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The Effect of Structured Diabetic Self-Care Education on Glycemic Control among Adults with Type-2 Diabetes: A Randomized Controlled Clinical Trial

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Abstract

In Sub-Sahara Africa, diabetes is adversely reducing life expectancy partially due to inadequate diabetes self-care practice. Numerous folks with diabetes lack the requisite skills and knowledge to effectively manage their own condition. This study determined the effectiveness of a structured diabetes self-care education (DSCE) intervention versus routine care on glycemic control among adults with type-2 diabetes attending a Family Medicine Clinic. We offered a DSME intervention and assessed how it affected patients' self-reported levels of diabetes knowledge, glycosylated hemoglobin (HbA1C) and diabetes self-care activities. Overall, there was poor diabetes knowledge at baseline (7.29 ± 2.81) among study participants. The difference in the mean Diabetes Knowledge scores before and after the DSME intervention was significantly greater in the intervention arm (mean difference = 13.29; 95% CI = 12.78 – 13.79; p <0.001). Both groups showed improvement in mean glycosylated hemoglobin from baseline to post intervention however, the mean difference (2.04%) between the intervention and the routine care groups was statistically significant (95% CI = 2.35 – 3.73; p <0.0001). Our study found significant improvements among the intervention group. The DSME tool impact positively on participants diabetes knowledge scores. Hence, our DSME intervention is clinically useful in diabetes mellitus self-care.

***Keywords**: Diabetic self-care education; Diabetes outcome**;** Glycemic control; Type-2 diabetes.*

Introduction

Diabetes Mellitus (DM) is a metabolic disorder of multiple etiologies characterized by chronic

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hyperglycemia with disturbance of carbohydrate, fat and protein metabolism. These all happens due to lack of insulin secretion, insulin inaction or both.[1],[2],[4] And this can manifest with typical symptoms of DM such as thirst, polyuria and weight loss. DM can be classified into Type 1 -Diabetes (usually due to β- cell destruction leading to absolute insulin deficiency) which was initially known as insulin dependent diabetes mellitus or juvenile diabetes.[1],[3] Secondly, Type 2 diabetes T2DM that accounts for 90–95% of cases is usually due to insulin resistance with relative insulin deficiency, predominantly from insulin secretory defect. The type 2 DM was formerly known as non-insulin-dependent diabetes (NIDDM). It includes people who have insulin resistance and usually have relative (rather than absolute) insulin deficiency at least initially, and often throughout their lifetime, these persons do not require insulin treatment to live. There are possibly many different causes of this form of diabetes. Though, the exact cause is unknown, autoimmune damage of β-cells does not occur.[4] Gestational DM is another type which is defined as any glucose intolerance first recognize during pregnancy. This is regardless of whether insulin or only diet modification was used for treatment or whether the condition persisted after pregnancy.[4],[5]

The African continent is currently facing the double burden of diseases with high prevalence of infectious diseases and steady increase of non-communicable diseases as a cause of death.[5],[6] DM which is a chronic, non-communicable disease with an increasing prevalence has now affected between 340 to 536 million adults (aged 20±79 years) globally. This represents about 14.5% globally.[1],[2] However, over the past decade the prevalence of diabetes has risen most rapidly in low- and middle-income countries (LMICs), a home of about 75% DM people. These countries more often than not lack the resources with which to adequately tackle the growing diabetes epidemic. In 2015, about 20% of global health expenditure on diabetes occurred in LMICs.[1-3],[6] In SSA, Nigeria has the highest amount of diabetes with an estimated 3.9 million people (or an extrapolated prevalence of 4.99%) of the adult population aged 20-79-years-old.[6-8] DM presents mostly during the peak income-earning period in a person's life. This results in loss of primary income in households which sometimes leads to poverty and despair. The repeated hospital visits with its consequent financial burden often interfere with patient's daily life, and sometimes resulting in the phenomenon known as "diabetes burnout" or "diabetes overwhelmus".[6],[7]

Poorly managed diabetes results in hyperglycemia and eventually serious micro-vascular and macro-vascular complications, which can lead to cardiovascular events, kidney failure, blindness, nerve damage and peripheral arterial disease, ultimately resulting in disability and/or mortality.[3],[9] However, tightly controlling blood glucose levels through the effective use of medications and the management of key lifestyle factors, such as diet and exercise, reduces the risk of serious complications.[3],[10] Given the chronic nature of the condition, it is therefore vital that individuals develop the knowledge and skills necessary to effectively manage their condition on a day-to-day basis away from professional healthcare facilities, and thereby prevent or delay the development of complications. [9-12] Diabetes self-management education (DSME or DSCE) [13-17] is therefore consider as a critical element of care for all people with diabetes and those at risk of developing the disease.[18-24] Diabetes Self-care, a subset of DSME is an example of Patient-Centered Care Method

