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Effect of diabetes self-management education on glycemic control, compared to usual care in Type 2 diabetic patients at the Family Medicine Clinic, Aga Khan University Hospital Nairobi

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EFFECT OF DIABETES SELF-MANAGEMENT EDUCATION ON GLYCEMIC CONTROL, COMPARED TO USUAL CARE IN TYPE 2 DIABETIC PATIENTS AT THE FAMILY MEDICINE CLINIC, AGA KHAN UNIVERSITY HOSPITAL NAIROBI

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A dissertation submitted in part fulfillment of the requirements for the degree

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ABSTRACT

Background

Globally, the magnitude of disease burden associated with diabetes is high. Poor glycemic control contributes greatly to this burden, especially in the occurrence of related complications. The value of Diabetes Self-Management Education (DSME) is evident in literature, and has been recommended as a way of optimizing glycemic and metabolic control and averting early onset of diabetes complications. Usual care involves spontaneous sharing of information during medical consultations without planned structure or defined time frame. In the African setting, the effect of DSME, and how it compares to usual care, is yet to be fully explored.

Objective

To compare the effect of a structured Diabetes Self-Management Education programme to usual care, in type 2 diabetic patients managed at the family medicine clinic, Aga Khan University Hospital, Nairobi (AKUHN).

Methods

This was an open label randomized clinical trial carried out at the outpatient family medicine clinic of the Aga Khan University Hospital, Nairobi. One hundred and forty type 2 diabetic patients were recruited, 70 patients randomly allocated to either group using a computer generated sequence. DSME was applied in the intervention arm by Certified Diabetic Educators (CDE) while the control group received usual care from the family medicine doctor. The primary outcome, glycated hemoglobin (HBA1c) was used to determine the mean difference in blood glucose control after 6 months of follow up. Secondary biomedical outcomes included blood pressure, body weight, height and BMI. Data was analyzed using the per protocol analysis. STATA version 12 software was used. Difference in means of the outcome variables was compared using the student t-test.

Results

A total of 96 patients (69%) completed the study, 55 in the DSME group and 41 in the usual care group. The mean (± SD) age of all the patients at baseline was 48.8 (± 9.8)

years with a mean (± SD) HBA1c of 9.9% (± 1.76). After 6 months of follow up, no significant difference was noted in the primary outcome (HBA1c) between both groups, with a mean difference of 0.37 (95% CI - 0.45 to 1.19; P = 0.37). DSME also made no remarkable change in any of the secondary outcome measures.

Conclusion

Overall, DSME did not show significant improvements in the primary or secondary biomedical outcomes. This may suggest that a well-trained family physician offering diabetes education may be just as good as a DSME trained educator. Further studies are however required to support this finding, particularly in primary care settings within the African context.

LIST OF ABBREVIATIONS

AADE – American Association of Diabetes Educators

ADA – American Diabetes Association

AKUHN- Aga Khan University Hospital Nairobi

BMI – Body Mass Index (BMI) (kg/m2)

BP – Blood pressure

CDE - Certified Diabetes Educators

CI – Confidence Interval

DESMOND - Diabetes Education and Self-management for Ongoing and Newly Diagnosed

DSME – Diabetes Self- Management Education

DSMT – Diabetes Self- Management Training

FMC – Family Medicine Clinic

HbA1c – Glycated hemoglobin

IBM - International Business Machines Corporation

IDF – International diabetes Federation

mmHg – millimeters of mercury

ROMEO – Rethink Organization to iMprove Education and Outcomes

SD – Standard Deviation

SMS – Short Message Service

T2DM – Type 2 Diabetes Mellitus

WHO – World Health Organization

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DECLARATION

I declare that this dissertation does not incorporate without acknowledgement any material previously submitted for a degree or diploma in any university and that to the best of my knowledge it does not contain any material previously published or written by another person except where due reference have been made in the text.

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Catherine Wanjiku Gathu

7th December, 2015

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1.0 INTRODUCTION

The scourge of diabetes worldwide is at an exponential rise. Globally, there are currently 382 million people diagnosed with diabetes, and this number is expected to rise by 55% to a figure of 592 million by 2035.(1) Once a disease of the West, the dynamics of this pandemic are rapidly evolving, with Sub Saharan Africa currently facing a humongous double burden, from both communicable and non-communicable diseases. This may be attributed to rapid urbanization, dietary alterations and physical inactivity amongst other lifestyle changes.(2) According to the International diabetes Federation (IDF) global estimates,(3) prevalence of diabetes in Kenya was estimated to be about 4% in 2011. If the current trend continues, the prevalence rate is predicted to rise to 5% by 2030, which means approximately 48,000 new diabetic patients being reported annually.

The magnitude of complications associated with diabetes and their complexities incur a tremendous economic burden to the patient, their families as well as entire health care systems. Good glycemic and metabolic control is essential for preventing long-term complications such as retinopathy, nephropathy, neuropathy, and cardiovascular diseases, and ultimately early mortality.(4) Despite the accessibility and proved efficacy of multiple forms of medication, many type 2 diabetic patients still fail to achieve or maintain glycemic control. An audit of type 2 diabetics done in Cape Town's public sector in 2011 (5) showed that approximately 80% of patients were uncontrolled (HbA1c$\geq$7%). If this is in any way a reflection of most populations, most diabetics will be faced with these grueling complications, which have the potential to kill millions of Africans in their most productive years. Prevention and control measures must be implemented. A one point improvement in HbA1c is associated with a 20% decrease in the occurrence of macro vascular complications and 30% to 40% decrease of microvascular complications.(6) Feasible, affordable and evidence based control measures are within the reach of all countries (7) and must be implemented to improve health outcomes for people with diabetes and avert the early onset of diabetes complications.

Diabetes education is a critical element of care, which aims at preventing or delaying the complications of diabetes.(8) A systematic review by Dube et al (9) suggests that DSME programs in developing countries have positive effects on HbA1c, knowledge, glycemic control, and behavioral outcomes on short-term follow-up. The awareness of diabetes self-management education/training in Kenya is gradually gaining ground. None the less, many diabetic patients are yet to receive this integral component of care, thereby putting them at risk of diabetes-associated complications.

Diabetes Self-Management Education (DSME) underscores behavioral change, by provision of background self-management education of diabetes and its related conditions. (8) Diabetes is essentially a lifestyle disease. DSME enables acquisition of knowledge and skills which are useful in people with, or at risk of diabetes, in their day to day management of their condition. (10) It entails an interactive, ongoing process involving the person with diabetes (or the care-giver or family) and a diabetes educator(s) intended to achieve optimal health status, better quality of life, and reduce the economic burden associated with diabetes care (11). Globally, DSME has been recognized as a key component for the management of type 2 diabetes. Therefore, American Diabetes Association (ADA) states that DSME should be offered right from diagnosis. (12)

With a rising threat of an increase in diabetes related complications, it is now imperative that a parallel increase in development of diabetes education as a specialty be implemented. In 2006, the first African diabetes education training manual (13) was published. It was intended for use by diabetes healthcare providers to train other providers working in primary care centers in Sub Saharan Africa, on diabetes knowledge that is culturally relevant and based on research. The effectiveness of this scheme, in causing an increase in the number of diabetic educators, is yet to be evaluated. Success of such strategies, require combined efforts, both by public and private stakeholders, towards creating awareness of this timely resource. It is hoped then, that the anticipated rise in diabetes educators, ultimately resulting in optimum diabetes care will be attained.

Implementation of comprehensive diabetic care involving a multi-disciplinary approach with inclusion of a diabetes educator has not been without its challenges. Most diabetics may settle for minimal care due to financial constraints as well as vast community unawareness on the role of education.(14) This study seeks to make an impact especially in our local set up, in advising whether family physicians should actually refer patients to educators in practice. It explores the impact that patient education centered on a primary health care unit within a tertiary hospital can have on diabetes outcomes.

The family medicine clinic at the Aga Khan University Hospital has been involved in diabetes care since its commencement. It embraces the role of a family physician in chronic disease management using a cost effective patient centered approach. The doctors work as part of a diabetes management team, in collaboration with diabetic specialists for complicated cases. Unfortunately, most patients still lack an integral part of diabetes care interventions; the certified diabetes educator.

