International Journal of Nursing Studies 79 (2018) 43–51

Contents lists available at ScienceDirect

International Journal of Nursing Studies

journal homepage: www.elsevier.com/locate/ijns

Effectiveness of a patient-centred, empowerment-based intervention programme among patients with poorly controlled type 2 diabetes: A randomised controlled trial

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ARTICLE INFO

Keywords:
Behaviour
Clinical trial
Empowerment
Poorly controlled type 2 diabetes
Self-management education
Transitional care

ABSTRACT

Background: Despite extensive efforts and advances in evidence-based diabetes management, poor glycaemic control still remains a challenge in many countries. There is a paucity of research addressing the needs of patients with poorly controlled type 2 diabetes, or exploring the effectiveness of empowerment-based interventions in this vulnerable population.

Objectives: To evaluate the effectiveness of a patient-centred, empowerment-based programme on glycaemic control and self-management behaviours among patients with poorly controlled type 2 diabetes.

Design: A prospective multi-centre, single-blind, randomised controlled trial.

Settings and participants: Adult patients with poorly controlled type 2 diabetes [Haemoglobin A1c (HbA1c) $\geq$7.5% in the recent six months] were recruited from two tertiary hospitals in Xi'an city, China.

Methods: A total of 242 eligible patients were recruited and randomly assigned to the intervention or attentional control groups after baseline measurement. Participants in the intervention group received a 6-week patient-centred, empowerment-based self-management programme, which is theoretically grounded on the principles of the Empowerment Process Model-setting personally meaningful goals, taking action towards goals and reflecting on the impact of action plans. Those in the attentional control group received health education classes and post-discharge follow-up. Outcome measures included glycaemic control (measured by HbA1c) and self-management behaviours. Data were collected at baseline, and at 8th and 20th week after enrolment. Intervention effect were analysed using the generalised estimating equation model on the basis of the intention-to-treat principle.

Results: Compared with the attention control group, the intervention group showed a non-significant HbA1c reduction of 0. 476% (Cohen's d effect size = 0.31, p = 0.162). The intervention group exhibited significant improvements in general diet management at the 8th-week (β = 0.740; p = 0.013), specific diet management at 8th-week (β = 0.646; p = 0.022) and 20th-week (β = 0.517; p = 0.043), and blood glucose self-monitoring at both the 8th- (β = 0.793; p = 0.009) and 20th-week (β = 0.739; p = 0.017) follow-ups. No intervention-related adverse events were observed.

Conclusions: Findings indicate that the patient-centred, empowerment-based self-management intervention program did not induce a significant HbA1c reduction. Whereas this intervention yields improvements in diet management and blood glucose self-monitoring among patients with poorly controlled type 2 diabetes.

What is already known about the topic?

- Despite extensive advances and efforts in evidence-based diabetes management, poor glycaemic control still remains common in many

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https://doi.org/10.1016/j.ijnurstu.2017.10.021
Received 13 December 2016; Received in revised form 25 October 2017; Accepted 27 October 2017

countries.
- Patients with poorly controlled type 2 diabetes find enormous difficulty in actively performing the behaviour needed to achieve glycaemic targets.

What this paper adds

- The patient-centred, empowerment-based intervention programme did not induce a significant HbA1c reduction, compared with the attentional control.
- Patients with poorly controlled type 2 diabetes who participated in the patient-centred, empowerment-based programme demonstrated improved performance in diet management and blood glucose self-monitoring.

1. Introduction

Despite extensive advances and collective prioritization of evidence-based diabetes management, poor glycaemic control still remains common in many countries (Litwak et al., 2013). More than 60% of patients with diabetes in the United States of America reported difficulty in achieving glycaemic targets; 36% of patients with type 2 diabetes in developing regions have never had their Haemoglobin A1c (HbA1c) measured, and among those who do have HbA1c measurements available, only 36.4% have optimal glycaemic control levels. Of 114 million Chinese diabetics, 74.2% remain untreated, and 63% of those who have been treated suffer from poor glycaemic control (Chan et al., 2014a, 2014b; Xu et al., 2013). Poor glycaemic control requires prolonged hospitalisation, frequent consultations and increased healthcare expenditure, placing a great burden on countries throughout the world, especially in resource-poor regions. In addition to physical and health expenditure problems, psychological issues frequently develop as part of the hyperglycaemia trajectory (Fisher et al., 2009). Therefore, care for patients with poorly controlled type 2 diabetes is a global priority (World Health Organization, 2014).