(PCCM), and is an important aspect of living with chronic disease.[25] It is an innovative health care that is grounded in mutually beneficial partnership among health care providers, patients and families.[3],[4],[11],[26] It applies to patients of all ages and may be practiced in any health care setting.[27] Diabetes self-care (DSC) activities or behavior are undertaken by people with, or at risk of diabetes in order to successfully manage the disease on their own under the guidance of their health care provider.[11],[12],[28] According to the American Diabetes Association (ADA); these are essential self-care behaviors in people with diabetes which predicts good outcomes.[14],[15],[29] They include healthy eating, being physically active, monitoring of blood glucose, compliance with medications, good problem-solving skills, healthy coping skills and risk-reduction.[15],[30] A number of meta-analyses of randomized controlled trials (RCTs) have provided support for DSME, demonstrating that compared to the routine treatment, DSME programmed typically lead to significant improvements in blood glucose control.[12],[16],[17],[31] Both group-based and individual-based DSME programmed appear effective, but group-based approaches are typically cheaper, and offer the advantage of allowing patients to meet and discuss their issues together.[18]

Like many chronic diseases, the patients must be taught to take absolute control of their own condition to be able to meet the daily challenges of the disease. [2-4] Structured Education in Diabetes Management (SEDM) helps ensure that the adaptation by the client is interwoven seamlessly with minimal disruption as possible to his/her daily routines. It is also aimed at minimizing the psychological and emotional burden that the disease brings to the patient, family as well as careers.[18-20] A review of diabetes self-management education revealed that education, is successful measure in lowering glycosylated hemoglobin levels.[3],[4],[15] Various strategies of self-management education such as face-to-face delivery, cognitive re-framing, teaching method, and exercise content, were more likely to improve glycemic control.[21],[22] It is now widely accepted that self-management should not only focus on knowledge and skills, but that self-efficacy and coping skills are equally important to achieve the desired patient outcomes.[22],[23] Education or training of T2DM patients in self-management is effective in reducing HbA1c levels; although research into the long-term benefits of educational programmed is limited.[21-24] We evaluated the effectiveness of a structured diabetes self-care education on glycemic control among patients with type-2 diabetes mellitus.

Hypothesis

Null hypothesis: No significant difference in both groups. Alternative hypothesis: The proportion of participants with clinical improvement in glycosylated hemoglobin will differ by 20% following the interventions (DSCE vs. Routine care).

AIM

To determine the effectiveness of structured diabetes self-care education (DSCE) versus routine care on glycemic control among adults with type-2 diabetes attending the Family Medicine Clinics in FMC Keffi.

Specific Objectives

1. To determine the medical and lifestyle history of the study cohorts

2. To determine the mean change in diabetes knowledge score among participants with type 2 diabetes in the two study arms using the diabetes knowledge questionnaire.
3. To compare the mean change in glycosylated hemoglobin among participants with type 2 diabetes receiving DSCE with those receiving the routine care using the chromatography automated chemistry analyzer.

Methods

Design, Participants and Setting

The study was a facility-based, single blind randomized control trial and the participants were randomized into two different treatment group (an intervention group & a control). The intervention group received the structured diabetic self-care education while the control group received the routine consultation.

Eligibility Criteria

Inclusion criteria
All type 2 diabetes patients who consented and 40 years of age whose glycosylated hemoglobin was ≥ 8.5% and met the following criteria:

- Who had received treatment and follow up for at least three months in the hospital
- Who possessed a mobile phone
- Who were free of any eye disease that would otherwise limit their ability to read prints
- Who could read and understand English Language

Exclusion criteria

- Who were ill, necessitating hospital admission
- Who had macro-vascular or micro-vascular diabetes complications (neuropathy, nephropathy); and/or had diabetes emergency (DKA, HONK, hypoglycemia)
- Who were not be available during the period of the follow up
- Women that were pregnant

Sample Size Determination

The sample size was determined using the formula for comparing two sample proportions. For an alpha of 0.05 and a power of 80 %, the difference of 20% between the proportions of intervention group (group receiving the diabetic self-care education) and the usual care group.

$N = (Z\alpha + Z\beta)^2 \times P\ (1 - P)^{13} / d^2$
Where; N =Minimum sample size required for each group
$\underline{Z\alpha}$ = alpha error of 5%; = the desired 95% confidence level; $\underline{Z\alpha}$=1.96 from a statistical table
$\underline{Z\beta}$= desired 80% power; $Z\beta$ = 0.842 from a statistical table
Variance expressed as P (1 – P) Where $P = P_A + P_B/2$
P_A= Proportion of patients expected to have improvement after DSCE intervention put as 75%
P_B = Proportion of patients in the control group (Usual care) expected to have improvement put as 55%.
Therefore; P_A = 75% = 0.75; and P_B = 55% = 0.55

Hence; $P = 0.75 + 0.55 = 1.30/2 = 0.65$
$1 – P = 1 – 0.65 = 0.35$
$d = P_A - P_B = 75\% - 55\% = 0.75 – 0.55 = 0.2$
$Z\alpha = 1.96$; $Z\beta = 0.842$; $P_A = 0.75$, $P_B = 0.55$; $P = 0.65$; $d = 0.2$, $(1- P) = 0.35$
Therefore, $N= (1.96 + 0.842)^2 \times 0.65 \times 0.35/0.2^2$

N = 44 subject per group. Therefore, the minimum sample size for both groups was 88. Allowing for 10% attrition, the total number of patients that was recruited for the study were 97.

