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Effectiveness of the diabetes education and self management for people with newly diagnosed Type II diabetes

A. Study Purpose and Rationale

About 346 million people worldwide have diabetes. More than 80% of diabetes deaths occur in low- and middle-income countries [1]. Type 2 diabetes comprises 90% of people with diabetes around the world [1]. Chronic hyperglycemia (high blood sugar) leads to many long-term complications of the eyes, kidneys, nerves, heart, and blood vessels [2]. In 2004, an estimated 3.4 million people died from consequences of hyperglycemia [1].

Diabetes is the tenth leading cause of death in Palestinian Territory (in 2005, it was responsible for 3.1% of deaths) [3]. In 2000, based on Ministry of Health, the prevalence of Diabetes was 9% among adults 30 years and above. Based on UNRWA, the prevalence of diabetes was 10.5% among adults 40 years and above (7.2% among those 40-49, 19.1% among 50-59, 24.8% among people 60 and above) [4]. By mid 2011, there were 1643 new cases of diabetes diagnosed in Ministry of Health Primary Health Care Clinics [3].

Diabetes management can be particularly difficult for newly diagnosed patients [5]. From the moment they are diagnosed, patients with Type II diabetes are expected to take a major role in the management of their disease, which is central to Diabetes Self-Management Education (DSME). This self-management includes monitoring and managing symptoms, adhering to treatment regimens, maintaining a healthy lifestyle, and managing the impact of the illness on a daily basis and for the rest of one's life. Lack of definition of outcomes specific to diabetes education has led to the use of metabolic measures such as glycosylated hemoglobin (HbA1c) as a determinant of success for diabetes programs [6]. In a study among patients with Type II diabetes, each 1% reduction in mean glycosylated hemoglobin (HbA1c) was associated with risk reductions of 21% (95% CI 17–24; $P < 0.0001$) for any end-point related to diabetes, 21% (95% CI 15–27; $P < 0.0001$) for deaths related to diabetes, 14% (95% CI 8–21; $P < 0.0001$) for Myocardial infarction and 37% (95% CI 33–41; $P < 0.0001$) for microvascular complications [2]. In a meta-analysis study of the effect of DSME for adults with Type II diabetes, the intervention decreased HbA1c by 0.76% (95% CI 0.34-1.18%) more than the control group at immediate follow up; by 0.26% at ≥ 4 months of follow up [7].

In 2011, United Nations Relief and Works Agency for Palestine Refugees (UNRWA) received a grant of 1,820,000 USD to improve management of Diabetes in UNRWA clinics in Palestinian Territory [8]. The project extends from March 2011 till May 2014. Among the study objectives is to strengthen 41 general clinics in West Bank, train 82 doctors and nurses in diabetes management and distribute patient pamphlets. Guidelines for the management of diabetes and other non communicable diseases have already been developed. However, follow-up and assessments of these interventions are absent [8].

The objective of this study is to determine the effectiveness of DSME for newly diagnosed patients with Type II diabetes versus the standard education intervention; distributions of patient pamphlets. Based on review of the literature, we expect that the structured group education program will decrease the level of glycosylated hemoglobin and contribute to positive changes in key illness beliefs at 3 months and at 12 months follow up.

B. Study Design and Statistical Analysis

This study is a multicenter cluster randomized controlled trial in the 41 UNRWA clinics that have been strengthened as part of the project to provide better management care for patients with Type II diabetes. Randomization will be at the clinic level, with stratification by change in HbA1c following one year of the project implementation, to ensure comparability of the intervention and control groups of clinics. Twenty one clinics will provide the usual care for all newly diagnosed patients with diabetes, where the control group will receive a brochure on diabetes self-management. Twenty clinics will invite all newly diagnosed patients with Type II diabetes to attend the self management course within 4-6 weeks of diagnosis. Recruitment of study participants will take place from September 2012 to April 2013. We expect that each clinic will have at least 60 patients with newly diagnosed type II diabetes over the period of 8 months. As each study participant will be followed for 12 months, the study duration will be from September 2012 till May 2014.

SPSS statistical program will be used for data analysis. T-test will be used to examine mean differences in the change in HbA1c between the control and intervention group at baseline, 3 months and 12 months follow up. To control for potential confounders, we will use linear logistic regression to adjust for clinic and baseline HbA1c. Based on previous studies the standard deviation of mean HbA1c was between 0.8-2.0 [9-12]. Taking the most conservative estimate; 2, with an anticipated 60 newly diagnosed patients with diabetes in each clinic over 8 months, the standard error of the mean (SD/\sqrt{n}) ($2/\sqrt{60}$) =0.258. Based on power calculations (<http://www.biomath.info/crc/>) with 20 clinics in the intervention arm, and 21 in the control arm, alpha 0.05, the study will have 80% power to detect a difference in the decrease in HbA1c between the 2 groups as small as 0.23%.

C. Study Procedure

The intervention will be devised as a group education program with a comprehensive curriculum to be integrated into routine care in the intervention group of clinics. Most of the curriculum will focus on lifestyle factors. Trained health care provider will deliver the program, lasting twenty four hours; seven 3 hour group sessions and one 3 hour individual session. The first three sessions will cover topics relevant to all patients; that is, physical activity, dieting and medication and monitoring of the disease. In the fourth session, patients will be given the opportunity to work on a personally relevant goal. The course will end with an individual session in which patients will evaluate the program, their own progress and their future plans. This will include personal issues that could not be dealt with during group meetings.

In addition to blood tests, all patients will be asked to fill a questionnaire on smoking, eating habits, physical activity, perception of their ability to affect the course of their diabetes, and the perceived seriousness and perceived impact of diabetes. In all 41 clinics participating in the study, data will be collected at baseline, 3 months and 12 months follow up.

D. Study Drugs

No drugs will be used in the study.

E. Medical Device

No medical devices will be used in the study.

F. Data collection

F.1. Blood tests

Glycosylated hemoglobin (HbA1c) is the main health outcome.

F. 2. Study Questionnaires

The questionnaire will have 4 sections. First, background characteristics: age, gender, and smoking. Second, eating habits and physical activity. Third, perception of their ability to affect the course of their diabetes: this will be measured using the Illness Perceptions Questionnaire. Fourth, perceived seriousness and perceived impact of diabetes using the Diabetes Illness Representations Questionnaire.

G. Study subjects

Inclusion criteria: Adult patients >18 years newly diagnosed with Type II diabetes in UNRWA clinics in West Bank.

H. Recruitment of Subjects

All newly diagnosed patients with Type II diabetes in each of the 41 clinics in the project will be recruited in the study. There will be no informed consent as each patient will receive the standard diabetes management program in each clinic.

I. Confidentiality of the Study Data

Study data will be coded to protect patient identity. Only the Principle investigator will have the list of names with the codes assigned to each patient and it will be kept in a locked cabinet.

J. Potential conflict of interest

There is no conflict of interest.

K. Location of the Study

The study will take place in 41 UNRWA clinics throughout West Bank/Palestinian Territory

L. Potential Risks

Risks of the study are minimal.

M. Potential Benefits

All patients newly diagnosed with Type II Diabetes will be part of the project that aims to ensure better management and care for patients with Diabetes. So, hypothetically speaking, all patients will benefit from the project itself. The additional potential benefit is for those of intervention arm where the health education may prove helpful in managing their disease.

N. Alternative Therapies

No alternative therapy in this study.

O. Compensation to Subjects

There will be no compensation for study participants.

P. Costs to Subjects

No additional cost will be incurred by participating in this study.

Q. Minors as Research Subjects

No minors included in this study.

R. Radiation and Radioactive Substances

No radiation will be used in this study.

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