This study was therefore timely. Knowledge, as conveyed by a certified diabetes educator, is one of the crucial steps leading to behavioral change. In motivated patients, application of the knowledge is even more important to effect change. Behavioral change counselling skillfully assists patients change unhealthy lifestyle behaviors. (15) This is an evidence based intervention to tackle the risk factors that are mainly associated with non-communicable diseases. It's built on the principle of a patient-centeredness. (16) In this study, education aimed at empowering the patients with knowledge and skill, to enable them make autonomous decisions about their daily management of diabetes. Favorable glycemic and metabolic outcomes were the desired health outcomes. Positive findings would lead to extrapolation of similar education designs and programmes, in other settings.

2.0 LITERATURE REVIEW

2.1 What is Diabetes Self-Management Education (DSME)?

Diabetes self-management education is a quality, highly structured education programme, tailored to help individuals with diabetes learn how to manage their disease comprehensively. (10) The goal is to equip diabetics with self-management skills and knowledge that will enable them to take charge of their own condition and avoid or delay the onset of diabetes-related complications. (17)

Many of the tasks inherent to diabetes management are done at home and under the direct control of the diabetes patient. Patient empowerment through education is thus essential to enable patients make informed decisions on their daily care. (10) DSME focuses on coaching the patient on key content area such as disease process, nutritional management, physical activity, medication taking and monitoring. (17)

2.2 What are the components of DSME?

American Association of Diabetes Educators has developed seven core self-care behaviors, known collectively as the AADE7™, to guide the process of DSME and help patients achieve the desired behavior change. (18) This includes educating patients on: healthy eating behavior, being active, monitoring of their blood sugar regularly, taking medication, problem solving, healthy coping, and reducing risks associated with diabetes complications. This framework is an evolution from a content based approach of diabetes education to an outcome driven practice(19) aimed at promoting clinical improvement and improved health status.

2.3 Who provides Diabetes Education?

Historically, nurses and dieticians provided diabetes education, mostly in hospital-based settings.(20) AADE now recognizes that multidisciplinary teams are most effective in providing this education.(10) These providers function at different levels and in different roles. However, some lack the depth of knowledge specific to diabetes. Hence,

delineating the roles of these multiple levels of providers is important, since there's a lot of diversity in skills that each possess. Five distinct levels of care that are differentiated by knowledge and credentialing, as proposed by AADE (10) include:

- Level 1 : Non-Healthcare Professional
  Health promoters and educators, Community Health Workers.

- Level 2 : Healthcare Professional, Non-Diabetes Educator
  Registered nurses, nutritionists, registered pharmacists

- Level 3 : Non-Credentialed Diabetes Educator
  Healthcare professionals with knowledge, skills and experience in diabetes care including registered nurses, registered dietitians, registered pharmacists, licensed mental health professionals, and exercise physiologists.

- Level 4 : Credentialed Diabetes Educator
  Diabetes educators who meet the academic, professional, and experiential requirements.

- Level 5 : Advanced Level Diabetes Educator/Clinical Manager

Level 1 and 2 have limited expertise in diabetes education and/or management, but provide supportive healthcare services to individuals with diabetes.(10) Certified Diabetes educators play an integral role in equipping diabetics with necessary clinical and behavioral skills to comprehensively tackle diabetes related issues.(10) They not only have the necessary credentials, but through continuous study and mentorship, have mastered the art of self-management training hence very well equipped. In Sub Saharan Africa, barriers to the provision of quality diabetes care and education includes limited numbers of trained diabetic educators. The availability of diabetes educators needs to be expanded and spread throughout the region to avail diabetics and their families of this invaluable resource.(13)

In a comparative study to determine who was more equipped to deliver this education, Siminerio et al (21) found out that those in the educator Diabetes Self-Management Support (DSMS) group achieved better HbA1c. Those in other DSMS group involving usual education, peer supporter or a practice staff maintained glycemic improvements but began to show trends toward worsening during a 6 month follow up period. These findings led to a conclusion that others (e.g. peer supporters, health care staff) may serve as part of the multidisciplinary team in diabetes care, but diabetes educators still serve a critical role in diabetes education.

2.4 Where is DSME done?

In the Kenyan public health system, diabetes health education is done within health facilities (22), mainly at the waiting areas through didactic teachings. Private settings may offer DSME in secluded clinics, with group or individual patients.

Literature has however shown that one crucial barrier to provision of DSME is accessibility to health care services.(23) To tackle this challenge, providers are warranted to understand the demographics of the population they are serving, identify potential challenges and come up with strategies to avert them.

By training health care workers in underserved communities, lower resource health facilities, including health centers, may also benefit from this critical element of care, as proposed in a South African study. (24) The ability of health promoters, who are similar to community health workers in Kenya, to deliver group diabetes education after receiving training, was demonstrated.

2.5 How long is DSME carried out?

Optimal contact time and frequency of education sessions required to sustain improvements in clinical outcomes through self-management lacks an agreed cut off.

Regular contact appears to enhance overall quality of life since learned behaviors lapse over time in the absence of reinforcement.(25)

A meta-analysis of the effect of DSME on glycemic control revealed that glycated hemoglobin decreased more with additional contact time between participant and educator. (8)

The Rethink Organization to iMprove Education and Outcomes (ROMEO) intervention incorporated a one hour education sessions delivered on a three monthly basis.(26) Favorable clinical, cognitive, and psychological outcomes were reported even after a period of 4 years thus implying that an ongoing model of education and care can result in long term improvements to clinical outcomes.

2.6 Role of Education

Knowledge is one of the greatest arsenals in the fight against diabetes. A cross sectional study aimed at assessing community knowledge on different aspects of diabetes in Kenya established that 71% of the respondents had poor knowledge of what diabetes is.(22) Since an average of two thirds of diabetics are undiagnosed (1) and living in the community completely unaware of their illness, this may indicate a huge knowledge deficit even amongst affected individuals. A study done in Nigeria by Puepet et al (27) found a similar level of knowledge deficit of diabetes (70%), among diabetics. Poor understanding of diabetes among patients is a potential barrier to attainment of the necessary control to avert complications.(10)

One of the major roles of self-management education is to improve glycemic control to the ideal target (HbA1c < 7.0%) as proposed by the American Diabetes Association.(28) Improving glycemic control will not only improve the quality of life of a diabetic,(29) but will also lower diabetes-related prescription regimens, resulting in lower costs and utilization trends. (30)

Behavior change facilitation is also a key goal in self- management. Programs incorporating behavioral and psychological strategies demonstrate improved outcomes.(19)

In addition, diabetes educators co-ordinate multidisciplinary diabetes care teams, provide continued care away from health facilities as well as offer training and supervision to other health professionals who facilitate diabetes education.(10)

2.7 Education designs

Information and education can be conferred differently. Numerous studies have attempted to explore which educational approach or delivery method has a greater impact on biomedical and psychosocial outcomes, related to diabetes. The results are contrasting and generalizability of much published research is still debatable.

Norris et al (31) performed one of the earliest meta-analysis of the effect of self-management training on glycemic control. The intervention was self-management education, which could be individual or group based, and of any duration and intensity. HBA1c decreased by 0.8% (95% CI 0.3 to 1.2) in the intervention group, than in the control group at immediate follow-up and by 0.3% (95% CI 0.1 to 0.5) at four months or longer follow-up. Improvement in metabolic profile was also noted with additional contact time between participant and educator.

A Cochrane review (32) looked at six studies comparing individual education to usual care and three studies comparing individual to group education. Assessment of HbA1c was done in the short term (6 to 9months), the medium term (12 to 18months) and longer term (greater than 18months). There was no significant difference of glycemic control in individual education when compared to usual care (P=0.08). What was noted in a sub group analysis was significant benefit of individual education in participants with HbA1c level greater than 8% (95% CI -0.5 to -0.1, P = 0.007).

Another Cochrane systematic review of group education in diabetes, (33) concluded that such education had a significant effect on HbA1c, fasting blood glucose levels, body weight, systolic blood pressure as well as diabetes knowledge. The 11 studies included in this systematic review showed evidence of improvements in the outcomes at 4 - 6months and at 12 months follow up. HBA1c had greatly improved in participants receiving group education compared to individual education (Difference 0.8%; 95% CI 0.0 to 1.6; Z = 2.07; P = 0.04).