Sampling Procedure

Consecutive patients with type 2 DM who met eligibility criteria ($HbA_{1c} \geq 8.5\%$, written informed consent) were recruited into the study and were given registration numbers. Primary care physicians consulting at these clinics at the time of recruitment were instructed to send consecutive T2DM adults directly to the researchers. However, patients who did not fulfil the inclusion criteria were managed by the researcher for that encounter. After obtaining informed consent, all eligible participants were randomized. Group allocation was made from a computer-generated random number of lists (Open EP1 version 2.3). Several random number lists were produced by an independent statistician until a list with 97 numbers of odd and even numbers were obtained. Participants with the corresponding even number were allocated into control group and to the DSCE (intervention) group if the corresponding number was an odd number.

Study Protocol

A written informed consent was obtained from the patients after been educated on the nature and purpose of the study. A study questionnaire was used to obtain socio-demographic data, medical, lifestyle and other relevant clinical parameters from the participants. The Body Mass Index (BMI) was calculated as weight in $Kg/meter^2$ and categorized according to the World Health Organization classification.[30] Also, metabolic parameters such as glycosylated hemoglobin (HbA_1c) and fasting blood glucose (FBG) were obtained using the HbA1c analyzer and blood glucose meter (One Touch glucometer) respectively after an overnight fast and the values were recorded accordingly. A lancet was used to get drops of blood from the pulp of the thumb after cleaning with methylated spirit. The drop of blood was placed on the window of the cassette of the HbA1c analyzer and the glucose meter The Diabetes knowledge of every participant was measured at baseline using the Patient's Diabetic Knowledge Questionnaire (DKQ). All the questionnaires were interviewer administered and were pre-tested in a pilot study.

Intervention Group

The intervention group contained 49 eligible participants depending on the randomization. The DSCE or DSME was adopted from the American Association of Diabetes Educators (AADE-7).[15] The specific goals of DSME were as follows: teaching the basic concepts of type 2 diabetes, identifying and counting carbohydrates, fats and protein, maintaining a healthy body weight, exercising regularly, and monitoring and controlling blood sugars.[13] Two weeks after the randomization, the participants received the

structured DSCE which was administered by the researcher and constituted the 1st follow-up education visit. The 2nd, 3rd and 4th educational intervention visits were administered by the researcher at week 4, 8 and 12 of the study respectively. The educational session was interactive and comprised components of the DSCE tool and their mean clinical outcome was computed across these periods.

Results

Ninety-one participants (93.8%), completed the study. This included forty-six in the intervention group and forty-five in the usual group. The attrition rate was therefore 6.2%. Figure 1 below shows the flow of participants through the study.

