Original research

Translational research for Diabetes Self-Management in Sri Lanka: A randomized controlled trial

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A R T I C L E   I N F O

A B S T R A C T

Aims: The study tested the hypothesis that a theory driven Diabetes Self-Management (DSM) intervention delivered by trained nurses would result in a clinically significant improvement in glycaemic control.

Methods: Patients with an HbA1c >7.5% (58 mmol/mol) and free of diabetes complications were enrolled into a randomized controlled trial ($n = 85$). Intervention consisted of four sessions and monthly follow up for 6 months. Biochemical tests, and diet and physical activity assessments were done in both groups. Analysis of covariance was used to test the effectiveness of the intervention.

Results: At 6 months, there was a significant difference ($P = 0.001$) in HbA1c between the groups controlling for baseline values and other variables. Based on the primary outcome, 28% in the intervention group achieved the target value of 6.5% HbA1c, compared to 8% in the "usual care" group ($P < 0.001$; $\eta^2 = 0.65$). The reduction in total energy intake and increase in physical activity was significant in the intervention group between baseline and follow up.

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Conclusions: The DSM intervention has resulted in a clinically significant impact on gly-caemia, change in diet and physical activity, and has demonstrated the feasibility of using it within existing care arrangements in a developing country setting.

1. Introduction

Type 2 diabetes mellitus (T2DM) is a major public health issue with high prevalence and mortality among South Asian populations who are more likely to develop the disease at a relatively younger age [1]. This population group has poorer glycaemic control and higher level of complications such as renal disease, blindness and neuropathy leading to amputation as compared to other population groups [2]. The prevalence of T2DM in persons over 20 years has been reported to be 10.3% in a national survey conducted in 2005–6; the prevalence of T2DM was twice as high in persons from urban areas (16.4%) as compared to persons from rural areas (8.7%) [3]. A more recent study reported that the age adjusted prevalence for T2DM was 20.3% for males and 19.8% for females in an urban cohort, and of those diagnosed with T2DM, only 23.8% were optimally controlled [4].

In many developing countries, especially in South Asia, primary care for patients with T2DM is provided through Diabetes Clinics in secondary or tertiary level hospitals. In Sri Lanka, the average time spent per diabetic consultation in an overcrowded, traditional physician–patient care model is 2–4 min, comprising instructions mostly on medication and rarely on lifestyle change [5]. Empowering the patient to make choices and to take responsibility for their actions is not promoted as a routine practice at these encounters [6]. Previous studies in Sri Lanka have documented the lack of knowledge of diabetes, obesity, poor attendance at clinics and non-compliance with oral medications as the main contributors to complications of T2DM [7].

In developed countries, Diabetes management guidelines recognize the importance of self-management and the role of the patient. The management of a chronic condition such as Diabetes requires an approach that addresses patient goals, priorities and lifestyle as well as their illness [8]. Researchers have incorporated "Diabetes self-management (DSM)" in the 'chronic care model' that has been extensively used in Diabetes Management [9]. However, there are very few reports in the literature of such DSM models [10,11] being tested in developing countries.

This paper describes the test of a DSM intervention using a number of components that were developed based on behavioural theory suitable for delivery within the existing health care system in Sri Lanka. A randomized controlled trial was used to evaluate the model. The results are presented and their relevance and feasibility for scaling up are discussed.

2. Methods

2.1. Study setting

In Sri Lanka, patients having T2DM are referred to diabetes clinics in tertiary or secondary government hospitals, where diagnostic tests and medication are provided free of charge. Most patients are diagnosed by non-specialist physicians and general practitioners and usually have received lifestyle modification advice and are on some type of medication which they have to purchase from the private sector before they register at the diabetic clinic in the hospital. For most patients in urban areas the Diabetes Clinics in these hospitals provide continuing care. Patient recruitment for the study was carried out at the Colombo North Teaching Hospital (CNTH) situated in the Gampaha District of the Western Province of Sri Lanka. The study intervention was carried out at a primary care clinic located at the Faculty of Medicine of the University of Kelaniya at Ragama in close proximity to the Colombo North Teaching Hospital. The study settings can be classified as urban/suburban with a diverse population comprising all ethnic groups and religions, though some of the minority groups are few.

2.2. Subject recruitment

Clinic staff at the Diabetes clinic provided study information to eligible participants (eligibility criteria given below) at their first clinic visit, and those agreeing to participate were offered a free HbA1c test.

1. Cases of T2DM attending the Diabetes Clinic conducted by a specialist endocrinologist at the Colombo North Teaching Hospital, Ragama, for the first time but diagnosed within the last 5 years;
2. Confirmed T2DM based on Fasting Plasma Glucose of >126 mg/dl (7 mmol/L) or 2-h post-prandial glucose of 11.1 mmol/L (Sri Lanka Clinical guidelines) [12];
3. Live within 10 km of the clinic;
4. Aged ≥40 years and <70 years;
5. Currently obtain oral medication and/or insulin from a regular source or have private means to purchase regular medication;
6. Willing for randomization.

At the second (monthly) visit, when results of HbA1c were available, all those with HbA1c over 7.5% (58 mmol/mol) were referred to the project medical officer. At this stage, patients with any diabetic complications, a history of cardiovascular disease and any serious illness, pregnancy, mental illness, cancer diagnosis in the last 5 years, or other conditions that may impede or prohibit participation in the study were excluded.

2.3. Treatment allocation

A computer generated algorithm was used by a researcher (not directly involved in the project) to randomize the patients to treatment groups. Those on the "usual care" arm continued