Diabetes Education and Self-management for Ongoing and Newly Diagnosed (DESMOND) module was delivered as a single group intervention involving six hours of contact time, with no further reinforcement of the messages. After 3 years, findings from this randomized controlled trial, demonstrated improvements across all biomedical outcomes, in both groups, though not statistically significant. (34) HbA1c decrease noted in both groups was not significantly different after adjusting for baseline and clustering (difference −0.02, 95% confidence interval −0.22 to 0.17). Commendable finding from the DESMOND group intervention is cost-effectiveness which is a key feature in patient centered approach to diabetes management. (35)

The X-PERT Diabetes Programme, a primary care structured group education initiative (36) showed that after 14 months, participation in the group programme led to improved glycemic control with greater reduction in HbA1c (−0.6%) compared to controls (+0.1%) under the individual approach (P< 0.001). Positive outcomes were also noted in other psychosocial and biomedical outcomes including total cholesterol, body weight, BMI, waist circumference, self-empowerment, diabetes knowledge and physical activity levels. Compared to the DESMOND trial, the intervention in the X-PERT trial was delivered over six, 2 hour, weekly group sessions with participants receiving double the contact time, which may confer additional benefits.

Other findings are depicted in a Randomized Controlled Trial involving 623 adults from Minnesota and New Mexico with type 2 diabetes randomized to group education, individual education, or usual care.(37) HbA1c reduction was noted more significantly

with individual education (-0.51%) than with usual care (−0.27%) (P=0.01) or group education (−0.24%) (P=0.01). The ideal HBA1c level of less than 7% was noted to be greater for individual education (21.2%) than for group (13.9%) and usual care (12.8%) (P = 0.03). However, no significant effects on blood pressure or weight were established, in either method of education or usual care.

Africa has also been involved in a few studies on diabetes education. A pragmatic cluster randomized controlled trial (38) to evaluate the effectiveness of group education was carried out in Cape Town, South African. Primary outcomes amongst others included a 1% reduction in HBA1c. A total of 4 monthly sessions of group diabetes education were offered. No significant improvement was noted in the primary outcomes after 12 months. Of note was a significant reduction in mean systolic (-4.65 mmHg, 95% CI 9.18 to -0.12; P = 0.04) and diastolic blood pressure (-3.30 mmHg, 95% CI -5.35 to -1.26; P = 0.002).

A smaller qualitative study done by Malan et al (39) measured the effect of group education on self-care activities in 84 patients across 6 clinics in the Western Cape of South Africa. After 4, one hour group sessions, significant improvements were noted in self-care activities, including adherence to a diabetic diet and physical activity.

Taken together, the outcomes from these studies show mixed results and suggest that different methods when employed at different settings may yield different results. Conclusion on whether one method is superior to another cannot yet be arrived at.

2.8 Model of communication

In reviewing literature, studies have shown the style of communication is as important as the message being communicated. Collaborative interventions focusing on knowledge through empowerment tend to demonstrate positive effects on glycemic control, especially in the short term.(31) Empowerment as a philosophy of care aims at establishing a collaborative approach by provider and participant, to facilitate the self-directed behavior change of patients. This has been the drive towards moving away from

primarily didactic interventions to a more patient centered approach, which encourages the patient to be an active participant in managing their own health. Behavior change counselling emphasizes that skills can be learnt, ultimately offering practical solutions to patients with risky lifestyle behaviors and how to overcome them. Additionally, feedback is considered an important factor in developing and maintaining a new skill, and can improve one's confidence to perform the learned skill or behavior. These models of education and counselling have been shown to have a positive impact on adherence to lifestyle interventions, especially when dealing with chronic non-communicable diseases.

2.9 Assessing impact of education

Assessing the unique contribution of education to diabetes outcomes is quite challenging (40) and this was acknowledged even amongst the earliest researchers on this topic. This is because agreed outcomes and indicators on which educational interventions can be based and against which their effectiveness can be monitored are deficient.

American Association of diabetes educators developed a framework to assess impact of education.(10) This is collectively known as the AADE7™ which incorporates 7 core self-care behaviors,(18) only important in as much as they can facilitate a measurable clinical outcome. In this study, glycated hemoglobin, blood pressure and weight, height and BMI will be used as indicators to assess for clinical improvement, overall intended to improve the health status of diabetics. These are outlined in the figure below (figure 1).

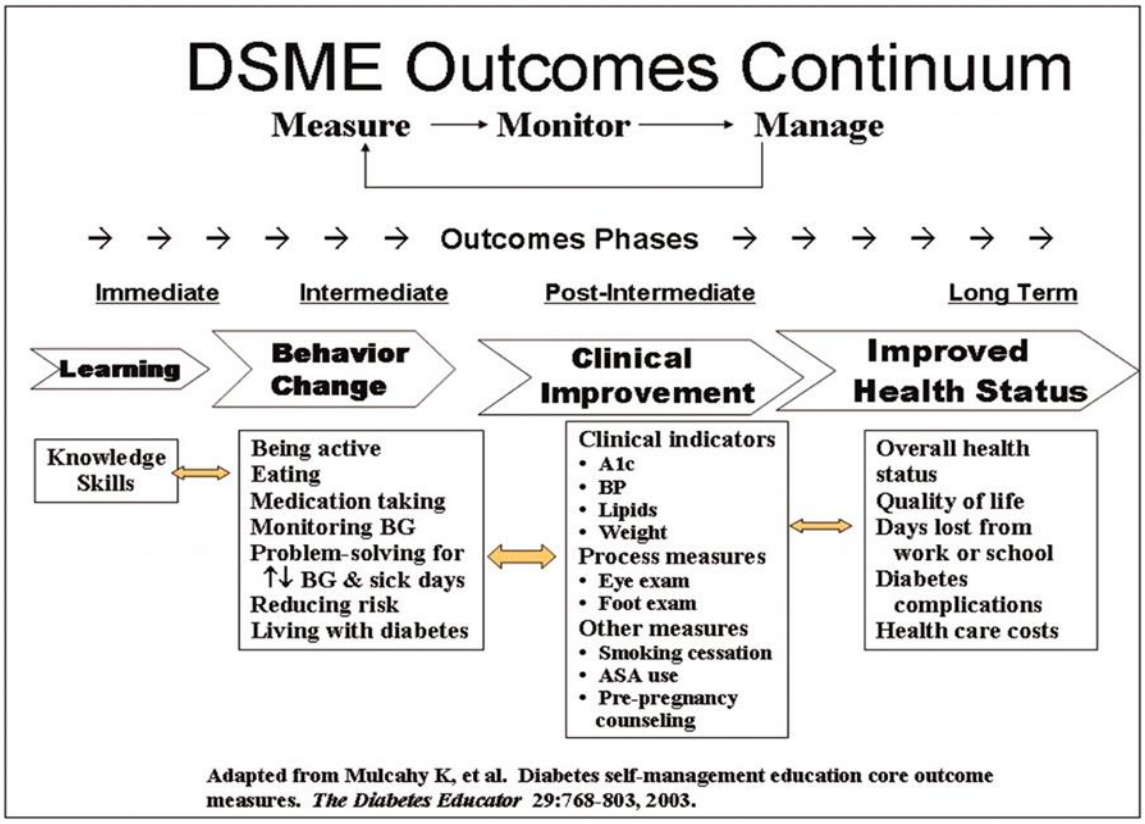


Figure 1: DSME Outcomes Continuum

3.0 STUDY JUSTIFICATION

The economic burden associated with diabetes is gradually crippling the development of affected nations. Most of the diabetes deaths, especially in Sub Saharan Africa, are in people under 60 years old, affecting a majority of the working population. (1) (22) Direct disease costs also pose an economic threat. Implementing moderately inexpensive, easy-to-use interventions such as diabetes education, can reduce morbidity and lessen the huge economic burden associated with diabetes.(1)

In the African region, the diabetes educator is an up-coming professional, who is little known, and therefore underused. (13) Lack of perceived value of diabetes educators, both by patients as well as primary care providers, may have contributed to this under use. Our study seeks to create awareness on the role that CDEs play in provision of diabetes education, by providing evidence based data from our local population.