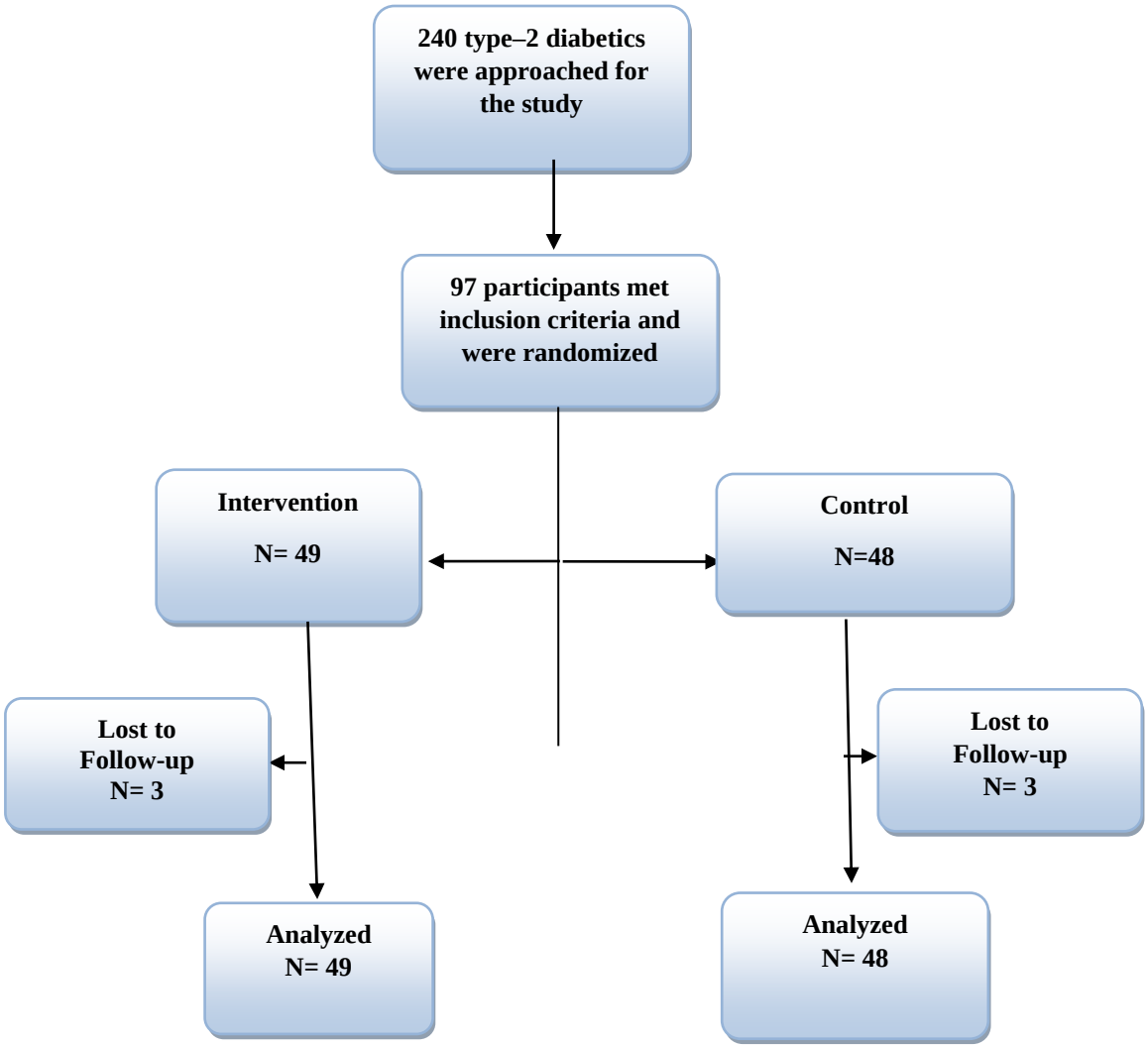


Figure 1: Study trial profile

Socio-demographic characteristics of participants

The participants in the study groups were both males and females with the mean age of 69.99 ±8.26. There were more females 64 (66.0%) in the study than males 33 (34.0%) with a p value of 0.32 which

was not significant. The participant's ages ranged from 40years to 75 years old. Other details of their characteristics are summarized in table 1 below.

Table 1: Socio-demographic characteristics of study participants

	Intervention (n=49)	**Routine Care (n=48)**			
Variables	**Freq. (%)**	**Freq. (%)**	**Total (97)**	**χ^2**	**P value**
Gender				1.00	0.32
Male	19 (57.6)	14 (42.4)	33 (34.0)		
Female	30 (46.9)	34 (53.1)	64 (66.0)		
Marital Status				2.64	0.45
Single	2 (28.6)	5 (71.4)	7 (7.2)		
Married	32 (51.6)	30 (48.4)	62 (63.9)		
Divorced	3 (37.5)	5 (62.5)	8 (8.2)		
Widowed	12 (60.0)	8 (40.0)	20 (20.6)		
Family type				1.47	0.23
Monogamous	27 (56.3)	21 (43.7)	48 (64.9)		
Polygamous	22 (44.9)	27 (55.1)	49 (35.1)		
Occupation				3.50	0.62
Civil Servant	4 (57.1)	3 (42.9)	7 (7.2)		
Trading	20 (57.1)	15 (42.9)	35 (36.2)		
Farming	8 (40.0)	12 (60.0)	20 (20.6)		
Housewife	6 (42.9)	8 (57.1)	14 (14.4)		
Artisan	5 (71.4)	2 (28.6)	7 (7.2)		
Retiree	6 (42.9)	8 (57.1)	14 (14.4)		
Educational attainment				0.97	0.62
Primary	9 (42.9)	12 (57.1)	21 (21.6)		
Secondary	30 (50.8)	29 (48.2)	59 (60.8)		
Tertiary	10 (58.8)	7 (41.2)	17 (17.5)		
Residence				0.38	0.54
Keffi	6 (42.9)	8 (57.1)	14 (14.4)		
Outside Keffi	43 (51.8)	40 (48.2)	83 (85.6)		
Income				0.55	0.76
<#20,000	3 (42.9)	4 (57.1)	7 (7.2)		
#20,000 – 50,000	28 (53.8)	24 (46.2)	52 (53.6)		
>#50,000	18 (47.4)	20 (52.6)	38 (39.2)		
Ethnicity				9.10	0.25
Hausa	9 (42.9)	12 (57.1)	21 (21.6)		
Igbo	3 (42.9)	4 (57.1)	7 (7.2)		
Afo	7 (50.0)	7 (50.0)	14 (14.4)		
Made	5 (71.4)	2 (28.6)	7 (7.2)		
Egon	9 (64.3)	5 (35.7)	14 (14.4)		
Igala	7 (70.0)	3 (30.0)	10 (10.3)		
Tiv	8 (50.0)	8 (50.0)	16 (16.5)		

