinical/metabolic parameters of outpatients with DM in a tertiary health care unit.

The hypotheses of the study were as follows:

Null hypothesis (H0): including family SS in the educational process does not result in better clinical/metabolic control among people with T2DM (there are no differences between groups).

Alternate hypothesis (AH): including family SS in the educational process results in better clinical/metabolic control among people with T2DM (the intervention group shows better clinical/metabolic control than the control group).

2. Method

This single-blind randomized controlled clinical trial focused on educational interventions for people with T2DM and a family member, who was referred to as a source of SS in caring for the disease. The participants were outpatients in a tertiary health care unit from June 2011 to May 2013 (Fig. 1).

2.1. Study sample

The sample size was calculated based on the expected results for the primary outcome variable (HbA1c) in accordance with the literature, using the following formula (Pocock, 1983):

$$n = \frac{p_1(1\text{-}p1)\pm p_2(1\text{-}p_2)}{(p_1-p_2)^2} \times f(\alpha,\beta),$$

where: $p_1 = 0.22$; $p_2 = 0.10$; $p_1\text{-}\,p_2 = 0.12$; $\alpha = 0.05$; $\beta = 0.10$; $1\text{-}\beta = 0.90$.

Therefore, the sample size was estimated to be 190 people or 95 per group. Potential participants were identified weekly by reviewing the medical records of subjects scheduled for that date and assessing the inclusion/exclusion criteria.

2.1.1. Inclusion criteria

The inclusion criteria included a T2DM diagnosis, a minimum age of 40 years and a lack of complications in an advanced stage. The selection of 40 years as the minimum age was justified by the fact that T2DM is commonly diagnosed in this age group (American Diabetes Association, 2016).

2.1.2. Exclusion criteria

The exclusion criteria included the presence of complications in an advanced stage, such as hemodialysis treatment, amaurosis, cerebrovascular accident sequelae, heart failure sequelae, previous amputations and/or active ulcers in the lower limbs; use of a wheelchair or stretcher; inability to maintain dialogue; and other serious diseases whose treatment could prevent participation in an educational intervention (e.g., chemotherapy, radiotherapy).

2.2. Randomization

Randomization was performed every 40 recruited subjects through simple randomization and occurred after the first data collection time point and before the start of the educational intervention. To minimize bias, randomization was performed by statistical software R.