DSME is offered by certified educators at Aga Khan University Hospital Nairobi (AKUHN). Since its inception, this programme has endeavored to provide evidence based learning, aimed at facilitating and supporting healthy self-care behaviors to diabetics and their carers. The effect of DSME is evident from various countries but there is very little evidence of its impact from Africa. The outcomes of our study will help establish whether a structured education programme (DSME) as offered by the certified diabetes educator has any benefit on behavioral change and ultimately glycemic and metabolic control, in a primary care setting within a tertiary hospital.

4.0 STUDY QUESTION

What is the effect of Diabetes Self-Management Education on glycemic control compared to usual care, among type 2 diabetic patients, managed at the family medicine clinic of Aga Khan University Hospital Nairobi (AKUHN)?

5.0 STUDY OBJECTIVES

5.1 Broad Objective

To determine the effect of Diabetes Self-Management Education compared to usual care, on glycemic control, in type 2 diabetic patients on follow up at the family medicine clinic of AKUHN.

Specific Objective

Establish the mean difference in HbA1c between the two groups after 6 months of usual care or DSME by a certified diabetic educator.

5.2 Secondary Objective

Compare the mean differences in BMI, systolic and diastolic blood pressure between the two groups after 6 months of usual care or DSME by a certified diabetic educator.

6.0 MATERIALS AND METHODS

6.1 Study design

This was a prospective, randomized controlled, open label clinical trial.

6.2 Setting

The study was conducted at AKUHN family medicine clinic. This is a private, urban based, primary care clinic, located within a referral hospital, in the capital city of Kenya. The clinic serves a multi-ethnic population, mainly from the middle and high socio-economic communities, regionally and even beyond. On average, 350 diabetic patients are followed up in this clinic, 220 of whom are registered in the clinics data base. The clinics are conducted by family medicine physicians.

6.3 Participants

The study population included sub-optimally controlled T2DM patients, aged between 18-65 years, who were on follow up at the family medicine clinic. Subjects were randomly assigned to either the intervention group or control group.

6.3.1 Inclusion criteria:

1. Patients confirmed to have Type 2 diabetes attending the family medicine clinic.
2. HbA1c above 8%
3. Aged between 18 years and 65 years.

6.3.2 Exclusion criteria:

1. Type 2 diabetics known to have anemia or on treatment for the same.
2. Patients known to have adverse Type 2 diabetes complications as listed below:
    - Advanced cardiovascular disorders (unstable angina pectoris, heart failure) or history of a cardiovascular event (stroke, myocardial infarction).
    - Diabetes Nephropathy Stage 3 -5
    - Grade III-IV retinopathy
3. Type 1 diabetes.
4. Gestational diabetes.

7.0 SAMPLING

7.1 Sample Size Estimation

Sample size calculation was done using Cohen's Formula from Open Epi statistical calculator software. Primary outcome was the difference in means of HbA1c between the two groups at the end of the study. The formula below was used:

$$N = \frac{2\,\delta^2 (Z\alpha_{/2} + Z_\beta)^2}{r^2}$$

Where:

- N is the sample size in each group (DSME or Usual care).

- $Z\alpha_{/2}$ – normal deviate corresponding to a type 1 error of 0.05. Represents the desired level of statistical significance, typically 1.96.

- Z_β - desired power of the study. A value of 0.8416 with β set at 80% power was used.

- δ is the standard deviation (estimated) of the outcome variable. Based on previous studies (34, 41-43) the standard deviation of mean HbA1c was between 0.8% - 2.0%. Taking the most conservative estimate, standard deviation of 2% was used.

- r is the minimally clinically significant difference in effect of two interventions (estimated effect size). In this study, it was set at 1% mean HBA1c difference based on previous studies (34) .

Calculating sample size:

$$N = \frac{2 * 0.02^2(1.96+0.8416)^2}{0.01^2}$$

N = 62.72, an average of 63 participants in each arm.

Therefore, total sample size = 126

- Anticipating a 10% drop out rate, final sample size;

  N = 63*100/90 = 70
  N = an average of 140 total participants

- Seventy participants were required in each group to have 80% power to detect an absolute difference in HbA1c levels of 1% between groups at the 5% significance level, assuming a Standard Deviation of 2%.

8: STUDY PROCEDURES

8.1 Screening

Study participants were identified from the already existing family medicine clinic diabetes registry and invited to the family medicine clinic within one month of study approval. The principal investigator was responsible for screening and recruitment of participants. Two hundred and twenty patients were invited to participate. On arrival, they were briefed on the study objectives, interventions and protocol. Those who did not meet the inclusion criteria were excluded. Thereafter an informed consent was sought to allow participation in the study. Patients who refused to sign the written consent were also excluded from the study.

8.2 Randomization process

Computer statistical software, STATA version 12, was used to generate random numbers which were then used to group the participants equally, into either the DSME or Usual Care group. The randomization allocation sequence remained concealed from the principle investigator and clinician to further eliminate conscious or unconscious selection bias. This was done with the help of a study assistant, who opened a sealed envelope with the allocation code, informing the patients of the group they had been assigned to.

8.3 Study Protocol

After recruitment, the patients filled in a standard data collection form (appendix one), briefly detailing their medical history and personal information.

Prior to consultation with the doctor, blood pressure, height and weight were measured by a trained nurse who was routinely supervised by the principle investigator to ensure adherence to the study protocol. Blood pressure was measured with a digital sphygmomanometer, which was regularly inspected and validated. The nurse ensured that patient was properly prepared and positioned prior to taking the reading. Height was

measured, without shoes, to the nearest centimeter, using a stadiometre that was inspected prior to commencement of the study for accuracy. Weight was measured, without shoes and heavy outer garments, to the nearest 0.1 kg, using a scale that was calibrated quarterly. BMI was calculated in kilograms per meters squared. The patient was then handed over to the primary doctor or principal investigator, who filled in the data collected by the nurse in the standard data collection form and sent the patient to the lab for HBA1c test. All tests were measured by one laboratory, the AKHUN main laboratory, where quality control measures were in place using standardized values. Blood samples were collected at baseline and at the end of the study period (6 months). HBA1c results were retrieved from their lab records and tabulated in the standard data collection form. The secondary outcome variables were also documented by the primary doctor or principal investigator at final consultation after 6 months.

DSME sessions with the CDE were arranged within a month from initial recruitment and consultation with the primary doctor in the intervention group. Subsequent appointments with the CDE were arranged after every 6-8 weeks, adding up to a total of 3 visits by the end of the study period. Patients in the control arm received quarterly follow up appointments by their family medicine physician, whereby usual consultations continued. Details of the two groups are outlined below:

8.3.1 Control arm – Usual Care

Usual care by the family medicine physician was delivered within the consultations at the family medicine clinic. Patients randomly assigned to the usual care group were managed according to the usual consultation practice by the family medicine physicians with no modification. It entailed a standard doctor's consultation; on average twenty to thirty minutes. A review of recent HbA1c level, medication compliance as well as a brief informal diabetes education session was offered. Patient education materials of all types, including written, audiovisual and computer-retrieved reading materials were used depending on the provider. Time constraints are common limitations to effective diabetes education in such consultations. Follow up was scheduled after 3 months as per usual

care or more often if indicated. Inter – provider variability on the content of diabetes education offered prevailed and there were no standard ways of monitoring to ensure consistency of content offered.

8.3.2 Intervention arm – Diabetes Self-Management Education

Intervention group was referred to the diabetes educator, who offered an individualized structured training to participants. The teaching style used involved an empowerment model, allowing patients to be active partners in the provision of their own diabetes care. The goal of empowering was to promote autonomous self-regulation so that the individual's potential for health and better quality of life is maximized. The programme was structured to focus on behavioral assessment, goal-setting and problem solving. The sessions were interactive, encouraging patient participation in determining and setting personal goals. Key messages included adherence to dietary changes, self-monitoring of blood glucose, engaging in physical activity, and other self-care topics. At the end of the sessions, a patient guide to diabetes booklet and graphic material illustrating several self-care activities such as foot care, were handed over to the patient for referencing. Subsequent consultations were mainly feedback sessions, aimed at reviewing previously discussed matters. Key messages were reinforced; challenges were addressed and additional information given.