Others	1 (12.5)	7 (87.5)	8 (8.3)
Religion		0.08	0.77
Christianity	32 (51.6)	30 (48.4)	62 (63.9)
Islam	17 (48.6)	18 (51.4)	35 (36.1)

Medical and lifestyle history of the study participants

Sixty-three participants (64.9%) had been diagnosed of diabetes between 3 months to <5years; 21 (21.6%) had been diagnosed of diabetes between 5 -10 years, and 13 (13.5%) had diabetes > 10years; while 78 (80.4%) of the participants had a family history of diabetes. Sixty-two participants (63.9%) were diagnosed with hypertension. This was not statistically significant when compared between the two groups (p = 0.477). All the participants were on oral anti-diabetic agents and none was on insulin. Details of other findings are summarized in table 2 below.

Table 2: Medical and lifestyle history of the study participants

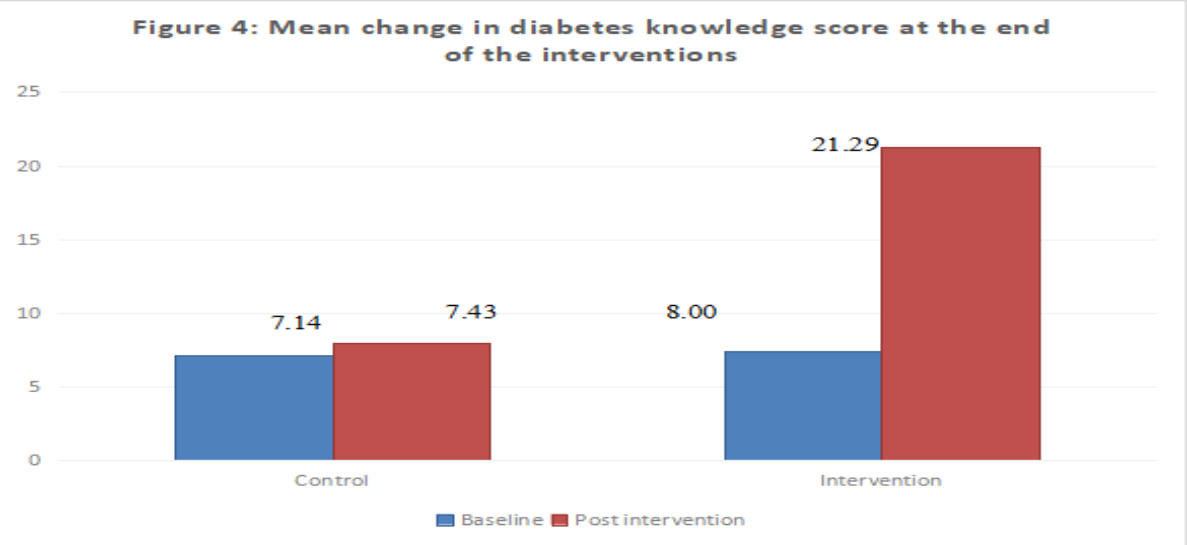
Variables	Intervention n= 49	Usual care n =48	Total (97)	χ^2	p-value
Family History of Diabetes				1.51	0.22
Yes	37 (47.4)	41 (52.6)	78 (80.4)		
No	12 (63.2)	7 (36.8)	19 (19.6)		
Duration of Diabetes				3.18	0.20
3 months - <5years	35 (55.6)	28 (44.4)	63 (64.9)		
5 – 10 years	7 (33.3)	14 (66.7)	21 (21.6)		
>10 years	7 (53.8)	6 (46.2)	13 (13.4)		
Medication currently taken				0.40	0.26
Oral hypoglycemic	49 (50.1)	48 (49.5)	97 (100.0)		
Oral hypoglycemic + Insulin	0 (0.0)	0 (0.0)	0 (0.0)		
Diagnosed with Hypertension				0.50	0.48
Yes	33 (53.2)	29 (46.8)	62 (63.9)		
No	16 (45.7)	19 (54.3)	35 (36.1)		
Alcohol Consumption				0.49	0.48
Yes	31 (53.4)	27 (46.6)	58 (59.8)		
No	18 (46.2)	21 (53.8)	39 (40.2)		
Smoking				0.51	0.24
Yes	11 (57.9)	8 (42.1.)	19 (19.6)		

Mean Change in Diabetic Knowledge Score Among Participants

At the 12th week follow up interventions, the intervention group (21.29 ±0.89) showed remarkable improvement in the mean diabetes related knowledge score compared with the usual care group (8.00 ±1.53). The mean difference in the Diabetes knowledge score at 12th week follow up intervention was

statistically significant when compared to the control group (mean difference = 13.29; 95% CI = 12.78 – 13.79; t = 52.61; p <0.001).

This is shown in the figure below.