Adherence to diabetes self-management regimen continues to be the most significant determinant to attain glycaemic target (Davies et al., 2013; Raz et al., 2013; Shrivastava et al., 2013; Tan and Magarey, 2008). Patients with poorly controlled type 2 diabetes find enormous difficulty in synthesizing self-management recommendations in the dynamic and complex daily context (Berenguera et al., 2016; Inzucchi et al., 2012; Juarez, 2012; Khattab et al., 2010; Schulz and Nakamoto, 2013; Zoffmann and Kirkevold, 2012). There is a great call to support and empower them to take a proactive self-management role in the disease trajectory.

A flourishing body of studies have illustrated that patient-centred, empowerment-based approach could boost patients' engagement in and commitment to diabetes self-management (Anderson et al., 1995; Chan et al., 2014a, 2014b; Cooper et al., 2008; Kuo et al., 2014). Prior research in this area, however, tend to recruit general patients with optimal glycaemic control (Kuo et al., 2014; Cheng et al., 2017). Consistent evidence supported that patients with poorly controlled type 2 diabetes have considerably disadvantaged characteristics (Ali et al., 2012; Benoit et al., 2005; El-Kebbi et al., 2003; Juarez, 2012; Khattab et al., 2010; Otiniano et al., 2012). Such patients may respond differently to an empowerment approach (de Boer et al., 2013; Schulz and Nakamoto, 2013; Wang et al., 2016). Drawing conclusions about the effectiveness of an empowerment approach in such patients remains difficult.

Given the promising evidence around empowerment-based intervention, a patient-centred, empowerment-based programme was designed and tested using a randomised controlled trial (RCT). This paper reports the testing of the following hypotheses: compared with participants in the attentional control group, patients with poorly controlled type 2 diabetes who receive the intervention programme will have significantly optimised glycaemic control (indicated by HbA1c level) and self-management behaviours (measured by the Summary of Diabetes Self-Care Activities, SDSCA).

2. Methods

This was a prospective multi-centre, single blind, randomised controlled trial with a parallel-group design using a stratified block randomisation (registration number: ChiCTR-IPR-14005492). It was carried out at two tertiary hospitals in Xi'an, China from April 2014 to October 2015. Before the commencement of the study, a computer generated block randomisation list using a block size of 4 at 1:1 ratio was created by an off-site researcher who were not involved in the practical conduct of the study. The generated random numbers were put into consecutively numbered and opaque sealed envelopes.

2.1. Participants and allocation

The inclusion criteria were: (1) adult patients (more than 18 years of age) diagnosed with type 2 diabetes, (2) with an HbA1c found to be over 7.5% in the recent six months, (3) being available for telephone follow-up and (4) being able to give written informed consent. Exclusion criteria were: (1) being involved in diabetes education programmes, and (2) with evolving cancer, serious cognitive problems, a psychiatric disease or a serious medical or health condition that would hinder their self-management of diabetes (e.g., end-stage renal disease and on dialysis, blindness or and heart failure).

Potential eligible participants were identified by research assistants via initial screening of medical records at Department of Endocrinology in each hospital. Potential participants were provided with invitation letters and information sheets; the research assistants orally explained the study purpose, procedure, benefits and risks related to their participation. After eligible patients consented to participate in the current study, a baseline assessment was conducted. Then, participants were assigned into one of the study groups in sequence of enrolment into the study. The concealed allocation was maintained by the following means: (1) when enrolling and randomising a new participant, the enrolling investigators opened the sealed envelope after participant's name was written on next available envelopes; the enrolling investigators were blinded to the trial design and study hypotheses; (2) the trained outcome assessors were blinded to trial hypotheses and group allocation throughout the study period.

2.2. Sample size

Considering the study hypotheses and outcomes, the sample size was calculated on the basis of the subgroup analysis result from a recent meta-analysis. The effect size of self-management interventions on HbA1c among patients with poorly controlled diabetes was estimated to be 0.397 (Tshiananga et al., 2011). Using G-power, a total of 242 participants, with 121 per group, would be adequate to achieve an 80% power to detect such an effect size at a 5% level of significance, allowing for a 20% attrition rate.

2.3. Intervention and control condition

2.3.1. Intervention

The 6-week patient-centred, empowerment-based intervention programme is theoretically grounded on the principles of the Empowerment Process Model-setting personally meaningful goals, establishing self-efficacy, promoting knowledge and skills, taking action towards goals and reflecting on the impact of action plans (Cattaneo and Chapman, 2010). The intervention programme reported here also drew upon our previous work which assessed the barriers perceived by Chinese patients with poorly controlled type 2 diabetes using a patient-centred instrument (Cheng et al., 2016). Weekly sessions were delivered by trained nurses to groups of 4–8 people in the first two