For this study, two volunteer certified diabetes educators offered the individualized DSME sessions. Diabetes educators involved were given a level 4 designation, according to AADE guidelines.(10) These were educators who had been trained for one year, specifically on diabetes education and met the academic, professional, and experiential requirements to administer this service according to AADE grading of qualifications of diabetes education providers. Amongst others, educators had been trained on behavioral change counselling and had also developed expertise in empowerment model, which was mainly used in providing the self-care education, in this study. The first session was arranged within a month from their initial consult with their primary care doctor. Each session lasted an average of one hour. The participants were scheduled to attend 3 sessions, each spaced out at 6 weeks intervals.

The content of the education delivered included the 7 core self-care behaviors as outlined by AADE, such as being active, nutrition, monitoring blood glucose, adherence to medication, amongst other topics. The educators used an interactive, open ended communication style, aimed at empowering the patients to be more pro-active in management of their condition. A standard AKUHN clinical sheet was used while delivering the education (see appendix 3) to ensure all core topics were covered. Teaching aids included visual guides on meal portion and food types to eat. Patient education handouts on pathophysiology of diabetes as well as the concept of self-management were issued at the end of the visit to complement the important dialogue between the educator and patients by reinforcing important health messages that were communicated. Additional information not included in the clinical form was also covered based on individual needs. Follow up with their primary care physician continued as usual, after every 3 months.

Patients in this arm also received telephone reminders, a week prior to their scheduled appointment with the diabetes educators, to ensure timely communication and confirmation of their visit. This was done by the principal investigator, since these patients were not within the usual hospital appointments database, which is normally programmed to deliver automatic reminders to hospital patients on their appointment dates. A hotline number was availed to them to consult with the diabetic educator at any given time of the day, which is part of the overall package offered by the diabetes educators at AKUHN.

9.0 DATA ANALYSIS

Outcome data was entered on an excel spreadsheet and STATA version 12.0 was used for analysis, which was done as per protocol. The characteristics of the two groups were similar at baseline hence there was no need to adjust for any of the baseline covariates.

Descriptive characteristics of the study patients in each arm were calculated as means ± SD for continuous variables and as percentages for categorical variables. Student's *t* test and Chi square ($\chi 2$) tests were used for comparisons between the 2 groups on baseline characteristics; χ^2 test for categorical variables and two-sample *t* test for continuous variables.

For the primary and secondary study outcome variables, the mean change after 6 months was calculated in both groups and subsequently tested using student's t test for statistical significance.

Results were expressed as means (± SD) between treatment groups. Differences were considered significant for $P < 0.05$.

10.0 ETHICAL CONSIDERATION

The study was commenced after written approval was obtained from the AKUHN Scientific and Ethical Review Committee.

Written informed consent was administered and signed by eligible participants before enrollment in this study, after explaining in detail the aims and methods of the study. The inconvenience of phlebotomy and the need for frequent hospital visits in view of the regular follow up required was also explained.

Blood collection for HbA1c testing was scheduled to coincide with consultation visits with the primary care physician, thus avoiding unnecessary additional visits to the hospital.

No extra cost was incurred by participants enrolled in the study. Cost of HBA1c was absorbed by the principle investigator, as part of the study budget, through a grant obtained from AKUHN dissertation committee.

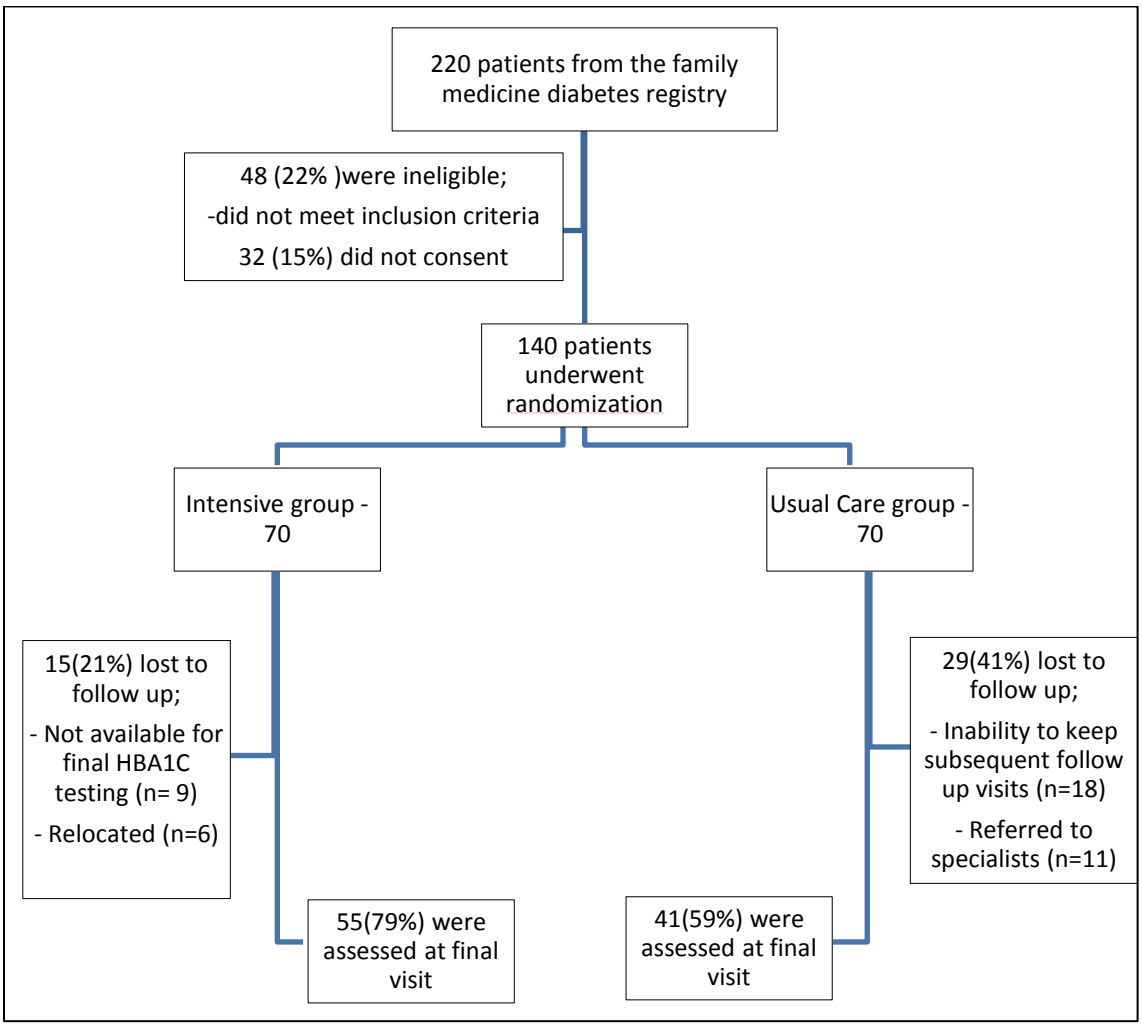
Confidentiality was maintained by proper and safe methods of data handling. Only the principal investigator, study supervisors and the primary care physicians had access to full patient data and results.

11.0 RESULTS

STUDY PATIENTS

The figure below shows enrollment, randomization, and follow-up of study participants.

Figure 2: Participants flow in the study



The study period was between April 2015 and September 2015. After 6 months of follow up, 96 patients (69% of those enrolled) had complete data. 44 patients (31%) had been lost to follow up and were not included in the final analysis.

The socio-demographic characteristics of the study population are shown in Table 1 below.

Table 1: Socio - demographic characteristics of participants

Characteristics of Participants at Baseline (n=140)	
Characteristics	**Average**
Mean age – years (SD)	48.8 (9.80)
Gender – no. (%)	
Male	78 (55.7)
Female	62 (44.3)
Duration of disease – no. (%)	
< 5yrs	69 (49.3)
5 – 10yrs	31 (22.1)
> 10yrs	40 (28.6)
Mode of treatment – no. (%)	
Oral hypoglycemic therapy	79 (56.4)
Insulin therapy	3 (2.1)
Combined (Oral medication and Insulin)	29 (20.7)
Diet and exercise	29 (20.7)
Level of education – no. (%)	
Primary	6 (4.3)
Secondary	27 (19.3)
Tertiary	107 (76.4)
Currently smoking – no. (%)	9 (6.4)
Consuming alcohol – no. (%)	54 (38.6)

The characteristics of participants at baseline were similar in most variables as depicted below (table 2).