Comparison of Mean Change in Glycosylated Hemoglobin and Other Clinical Parameters Among the Participants:

Following the 12th week interventions, the mean glycosylated Hemoglobin had improved from base line (9.57 ±1.96 to 5.83 ±0.53) post intervention for the intervention group. Similar improvement was noticed in the control group with a mean change of 9.79 ±1.52 at baseline to 8.09 ±1.28 post intervention. The mean difference (2.04) between the intervention and the routine care groups was statistically significant (95% CI = 2.35 – 3.73; p = <0.0001).

Table 3 Comparison of mean change in glycosylated hemoglobin and other clinical parameters among the participants.

	Intervention Mean ±SD	Usual Care Mean ±SD	Mean diff.	95% CI	T	p-value
Glycosylated Hemoglobin						
Baseline	9.57 ±1.96	9.79 ±1.52	0.78	0.08 – 1.49	2.219	0.09
Post-intervention	5.83 ±0.53	8.09 ±1.28	2.26	1.86 – 2.65	11.395	<0.001
Mean Change (effect)	3.74 ±1.85	1.70 ±1.58	2.04	2.35 – 3.73	8.750	<0.001

t; p-value	16.18;<0.0001	6.23;<0.0001				
BMI						
Baseline	29.50 ±6.40	27.64 ±4.97	1.86	-0.45 – 4.17	1.22	0.11
Post-intervention	25.86 ±4.01	24.34 ±4.96	1.52	-0.29 – 3.34	1.60	0.09
Mean change (effect)	3.64 ±2.55	3.30 ±1.29	0.34	-0.47 – 1.15	0.82	0.41
t; p-value	3.35; 0.01	3.27; 0.01				
Systolic BP						
Baseline	135.71 ±13.07	140.00±14.29	4.29	1.21 – 9.78	1.549	0.13
Post-intervention	130.00 ±7.64	132.86 ±8.90	2.86	0.47 – 6.18	1.706	0.09
Mean change (effect)	5.71 ±7.36	7.14 ±10.41	-1.43	-50.05 2.19	-0.785	0.43
t; p-value	2.62; 0.01	2.95;0.004				
Diastolic BP						
Baseline	84.29 ±7.36	82.00 ±9.35	2.29	-1.09 – 7.66	5.68	0.18
Post-intervention	81.43 ±3.54	80.00 ±7.64	1.43	-0.96 – 3.82	1.188	0.23
Mean change (effect)	2.86 ±1.07	2.00 ±1.40	0.86	0.35 – 1.36	2.25	0.009
t; p-value	2.43; 0.02	1.16; 0.25				
Waist Circumference						
Baseline	95.29 ±16.61	97.57 ±10.72	2.28	-3.32 – 7.89	0.809	0.42
Post-intervention	90.14 ±16.01	95.43 ±11.68	5.29	0.34 –10.91	1.867	0.06
Mean change (effect)	5.14 ±2.12	2.14 ±4.90	3.00	1.49 – 4.51	3.93	<0.01

t; p-value	1.55;<0.12	0.42; 0.68

DISCUSSION

Diabetes self-management education (DSME) is a critical element of care for all people with diabetes and those at risk of developing the disease. Very few studies have evaluated DSME programmed in Nigeria and the West African Region. With the rising burden of diabetes in Africa and the high proportion of undiagnosed diabetes in the continent, there is the need for the development and introduction of better preventive strategies to reduce the impact of diabetes.[2],[4] Diabetic self-care education if well implemented will go a long way to improve patients well-being, decrease morbidity and mortality and maintain the normal blood glucose level and glycosylated hemoglobin level desirous for the patient to have a near normal life. It is therefore essential for physicians to know what diabetic self-care education is all about especially the components so that they will be able to teach their patients the care and knowledge they require.[16],[25],[28].

Socio-Demographic Characteristics and Clinical Outcome of Study Participants

At baseline, our findings showed no significant differences between the usual and the intervention groups. This suggests that randomization was effective with regards to distribution of participants in the groups. Only 6.2 % of the participants dropped out of the study before the 13-week of the study. The dropout rate was similar in both intervention and the routine care groups of 3.1% respectively. This is explicable in the context of an environment where the methods and processes of communication between physician and patient are extremely improved. The study participants lost to follow-up were unlikely to be an important cause of bias in the outcome of this study. The low attrition rate may be because of satisfactory information and education of the patients before the commencement of the study, hence the importance of education of patient by physicians.

