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Cluster randomised controlled trial: Educational self-care intervention with older Taiwanese patients with Type 2 diabetes mellitus——Impact on blood glucose levels and diabetic complications

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KEYWORDS
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Summary
Aims: To investigate whether self care behaviours, medical outcomes and quality of life of Taiwanese elderly with Type 2 diabetes mellitus (DM) can be improved by delivery of an educational health care package.
Background: DM is a major health problem in developed and developing countries, with older adults constituting about half of the diabetic population. Type 2 DM is the most rapidly increasing chronic disease in Taiwan.
Methods: During 2005 and 2006, Taiwanese elderly with Type 2 DM ($n = 500$) were randomly allocated to either an intervention or control group. Data collection using validated instruments occurred at baseline and 6 months follow-up. Main outcome measures were blood glucose levels and diabetic complications.
Results: At baseline, 88.4% participants in the control and 78.8% in the experimental group had a blood glucose level above normal range ($p = 0.076$); respective results at 6 months were 92.4% for the control group and 60.4% for the experimental group ($p < 0.001$). The multivariate adjusted result showed that the intervention group was 11.1 times less likely to have blood glucose levels above normal ($p = 0.002$) at 6 months follow-up compared to the control group. Occurrence of complications was significantly fewer in the intervention group at baseline and at 6 month follow-up compared to the control group (baseline: 42.0% versus 82.1%, $p = 0.003$; 6 month follow-up: 48.4% versus 87.0%; $p = 0.006$).

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Conclusion: Although overall occurrence of complications remained unchanged, the educational health care package specifically developed for Taiwanese elderly with Type 2 DM improved blood glucose levels.

Introduction

Type 2 diabetes mellitus (DM) is a metabolic disorder characterised by chronic hyperglycemia with disturbances of the carbohydrate, fat and protein metabolism. It is associated with reduced life expectancy, significant morbidity due to specific DM related microvascular complications, increased risk of macrovascular complications (ischaemic heart disease, stroke and peripheral vascular disease), and diminished quality of life (WHO, 2006). Poor glycemic control in persons with Type 2 DM mellitus has other serious consequences related to cognitive function, psychological status, for example depression, anxiety and stress, and the likelihood of increased medical complications such as retinopathy, renal failure, neuropathy with the risk of amputation, cardiovascular disease, mortality, and increased medical costs (Wangberg, 2008).

Background

DM is now recognised as a major health problem in developed and developing countries with approximately 1 in 20 deaths attributable to the disease (WHO, 2008). Recent WHO Global Burden of Disease estimates predict that the worldwide burden in adults to be around 366 million by the year 2030, with approximately two thirds of those persons expected to live in developing countries (WHO, 2006). DM is the most rapidly increasing disease in Taiwan (Chang, 2003) and it is expected that the number of people with DM in Taiwan will increase to 300 million by the year 2025 (Chou et al., 2002). Further, people living in the rural areas of Taiwan have been found to have a higher likelihood of diabetes, which may be accounted for in some way by the higher numbers of Aboriginal people living in those areas (Chen et al., 2006). World-wide, older adults constitute about one-half of the diabetic population. In this age group DM is a serious disease linked to a higher mortality rate and shorter life expectancy, mostly due to increased atherosclerotic complications (Wandell and Tovi, 2000). The trend is similar in Taiwan, especially in rural areas (WHO, 2006).

Many people with DM struggle to adhere to recommended protocols of self-care and blood glucose management and thus risk the development of harmful complications (Diabetes Prevention Programme Research Group, 2002; Huang et al., 2004). The United Kingdom Prospective Diabetes Study (UKPDS), a randomised, prospective, multicentre trial, indicated that improved glucose control in patients with newly diagnosed Type 2 diabetes mellitus greatly reduces the risk of clinically evident microvascular complications (Holman, Sanjoy, bethel, Neil, & Matthews, 2008).

It has been well recognised that in general, between 50% and 80% of people living with DM have deficits in knowledge and self-care skills (Clement, 1995). As a result, the health education model (HEM) was used as the theoretical basis for the study was based on the revised pender health promotion model (RHPM) (Pender, Caroly, & Murdargh, 2006). Improving diabetic patient knowledge and changing attitudes to self-care is one way to work towards achieving better outcomes for people with diabetes. The model recognises that for patients to be empowered in self-care, health care providers must provide the information and skills required for change. Therefore, a specially designed education programme suited to the needs of elderly Taiwanese rural dwellers with diabetes was developed.

The study

Aim

The aim of the present cluster randomised trial was to investigate the effects of an educational intervention programme for Taiwanese elderly with Type 2 DM, many of whom have low levels of literacy, on blood glucose levels and DM complication rates.

The study addressed two main hypotheses involving the following two outcome variables: (1) percent of patients with a well-controlled blood glucose level implying to have a blood glucose level in normal range (AC: 70—110 mg/dl or PC: 90—140 mg/dl) and (2) percent of patients with positive markers for DM complications. Markers considered were serum creatinine (normal range: 0.6—1.5 mg/dl), urine analysis (normal: protein and glucose both zero), microalbumin (normal: less than 30 mg), cholesterol (normal range: 130—225 mg/dl), triglyceride (normal range: 50—130 mg/dl), blood pressure (normal range: 120/80 mmHg, systolic phase is 120 mmHg and diastolic phase 80 mmHg in adult), and cataract or retinopathy present. Both outcome variables were dichotomised. Ranges for blood markers were set at current country levels at the time of the study.

Design

The present cluster randomised controlled trial with follow-up after 3 and 6 months was conducted in central and northern Taiwan between 2005 and 2006. The study was approved by the relevant human ethics committees.

Study protocol

Letters describing the study and seeking permission for the investigators to phone the potential participants were mailed from the participating health facilities to persons who met the sampling inclusion criteria. Each letter contained a self-addressed return envelope allowing interested persons to send back the signed consent form. Baseline questionnaires were mailed, and were either returned by mail after completion ($n = 35$) or were completed during a face-to-face interview with the researchers in case participants