Table 2: Baseline characteristics of participants; Intervention vs Usual Care group

Characteristics	**Baseline**		
	Intervention N= 70	**Usual Care N= 70**	**P value**
Mean age – years (SD)	50.2 (9.93)	47.5 (9.54)	0.10[t]
Gender – no. (%)			
Male	41 (59%)	37 (53)	0.49*
Female	29 (41%)	33 (47)	
Mean metabolic profile (SD)			
BMI	28.5 (3.73)	28.8 (3.80)	0.62[t]
Mean baseline blood pressure -mm Hg (SD) :			
Systolic	134.3 (14.63)	134.8 (12.46)	0.84[t]
Diastolic	80.7 (10.53)	82.6 (11.16)	0.30[t]
Comorbid – no. (%)			
Hypertension	34 (49)	20 (29)	0.02*
Baseline HBA1c – mean (SD)	9.7 (1.78)	10.0 (1.74)	0.23[t]
Duration of diabetes – no. (%)			
<5 years	34 (49)	35 (50)	0.62*
5-10 years	14 (20)	17 (24)	
>10 years	22 (31)	18 (26)	
Mode of medication – no. (%)			
Diet and Exercise	11 (16)	17 (24)	0.20****
Oral	42 (60)	37 (53)	
Oral and Insulin	14 (20)	15 (22)	
Insulin	3 (4)	1 (1)	
Level of Education – no. (%)			
Primary	6 (9)	1 (1)	0.16*
Secondary	12 (17)	15 (21)	
Tertiary	51 (74)	54 (78)	
Currently smoking – no. (%)	5 (7)	4 (6)	0.73*
Consuming alcohol – no. (%)	25 (36)	29 (41)	0.49*
* - Chi square test t - T test			

The mean (± SD) HBA1c at baseline was 9.9% (± 1.76), both groups combined. 39% of the patients (54 of 140) of the patients had hypertension, with more patients in the intervention group. Only 31 (22%) of the patients had normal weight (BMI 19.5 – 24.5). The rest were either overweight or obese and were equally distributed in both groups.

Characteristics of patients lost and those returning for follow up are noted below.

Table 3: Characteristics of participants; Returned for follow up vs Lost to follow up

Characteristics	**Baseline**		
	Returned for follow up N= 96	**Lost to follow up N= 44**	**P value**
Mean age – years (SD)	49.2 (9.59)	47.9 (10.29)	0.46[t]
Gender – no. (%)			
Male	55 (57)	23 (52)	
Female	41 (43)	21 (48)	0.58*
Mean metabolic profile (SD)			
BMI	28.7 (4.20)	28.5 (2.56)	0.73[t]
Mean baseline blood pressure -mm Hg (SD) :			
Systolic	134.2 (14.95)	135.3 (9.92)	0.67[t]
Diastolic	81.9 (10.25)	80.9 (12.17)	0.61[t]
Comorbid – no. (%)			
Hypertension	45 (47)	9 (20)	0.003*
Baseline HBA1c – mean (SD)	9.8 (1.72)	10 (1.88)	0.66[t]
Duration of diabetes – no. (%)			
<5 years	46 (48)	23 (52)	
5-10 years	19 (20)	12 (27)	0.30*
>10 years	31 (32)	9 (21)	
Mode of medication – no. (%)			
Diet and Exercise	14 (15)	14 (32)	
Oral	58 (60)	21 (48)	0.07*****
Oral and Insulin	21 (22)	8 (18)	
Insulin	3 (3)	1 (2)	
Level of Education – no. (%)			
Primary	6 (5)	2 (2)	
Secondary	14 (15)	13 (30)	0.33*
Tertiary	76 (80)	29 (68)	
Currently smoking – no. (%)	7 (7)	2 (5)	0.54*
Consuming alcohol – no. (%)	33 (34)	21 (48)	0.13*
* - Chi square test t - T test			

There were no differences between the groups in those who dropped out and those who remained, except in the frequency of hypertension.

Table 4 below shows the mean (± SD) change in biomedical outcomes in both study groups at 6 months.

Table 4: Summary of the mean differences of primary and secondary outcomes between both groups

OUTCOME	CONTROL GROUP (n=41)			INTERVENTION GROUP (n=55)			DIFFERENCE OF THE DIFFERENCE (mean ± SD)	P value
	Baseline (mean ± SD)	6 months (mean ± SD)	Mean difference (mean ± SD)	Baseline (mean ± SD)	6 months (mean ± SD)	Mean difference (mean ± SD)		
HBA1c (%)	9.9 ±1.45	9.3 ±1.75	- 0.60 ± 1.54	9.8 ±1.90	8.8 ±1.89	- 0.98 ± 2.29	0.37 ± 0.41	0.37
Systolic Blood Pressure (mmHg)	134.1 ±13.61	133.8 ±11.54	-0.29±11.16	134.3 ±15.99	132.6 ±15.32	- 1.78 ±13.47	1.49 ± 2.59	0.57
Diastolic Blood Pressure (mmHg)	83.5 ±10.07	82.6 ±9.86	-0.90±11.48	80.8 ±10.32	78.0 ±9.04	- 2.80 ±10.37	1.89 ± 2.24	0.39
BMI	28.9 ±4.48	29.3 ±4.55	0.41 ±0.76	28.6 ±4.03	28.9 ±3.87	0.37 ± 1.21	0.04 ± 0.22	0.86

Effects on Glycated Hemoglobin

The mean difference in HBA1c in the two groups at the end of the study was 0.37, with a standard deviation of 0.41 (95% CI - 0.45 to 1.19; P = 0.37). The mean HbA1c for both groups at the end of the study had decreased cumulatively by 0.82 (95% confidence interval -1.22 to -0.41) p = 0.0001. The observed decrease (mean ± SD) in the usual care group was less (-0.60 ± 1.54) p = 0.02, compared to the intervention group (–0.97 ± 2.29) p = 0.003.

Effects on secondary outcomes

Secondary biomedical outcomes included blood pressure, body weight, height and BMI. Mean difference was not statistically significant between the two groups in any of the secondary outcomes at the end of the study.

Unlike the other outcome variables which were noted to decrease, mean BMI had increased in both groups at study end, though this incremental change between the two groups was not statistically significant (Mean difference, 0.04; P = 0.86).

12.0 DISCUSSION

The effectiveness of self-management education in diabetic patients has been proven through a number of randomized controlled trials (31), most of them done in the Western, more developed countries. However, our study did not show such similarities in effectiveness. No significant improvement was noted in the primary outcome, mean HBA1c, between the two groups at study end. The lack of similarities in our study compared to aforementioned may be due to differences in methodology, heterogeneity of population and the high dropout rates that were recorded.

None the less, a few studies done comparing individualized education to usual care have shown similar results to our study. A Cochrane review (32) looked at 6 such studies and found that individual education did not significantly improve glycemic control. Three of those studies in the same review assessed the mean difference in HbA1c at 6 to 9 months and noted a reduction of 0.2% with a trend to favor individual patient education. However this did not reach significance (95% confidence interval (CI) -0.5 to 0.03, P = 0.08). In the African context, Mash et al (38) assessed the effectiveness of group diabetes education using health promoters and reported no significant difference in primary and secondary outcomes, with an exception of significant blood pressure improvements in the intervention group.

Inspite of the lack of statistical significance in the mean difference in HBA1c, there was a trend towards a reduction in HBA1c. The decrease in HBA1c observed in both the intervention group (-0.97%, CI -1.59 to −0.35) and the control group (-0.60%,CI -1.09 to -0.12) is similar to what was observed in the DESMOND trial (44), which showed improvements in all biomedical outcomes at 3 years, but no significant differences. It is worth noting that the DESMOND trial used a group based approach, in offering their education. A Cochrane review by Deakin (33) reviewed 11 studies, 3 of which were included in a meta-analysis for glycated hemoglobin at four to six months. Results showed that patients in the group education had significantly reduced HBA1c of 1.4% (95% CI 0.8 to 1.9; P < 0.00001) compared to usual care. This may suggest that individualized education like in our study, and grouped diabetes education sessions may

both show some improvement in HBA1c. This is merely observational, since showing similarities between the two education methods was not part of the primary or secondary objectives. By 14 months the X-PERT group (36) compared with the control group also showed similar decrease in the mean HbA1c (- 0.6% vs. + 0.1%, $P < 0.001$). Our study was not powered to detect this absolute reduction, but was rather looking for a significant mean difference in HBA1c, at study end, between the two groups. Additionally, since reductions in HBA1c were noted in both groups in our study, it may also imply that usual care does not offer a significant disadvantage when compared with DSME.