A randomized controlled trial at the University of Calabar Teaching Hospital (Nigeria),[3] which evaluated whether an intensive and systematic diabetic self-management education (DSME) programmed, using structured guidelines, could improve glycemic control compared to the existing patient education, reported that lost to follow up was 10% in the intervention group as compared to the control group of 14%. This is not similar in our study with attrition rate of 3.1 % in both groups. This is probably due to more follow up technique of calling the patients in this study, and the sending of text messages before each consultation making participants seeing the importance of the study. A study on the effectiveness of a community-based diabetes self-management education (DSME) programmed in a rural agricultural setting, reported a low rate of lost to follow up in both the intervention group and the usual group.[8],[17] This is similar to the findings in this study. This could be because most of the people recruited in the study live within the community and could easily be accessed by the researcher and most of the respondents were illiterate so they were eager to receive and practice any form of diabetic education that could better their life. Though in this study the attrition rate were mainly due to relocation to a new town. A study by Gatha CW and co- researchers on the effect of diabetes self-management education on glycemic control among type 2 diabetic patients at a Family Medicine clinic in Kenya reported a baseline mean age of all patients to be 48.8 years with a loss to follow-up which

was significantly more common in the usual care group than the intervention group (41% vs. 21%).[11] This was not similar to the findings of this research. This could be due to the poor diabetic knowledge among the respondents whom most of them do not understand the importance of the research and being that such level of diabetic self-care education was rarely practice in Kenya. The mean age of the patients who participated in the research being 48.8 years was also not similar to this research with a mean age of 69.99 years. The study participants were between the ages of 40 years to 75 years with the mean age of 69.99 years. The aggravation of insulin resistance with age, increased inactivity and longevity of diabetes patients due to enhanced care are possible reasons for the rising prevalence of type 2 diabetes with age.[6],[9],[31] The figures in this study are similar to global figures.[4],[8],[22],[27]The mean age of 69.99 years found in this study is similar to observations in Nigeria and other Sub-Saharan African countries where an age range of 40-65 years was reported.[3],[6],[7],[22] In our local Centre (FMC Keffi), all type 2 diabetes that were diagnosed and manage were from the ages of 40 years and above.[32] In Nigeria, the risk of diabetes increases 3-4 times after the age of 44 years.[8],[25] It was however low compared to reports from developed nations where most diabetics were over 64 years of age.[22],[26].

This study showed that majority (62%) of the participants were married, with most having secondary education (59%), with 17% having tertiary education and 21% having primary education. This was different from a previous study by Gatha CW and co- researchers at a family medicine clinic in Kenya[11] which showed that majority (76.4%) of the study participants had tertiary education while 19.3% had secondary education and 4.3% had primary education.[11] The high number of married participants in the present study was probably due to the fact that the majorities of the participants were in the middle age group and hence are more likely to be married. The low level of tertiary education may be due to the poor family income.

Gatha CW and colleagues reported that 2.1% of their patients were on oral DM drugs, while 20.7% were on both oral drugs and insulin and majority of their patients were on diet control which is about 56.4%. In this study all the patients recruited were on oral DM agents only. This is probably because most of the patients were not ill necessitating hospital admission. None of the participant was on diet control as compared to the above study where majority of the patients were on diet control. This is probably because participants recruited had poor glucose control and diet alone would not have controlled their blood glucose level.

The lower mean age of diabetes compared with patients in the developed world may be a reflection of the lower life expectancy of Nigerians (which was an average of 54.3 years in 2018) compared with the developed world (78.54 years in 2018), as well as the reduced survival of Nigerian diabetic patients.[4],[9],[10],[12].There were more females 64 (66.0%) in the study group than males 33 (34.0%) with a p value of 0.32, which was not significant. The higher percentage of females in this study might have been due to higher seeking health behavior in females than males.[23]

In this study sixty-two percent of the respondents were Christians, while about thirty five percent were Muslims. This finding was similar to a study in Lagos South West Nigeria where about two-thirds (68.2%) were Christians while 31.8% were Muslims.[23] It is however different from the Nigerian national values of 46% of Christians and 54% as Muslims.[31] No other religious groups were captured

in this study and in the Lagos study which is similar to national values as traditionalists are less than one per cent.[31] In contrast, a study in Northern Nigeria reported that most of the respondents were Muslims , and a few of the respondents were Christians. [29] The tribal spread among the ethnic groups in this study showed that 21 % were Hausa, 7% were Igbo, Afo and Igno were 14% each, made 7%, Igala 10%, Tiv 16% and other tribes were 8%. This could be because the main inhabitants in the town were the minority tribe in the study location being Keffi close to Abuja the Federal Capital Territory of Nigeria which is a mix of the country's ethnic groups which was well represented in the study.

At baseline both groups showed poor diabetes knowledge which suggest that the knowledge of DM is not dependent on educational qualification at baseline. Reason could be due to the usual care that does not take into cognizance adequate diabetes education since DSME was not fully in practice in our local Centre.

A Descriptive, cross sectional survey research design which was conducted by In Zucchi and colleagues on type 2 diabetes out-patients attending Endocrinology Clinic at the University of Ukyo Teaching Hospital (UUTH) and University of Calabar Teaching Hospital (UCTH) between June 2012 and February 2013 on Diabetes Self-care Knowledge (DSCK-30) which evaluated knowledge of self-care practices. Socio-demographic information and respondents' opinion on the possible barrier(s) to knowledge of self-care reported that Diabetes self-care knowledge was generally high among the population studied. Educational status, monthly income, duration of diabetes and negative attitude to disease condition predicted knowledge level. [18],[28].The findings are not similar to this study which reported that diabetic knowledge among study participants was poor in both the routine group and the intervention group.

