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Multifactorial intervention in individuals with type 2 diabetes and microalbuminuria: The Microalbuminuria Education and Medication Optimisation (MEMO) study

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ABSTRACT

Aims: To determine whether tighter cardiovascular risk factor control with structured education in individuals with type 2 diabetes (T2DM) and microalbuminuria benefits cardiovascular risk factors.

Methods: Participants from a multiethnic population, recruited from primary care and specialist clinics were randomised to intensive intervention with structured patient (DESMOND model) education ($n = 94$) or usual care by own health professional ($n = 95$). Primary outcome: change in HbA1c at 18 months. Secondary outcomes: changes in blood pressure (BP), cholesterol, albuminuria, proportion reaching risk factor targets, modelled cardiovascular risk scores.

Results: Mean (SD) age and diabetes duration of participants were 61.5 (10.5) and 11.5 (9.3) years, respectively. At 18 months, intensive intervention showed significant improvements in HbA1c (7.1(1.0) vs. 7.8(1.4)%, $p < 0.0001$), systolic BP (129(16) vs. 139(17) mmHg, $p < 0.0001$), diastolic BP (70(11) vs. 76(12) mmHg, $p < 0.001$), total cholesterol (3.7(0.8) vs. 4.1(0.9) mmol/l, $p = 0.001$). Moderate and severe hypoglycaemia was 11.2 vs. 29.0%; $p = 0.001$ and 0 vs. 6.3%; $p = 0.07$, respectively. More intensive participants achieved ≥ 3 risk factor targets with greater reductions in cardiovascular risk scores.

Conclusions: Intensive intervention showed greater improvements in metabolic control and cardiovascular risk profile with lower rates of moderate and severe hypoglycaemia. Intensive glycaemic interventions should be underpinned by structured education promoting self-management in T2DM.

1. Introduction

Current evidence for the management of diabetic nephropathy suggests a strategy of targeted multiple risk factor control to improve cardiovascular and renal outcomes [1–3]. The Steno-2 study conducted in a Caucasian population within a tertiary care setting, evaluated the effects of intensive multifactorial intervention with behavioural modification in

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individuals with T2DM and microalbuminuria demonstrated significant benefits in microvascular and macrovascular events and mortality [1,2]. The effect of patient education on behavioural changes showed a modest change in nutrient intake with no changes in smoking habits or exercise [4]. In particular, the Steno-2 educational programme did not incorporate a structured education programme and failed to address theoretical principles to guide intervention design [5]. Furthermore, it is not clear if the impressive results from the Steno-2 study are readily achieved and applicable in either a multiethnic population or in different health care settings.

Structured self-management patient education has been shown to induce long lasting behavioural changes which can lead to improvements in biomedical and behavioural outcomes [6,7]. However, no randomised prospective trials have evaluated the potential impact of structured patient education combined with intensive medical therapy in a multiethnic population with established T2DM and nephropathy.

The Microalbuminuria Education and Medication Optimisation study was designed to test the hypothesis that tighter control of cardiovascular risk factors with a structured self-management education programme in high risk individuals with T2DM would result in additional clinical benefits and improvements in long term cardiovascular and renal outcomes. Our aim was to deliver an intensive intervention using tight risk factor targets, medication optimisation and structured education based on the Diabetes Education and Self Management for Ongoing and Newly Diagnosed (DESMOND) model of patient education and self-management in individuals with T2DM [8] and microalbuminuria from a multiethnic population, recruited from primary care and specialist care clinics and determine the efficacy of such a strategy compared to standard care. This paper reports the results after 18 months of an intensive multifactorial intervention on the primary outcome of change in glycated haemoglobin and secondary outcomes which includes changes in other cardiovascular risk factors.

2. Subjects and methods

2.1. Study subjects

Individuals between 25 and 80 years of age with a confirmed diagnosis of T2DM on diet, oral anti-diabetic agents or insulin and microalbuminuria (defined as an albumin creatinine ratio of $\geq$2.5–30 mg/mmol/l in males and $\geq$3.5–30 mg/mmol/l in females) [9] and confirmed by two out of three positive early morning urine samples or overt proteinuria with a serum creatinine of $<$180 μmol/l were eligible. Exclusion criteria were: individuals with a history of malignancy, chronic liver disease or life expectancy of less than five years, learning disability/ mental incapacity or immobility which precluded them from attending educational sessions, serum creatinine $>$180 μmol/l or if participating in another research study.

Individuals were referred both from primary care practices and specialist diabetes clinics in Leicestershire, UK from September 2006 to April 2007. The study protocol was in accordance with the Declaration of Helsinki and was approved by the Leicestershire Research Ethics Committee. All study participants gave written informed consent.

2.2. Study design

The study was a randomised, parallel-group, prospective trial. The intensive intervention was delivered for 18 months and a four year follow-up is planned to allow monitoring of important renal and cardiovascular outcomes including cardiovascular morbidity and mortality. Participants in both groups were followed up at 3 monthly intervals. The control group received standard care by their own clinician according to local guidelines [10], which are consistent with NICE guidance on the management of individuals with T2DM and diabetic nephropathy [11,12], and also provides additional information on management of individuals with T2DM of South Asian ethnicity. Participants in the control group were not seen or treated by the study physician/team and had usual access to education provided as part of standard diabetes care in either primary or secondary care.

Education Medication Optimisation group participants were followed up every three months on a ''one-to-one'' basis. Lifestyle changes, physical activity, medication adherence and self-titration of medication were discussed and written in the participant's record books, which also provided them with general information on T2DM, healthy eating, physical activity and exercise. Treatment targets were: HbA1c $\leq$6.5%, blood pressure of $\leq$130/70 mmHg respectively, total cholesterol of $\leq$3.5 mmol/l and LDL cholesterol of $\leq$2.0 mmol/l or a 30% reduction below baseline lipid levels. Initiation and optimisation of medications was carried out in a step wise manner on an individual basis and as per existing guidelines on the treatment of T2DM [11]. Treatment targets and results were discussed at each visit and participants were supported to pursue these goals and take a pro-active part in decision making and planning lifestyle changes in keeping with the self-efficacy theory of behavioural change [13].

Structured education was based on the DESMOND model of patient education [6]. The content of the educational programmes was underpinned by an empowerment philosophy and sound theoretical principles of adult learning [5,14]. The educational programme was delivered by trained DESMOND educators who are part of an ongoing quality assurance and professional development programme [5]. All participants in groups of 8–10 individuals per session were invited to attend an initial 3 h education session focussing on microalbuminuria. Briefly, the initial educational session explored the different experiences and perceptions of participants pertaining to early kidney disease\microalbuminuria in T2DM. Participants were given clear, concise and easy to understand information on microalbuminuria, potential complications of having microalbuminuria which could be largely avoided by controlling cardiovascular risk factors, working out the roles of blood pressure, lipid profiles, blood glucose and lifestyle issues (weight loss, physical activity, food choices) in reducing cardiovascular risk, identifying their current risk factors and explaining how they could reduce their own cardiovascular risk. Basic information on T2DM and its complications, weight management and physical activity were included within these educational sessions. Participants were offered additional education sessions on blood pressure, cholesterol, glycaemic control and weight management. Individuals on insulin were enrolled into group insulin management sessions conducted