The decline in HBA1c in the control group is unlikely to be due to contamination by patients in the intervention group, since recruitment was done individually and participants may not have even been aware of other participants in the study. However, since the family medicine doctors providing usual care were not blinded, it is possible that there was a change in the way usual care was provided, which might have had an effect on the outcome.

Inspite of our short study period, lack of significant improvement in glycemic control may not necessarily be attributed to this, since other studies have shown significant improvements, even in shorter durations. A randomized study by Patti et al (45), demonstrated an improvement in HbA_{1c} (mean difference, $p = 0.05$) which was achieved by 3 months in both groups (individual and group education), and these improvements were sustained at study end (6 months). None the less, it's important to mention that knowledge has a tendency to lapse over time. A meta- analysis noted that although self-management training improved diabetes control at immediate follow-up, the benefit declined between1 and 3 months after the intervention ceased(46) concluding that knowledge needs to be reinforced, for improvements to be sustained over a long time.

It is worth noting that in DSME, the style of communication is as important as the message being communicated, as noted by Norris et al.(31) A collaborative approach in the education sessions may be more effective than a didactic teaching session in improving glycemic control. This study utilized a similar communication style. However,

the educators did not receive any training before the study commenced, nor were they routinely assessed to ensure fidelity to study protocol and communication style. This is a key methodological limitation that may have compromised the quality of the intervention.

Knowledge on its own cannot be viewed as an independent variable affecting change. Other factors are needed to achieve and sustain behavioral change, including motivation, a good support system, amongst others. These were not included in the analysis and may partly account for the lack of a consistent positive relationship between education and glycemic control in our study. Additionally, attendance of education sessions in the intervention group, may not necessarily translate to improved self-care skills. A questionnaire administered before and after the education intervention may have been useful to determine absorption of the education content. This was not done in this study and may be an important drawback.

Across all secondary biomedical outcomes, with the exception of BMI, improvements were seen in both groups, with no significant differences at six months. Other studies have shown similar results in blood pressure and other metabolic outcomes. A recent meta- analysis (47) demonstrated no significant effect on BMI, blood pressure on the group based intervention, despite positive effect on other outcomes. Therefore, this finding is not unique to our study.

Despite a marginal rise in BMI in both groups, the mean change was not significant at six months. There may have been insufficient weight loss to affect BMI. Specific self-care activities such as dietary changes and physical activity, which have a more direct relationship to body weight, were also not assessed. To address weight and diabetes control some of the studies done (48) suggest that Motivational Interviewing has the potential to facilitate change in unhealthy behavior affecting weight. Patients need to be highly motivated to incorporate changes in nutrition and exercise in their everyday living. The readiness for change was not assessed in our study patients beforehand, nor was motivational talk to resolve any ambivalence included in the intervention. Other studies have used this method of interviewing,(38) but the anticipated improvements were not

noted due to partial fidelity to the guiding style of interaction by providers. It is possible that lack of fidelity to a structured education approach, may affect effectiveness of an intervention especially regarding change in behavior, though in our case we cannot prove for a fact, that the educators did not follow the educational design prescribed.

The retention rate for our study subjects was 69% at the 6-month follow-up visit, suggesting a need to anticipate and address reasons for drop out in future studies, to avoid this. Lower rates of as much as 54% return rate has been reported previously (31) , (45) although this did not seem to affect the effectiveness of the intervention. Regionally, a South African study (38) found a similar rate (55% in both groups) although the outcomes in this study were disappointing. The high dropout rate in our study was due to a variety of factors, including relocating away from health care facility, referrals to specialists as well as inability to keep subsequent follow up visits. Since there were no differences between the two groups (those who dropped out and those who remained), this was not considered to affect the internal validity of the results in our study.

13.0 STRENGTHS AND LIMITATIONS

The study design involved randomization, with reasonably well matched participants in the control and intervention groups. There was no interaction between the two groups hence the study was successful in minimizing contamination.

An important shortcoming in this study is lack of evaluation of the DSME intervention that the diabetes educators were providing. The educators were not supervised during the any of the education sessions making it impossible to assess fidelity to the planned educational programme. This was an important oversight in our study, which may have affected the effectiveness of the intervention.

This study did not address qualitative issues surrounding effectiveness of an educational approach, such as knowledge acquired, improvements in self-care activities, psychological factors amongst others, which would have been important to further enrich this discussion.

Potential confounders to the learning process include motivation and attitude, emotional barriers especially for newly diagnosed patients, family and social support, all of which were not factored in assessing the effectiveness of the intervention. This may be a source of bias, favoring certain participants over others.

Changes in treatment were also not assessed in both groups of the study cohort. This may serve as a confounding variable in measuring the effect of the educational component.

The retention rate for our study participants was 69% at the 6-month follow-up visit. Therefore, it may appear that this study may have been limited by a high dropout rate.

14.0 RECOMMENDATIONS

A detailed description of the education intervention, clearly outlining the structure of each of the education sessions as well as particular model and style of communication may help in auditing its adherence. This may also aid in its potential application to other clinical settings and should be considered by future researchers on this subject.

Educators may require training or evaluation of their skills before study onset, to ensure that their teaching conforms to a prescribed format as outlined in study protocol. Frequent assessments and reinforcement of skills learnt in training may be also important.

Future studies should also aim at looking at qualitative improvements made by DSME, such as knowledge acquired and improvements in self-care activities. Application of skills learnt is a direct measure of diabetes education and may be a more useful assessment of an education intervention particularly in the short term. A satisfaction survey may also be considered as a tool for educators to evaluate effectiveness of their teaching methods.

Effects of the educational component should not be examined independently. Other variables such as changes in medication over time, motivation, social support should be incorporated in the analysis for a more accurate assessment.

Group based self-management programme may be an option worth exploring in future trials especially in primary care settings. It is not only cost effective, but also saves time for the provider and allows interactions between patients which may lead to better outcomes.

There is needed a better assessment for reasons for drop out of study populations in order to maximize efficiency and improve retention rates.

15.0 DISSEMINATION OF FINDINGS

The findings from this study will be presented to faculty board of examiners and disseminated to all family physicians at the family medicine clinic, AKUHN.

The information will also be distributed to diabetes educators, locally at AKUHN and regionally within the country.

The results will also be submitted for possible publication to a local medical journal, the African Journal of Primary Health Care and Family Medicine, as a contribution to the regional body since data on DSME and its impact particularly in Sub Saharan Africa is scarce.

16.0 CONCLUSION

Overall, DSME did not show significant improvements in the primary or secondary biomedical outcomes. This may suggest that a well-trained family physician offering diabetes education may be just as good as a DSME trained educator. Further studies are however required to support this finding, particularly in primary care settings within the African context.

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APPENDICES

APPENDIX 1: PATIENT CLINICAL DATA COLLECTION SHEET

EFFECT OF DIABETES SELF-MANAGEMENT EDUCATION ON GLYCEMIC CONTROL, COMPARED TO USUAL CARE IN TYPE 2 DIABETIC PATIENTS AT THE FAMILY MEDICINE CLINIC, AGA KHAN UNIVERSITY HOSPITAL NAIROBI

Principal investigator: Dr. Catherine Gathu
Family Medicine Resident, AKUHN
Email: catherine.gathu@aku.edu

You have been asked to participate in the study titled above. Kindly fill out the questionnaire below. Your assistance is greatly appreciated.

Part 1: To be filled by patient

BIODATA **DATE……/……/……**

Patient Names …… AK No……....

Mobile Tel No……

Age……. Sex ……

(Please tick the most appropriate response below)

CLINICAL DETAILS

Duration of diabetes

a) < 5yrs

b) 5-10 yrs.

c) >10 yrs.

Mode of treatment

a) Oral medication

b) Insulin

c) Oral medication and Insulin

Days missed taking medication

a) Never

b) Once a week

c) Once a month

Do you have any diabetes complications you are aware of or have been told about by your doctor?

a) Yes b) No

If so which ones?

a) Heart

b) Kidney

c) Eye complications

d) Feet - burning (Yes……..No……..) or ulcer (Yes…….No……

Do you have Hypertension? Yes……No……..

a) If so, are you on treatment? Yes……No……..

