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A cluster-randomized trial to estimate the effect of mobile screening and treatment feedback on HbA1c and diabetes-related complications in Tshwane primary health care clinics, South Africa

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ABSTRACT

Aim and objectives: Our study had two primary objectives. The first was to evaluate the effect of an expert review with an individualised patient management plan on change in HbA1c. The second was to determine whether a mobile screening unit would increase the proportion of patients screened for glycaemic and lipid control, as well as diabetic complications as compared to the standard guideline-driven clinic care.

Methods: We conducted a cluster-randomised trial and enrolled 599 diabetic patients from twelve primary health care clinics in the Tshwane district of South Africa. The study was carried out in three phases: Phase 1 was a historical twelve-month record review to determine baseline characteristics; Phase 2 was the provision of the intervention (active screening for metabolic control and diabetes-related complications and health education targeting health care workers and diabetic patients) compared to the control group (routine care with similar education given to health care workers and diabetic patients) with a follow-up which included a clinical assessment. Phase 3 was a repeat of the record review to assess post-intervention changes following the proposed individualised patient management plan in the intervention clinics, and self-initiated by the health care professionals in the control clinics, based on training and results-sharing.

Results: No significant changes in the HbA1c between the intervention and control clinics after one year were observed. The mean Hba1c changed from 8.68 to 8.53% (intervention) and from 8.95 to 8.76% (control) ($p = 0.92$). Significant differences were observed in screening for diabetic complications when active screening was done by a dedicated team. The increase observed was more than 60% in all indicators monitored. Significant changes were also seen in the control clinics for two measured outcome variables (HbA1c test ordered from 15% to 25% ($p = 0.02$) and serum-creatinine test ordered increased from 11% to 19% ($p < 0.001$)). There was no significant difference in the proportion of actions taken, or not taken, between the control and interventions arms ($p = 0.83$). The proposed changed patient management plans by the expert review team were implemented in only 29% of patients in the intervention arm.

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Conclusions: A comprehensive programme that integrates clinical evaluations, active screening and an individualised patient management plan did not lead to significant improvement in the HbA1c levels. However, screening for glycaemic and lipid control, as well as diabetic complications, improved dramatically with a dedicated team. The lower than expected rate of uptake of the specialists-proposed patient management, with the resulting non-significant change in glycaemic control, needs further investigation.

1. Introduction

More than 1.1 billion of the world's population live on the African continent and this will increase to 2.4 billion by 2050. The greatest increase will be in the populations of sub-Saharan Africa. Life expectancy is predicted to rise and as the population grows, so too will the rates of obesity, cancer, heart disease and type 2 diabetes [1]. The International Diabetes Federation estimates that there will be a 109% increase in the prevalence of diabetes in Africa between 2013 and 2035. This rise in the prevalence of diabetes in Africa will be the largest in any continent in the world [2]. Health systems in Africa have already been severely weakened by diseases such as malaria, tuberculosis and HIV/AIDS and the continent is now faced with the rising burden of non-communicable diseases, which necessitates the need for innovative service delivery models to manage non-communicable diseases [1].

South Africa (SA) is an upper-middle income country, with a population of 54 million in 2014 and 62% of the population is urbanised [3]. Primary health care (PHC), delivered through a district health system which is mainly nurse-driven, forms the cornerstone of health care delivery. Primary health care is available at no cost to users. The essential drug lists and standard treatment guidelines with national policy documents drive the delivery of health care services [4]. Primary care services are provided by both provincial (clinics and community health centres) and local government (clinics).

The 2013 estimated prevalence of diabetes in Africa was 4% and in South Africa 9.3% [2]. The diabetes epidemic in SA is led by the Indian population, due to a genetic predisposition (9–11%), followed by 8–10% in the coloured community, 5–8% in the black community and 4% among whites [3,5].

The management of diabetes is a challenge to health care systems worldwide. The United Kingdom Prospective Diabetes Study (UKPDS) showed that improved control of glucose and blood pressure resulted in significant reductions of diabetic complications [6]. Diabetic retinopathy and nephropathy are the leading causes of preventable blindness and end-stage kidney failure in the United States of America, and more than 60% of lower limb amputations occur in diabetics [7]. High prevalence rates for poor glycaemic and blood pressure control as well as diabetic complications have been reported for the diabetic population of the Tshwane district in Gauteng province, South Africa [8].

The quality of primary diabetes care is dependant on both multidisciplinary management and rigourous follow-up [9]. The Belgian Diabetes Project Group identified 34 indicators (31 process and three outcome) from five domains that is important for quality care, namely control of glycaemia, early detection of glycaemic complications, treatment of complications, cardiovascular disease and quality of life.

In the present study we investigated the effect of mobile screening and an expert review panel providing an individualised patient management plan on both the HbAc1 levels as outcome indicator as well as screening frequency for diabetes-related complications as process indicators of quality of care provided to diabetic patients at primary care level in South Africa.

2. Methods

2.1. Study design and setting

We conducted a cluster-randomised trial in primary care clinics in the Tshwane district of South Africa (Fig. 1). As a mobile unit was used to collect information, all patients at a facility had to be treated the same way to prevent bias, therefore we had to use clinics as the clusters and did not randomise at the individual level. A list was compiled where the 64 clinics providing PHC services were stratified by the three strata within the South African health system: 1. clinics managed by local government; 2. clinics managed by provincial government and 3. community health centres managed by the provincial government. Four clinics were randomly selected from each strata, totalling the twelve clinics selected for the study. Allocation to intervention and control groups within the four clinics in each strata was done randomly. We enrolled 599 diabetic patients from the selected clinics. The study was carried out in three phases: Phase 1 was a historical twelve-month record review to determine the baseline characteristics of care; Phase 2 was the provision of the intervention (active screening for metabolic control and diabetes-related complications and health education targeting health care workers and diabetic patients) compared to the control group (routine care with similar education given to health care workers and diabetic patients) with a follow-up which included a clinical assessment. Phase 3 was a repeat of the record review and laboratory tests one year later to document post-intervention changes to HbA1c levels. A second objective was to monitor the implementation of the individualised patient management plan for every diabetic patient in the intervention clinics, and to monitor self-initiation by the health care professionals in the control clinics, based on education and results-sharing (with the patients and the healthcare providers).

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