SOCIAL HISTORY

Level of education

a) Primary

b) Secondary

c) College/ University

Residence

- Estate or village……
- Town……

- County…….

Do you smoke?

a) Yes……..Number of sticks/day……..Duration…….
b) No
c) Past Smoker……..

(State in years)

Do you take alcohol?

a) Yes
b) No

(If yes, how frequently?)

- Daily
- Weekly
- Monthly

PART 2: To be filled by patient's primary care physician/ principal investigator

BIOMEDICAL

	Baseline Date obtained……	After 6 months Date obtained……..
Weight		
Height		
BMI		
BP		
HBA1c		

APPENDIX 2: SAMPLE CONSENT FORM

CONSENT TO PARTICIPATE IN RESEARCH

EFFECT OF DIABETES SELF-MANAGEMENT EDUCATION ON GLYCEMIC CONTROL, COMPARED TO USUAL CARE, IN TYPE 2 DIABETIC PATIENTS AT THE FAMILY MEDICINE CLINIC, AGA KHAN UNIVERSITY HOSPITAL NAIROBI

This informed consent form is for type 2 diabetic patients, who attend the Family Medicine Clinic, and who we are inviting to participate in research on Diabetes Self-management Education and its effect on glycemic control.

Name of Principal Investigator: Dr. Catherine Gathu
Family Medicine Resident –AKUHN
Email – catherine.gathu@aku.edu

Name of Organization: The Aga Khan University-EA Nairobi

This informed consent form has two parts:

- Information sheet (to share information about the research with you)
- Certificate of consent (for signature if you agree to take part)

PART I: Information Sheet

Introduction

I'm Dr. Catherine Gathu, a third year family medicine resident at the Aga Khan University Hospital. I'm carrying out a study to establish whether individualized diabetes education by certified diabetes educator improves control of sugars for patients with type 2 diabetes, compared with the usual education provided at the family medicine clinic by your doctor.

Please take some time to read the information presented here, which will explain the details of this project. You may ask the principal investigator, primary doctor or the diabetes educator any

questions about any part of this project that you do not understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you will be involved, should you consent.

Your participation is entirely voluntary and you are free to decline to participate. If you say no, this will not affect you negatively in any way. You are free to withdraw from the study at any point, even if you do agree to take part initially. Your withdrawal from research due to refusal will be always upheld.

This study has been approved by the ethics committee of the Aga Khan University Hospital Nairobi and will be conducted according to the ethical guidelines and principles of good research practice.

What is this research about?

Diabetes is quite common in our settings. The reason I am conducting this research is to find out whether an individualized diabetes education session with a certified diabetic educator compared with the usual education that one receives from the doctor, will make any difference on glucose control.

Who will participate?

Type 2 diabetic patients managed at the Family Medicine Clinic, who are willing and eligible for the study, will be invited to participate.

What will be the research intervention?

This research will involve receiving education on diabetes, either from your doctor or from a certified diabetic educator. Follow-up visits at the clinic with your doctor will continue as usual, in both groups. HBA1C testing at the beginning of the study and at six months will be carried out and recorded.

This research will involve you being randomly grouped by computer into either of 2 groups:-

GROUP ONE (usual care approach) - will receive the usual care from your primary care doctor at the Family Medicine Clinic.

GROUP TWO (diabetes educator approach) - will be referred to a certified diabetes educator for a free individualized education session, primarily focused on your needs as a patient. The education will be offered for a minimum of one hour, at 6 - 8 weeks interval between sessions, with a total number of 3 sessions by the end of the study period (6 months). No consultation fee will be required at the scheduled appointments with the certified diabetes educator.

What procedures will be involved in this study?

First, you will be asked to fill a form showing you are willing to participate in the study. Then you'll be asked to fill a simple questionnaire that provides details about you and your medical history pertaining to diabetes.

Your primary doctor or principal investigator will fill out the rest of the details from your personal file (weight, height, BMI) and from your lab results (HBA1c).

You will then be advised to continue with education, depending on the group you've been selected to (with your primary doctor or with the certified diabetic educator).

How long will I be in the study?

Participation in the study is expected to last 6 months.

What side effects or risks can I expect from being in the study?

No personal risk is expected should you agree to participate in the study.

Benefits

Your participation is likely to help us establish if personalized diabetic education, focused on meeting individual challenges amongst type 2 diabetic patients, has any effect on attaining better control of the glucose, compared to the education that one receives from the primary care doctor during the usual clinic visits.

The group selected to receive education from the certified diabetes educator will receive additional teachings for a longer duration and offered additional education material.

Results obtained from the study will be communicated to all participants. Future clients are likely to benefit in getting the education intervention with the best results in the control of diabetes.

No money or gifts will be given to participate in this research.

Confidentiality

The information collected during the research will be handled professionally, with utmost respect and kept confidential. Number identifiers will be used instead of your name. This information will form part of the analysis at the end of the study and ALL notes / recorded material will be effectively destroyed.

CONSENT

If you wish to participate, please sign below. You may request a copy of this form to keep.

PART 2: Certificate of Consent

DECLARATION

I have read the above information and all queries clarified to me. I consent voluntarily to take part in this research as a participant.

DATE: _____ TIME: _____

PARTICIPANTS SIGNATURE: _____

WITNESS SIGNATURE: _____

CONSENTING TEAM MEMBER: _____

PRINCIPAL INVESTIGATOR: DR. CATHERINE GATHU

CONTACT: 0721-659106

APPENDIX 3: DIABETES EDUCATION GUIDE

The Aga Khan University Hospital
P.O. Box 30270 - 00100 GPO, Nairobi
Tel: +254 20 366 2000 / 374 000
Mobile: 0733 640 770/ 0722 204 146/7
Email: contact-us@aku.edu

Addressograph

Diabetes Teaching Guide Form
Diabetes Clinics

Diabetes Educator: _____

	Date		Date		Date		Date	
	Initial Education	Assessment Understanding	Education	Assessment of Understanding	Education	Assessment Understanding	Education	Assessment Understanding
Pathophysiology of diabetes								
1. Type 1								
2. Type 2								
Concept of self- management								
Medication								
1. Insulin								
Type								
Dosage								
Action								
Timing								
Injection technique								
Use of pens/syringe								
Site rotation								
Storage								
Disposal of needles								
2. Oral hypoglycaemics								
Type								
Dosage								
Action								
Timing								
Meal planning								
1. Effect of food on BG								
2. Concept of healthy eating								
3. Timing/frequency of meals & snacks								
4. Weight control								
5. Alcohol								
Exercise								
1. Effect on blood glucose								
2. Suitable exercise program								
3. Timing of exercise								
4. Need for snacks								
5. Adjustment of insulin								
Blood glucose monitoring								
1. Reason for monitoring								
2. Use of testing								
3. Timing & frequency								
4. Recording results								
5. Interpreting results								
6. Supplies								

AK 777 5/4/2012

	Date		Date		Date		Date	
	Initial Education	Assessment Understanding	Education	Assessment of Understanding	Education	Assessment Understanding	Education	Assessment Understanding
Acute complications								
1. Hypoglycemia								
Causes								
Symptoms								
Treatment-conscious								
unconscious (Glucagon)								
2. Hyperglycaemia								
Causes-diet								
• illness								
• stress								
• medications								
• hormones								
• change in insulin								
• Symptoms								
• Treatment								
3. Diabetic Ketoacidosis								
Pathophysiology								
Use of ketone strips								
Conditions for testing								
Treatment								
Chronic Complications								
1. Importance								
2. Retinopathy								
3. Nephropathy								
4. Neuropathy								
5. Erectile dysfunction								
6. Macrovascular disease								
Skin and Foot Care								
1. Sick day guidelines								
2. Reasons to contact HCP								
Travel								
Emotional Aspects								
1. Acceptance of diabetes								
2. Chronocity of diabetes								
3. Family concerns								
Hotline Number								
Signature								

GRADING LEVEL OF KNOWLEDGE

1= No Knowledge ☐ 2 = Poor ☐ 3 = Fair ☐ 4 = Good ☐ 5 = Excellent ☐