At base line the mean glycosylated hemoglobin at both the intervention and the routine group was not significant with a p value of 9.68 ±1.79. The fasting blood glucose for both the intervention and the routine group was also not significant with a p value of 0.66. All the participants seen were on oral anti-diabetic agents, this was because most of the diabetics did not present as emergency warranting insulin, and were type-2 diabetics who have been attending the clinic at least 3 months before the study. On the whole, there was a poor knowledge of diabetes mellitus demonstrated by the participants in this study at baseline, both at the intervention and the usual care. DSCE was poorly practiced in the local Centre where the study took place. This could be the reason for the poor glycemic control at base line. A study carried out by Adeyemi O etal [26] reported that the practice of regular medical check-up was poor among type 2 DM, and this may be associated with inadequate knowledge about specific diabetic complications. He advocated for awareness to be increased on diabetic complications and need for routine evaluation among type2 DM patients. The importance of DSCE cannot be over emphasized.

Post Intervention Outcome Measures

One of the primary objectives of this study was to compare the mean change in glycosylated hemoglobin among participants with type 2 diabetes receiving DSCE with those receiving the usual care using the chromatography automated chemistry analyzer. At the end of the 12 weeks follow up interventions, the mean glycosylated hemoglobin had improved from base line (9.57 ±1.96 to 5.83 ±0.53) post

intervention for the intervention group. Improvement was also noticed in the usual group (control) with a mean change of 9.79 ±1.52 at baseline to 8.09 ±1.28 post intervention. The mean difference (2.04) between the intervention and the usual care groups was statistically significant (95% CI = 2.35 – 3.73; p = <0.0001). This was because better self-care behavior led to better blood glucose control. Also, the participants that received the Diabetes Self-Care Education were more likely to have changed their behavior because all the aspect of the DSCE were adhered to and a follow up phone call to remind patients to come for follow up was strictly adhered to. The Significant decreases in HbA_{1c} have been demonstrated in most trials using various structured group or individual education programs especially among diabetes with HbA_{1c}>8.5%.[4],[15],[24],[29].

A similar study carried out by Essien teal in university of Calabar Teaching Hospital [3] reported that intensive patient education among diabetes patients using structured DSCE gave a better outcome than the usual care. In that study participants in the intervention group had a mean six-month HbA_{1c} (%) of 8.4 (95% CI: 8 to 8.9), while participants in the conventional group had a mean six-month HbA_{1c} (%) of 10.2 (95% CI: 9.8 to 10.7). The difference was statistically significant. (P < 0.0001). The study however had a total of 59 participants in each of the group, as compared to 97 participants in total in this study. The study was carried out for 6 months as compared to 5 months in this study; the two studies were carried out in a LMIC both in a tertiary institution in Nigeria.

Another study carried out on the effect of diabetes self-management education on glycemic control among type 2 diabetic patients at a family medicine clinic in Kenya [11] reported that there was no improvement in the primary outcome which was glycosylated hemoglobin in both the intervention group that received the diabetic self-care education and those that received the usual care. The study reported that the short-term biomedical benefits of a structured educational approach seemed to be limited. This suggested that offering a short, intensified education programmed might have limited additional benefit above and beyond the physicians' comprehensive approach in managing chronic conditions like diabetes. The study was however carried out within six months as compared to five months of study in this research. The lack of improvement in glycosylated hemoglobin might be due to the way the diabetic self-care education was administered, and the number of times the patient presented for follow up.

Diabetic self-care education research suggests that clinical outcomes are unlikely to change unless there is knowledge.[23] The significant change in the HbA_{1c} may have been due to the diabetes-related knowledge acquired during the course of the intervention as evident by the increase in diabetes related knowledge in this study. Similar trend was also found with the significant decrease in the FBG among study participants; with the intervention group (8.40 ±2.31 at baseline to 4.17 ±0.47mmol/L at post-intervention) with a p value of < 0.001 showed better outcome than usual group (7.98 ±1.34 at baseline to 6.12 ±1.82mmol/L at post intervention). In this study, it was proven that DSCE after three months improved the level of HbA1c and FBG of participants. To encourage behavior, change and the maintenance of healthy diabetes-related behavior, continuing support for patients with diabetes is particularly important in terms of diabetes self-care and compliance with activities recommended by the physician, enhanced to a greater extent from baseline to post-intervention.

A study in Southern Nigeria reported that Poor knowledge of DM and suboptimal level of adherence to treatment regimen remains a recurring problem among DM patients. and also reported that improving

the knowledge of DM and adherence to treatment regimen would help in reducing the rate of morbidity and mortality among patients.[18],[26],[28].

Three months after this study the mean change in diabetes knowledge score among participants with type 2 diabetes in the intervention group had improved more than the usual care group. The mean change at base line for the intervention group was7.43 ±2.75 and at post intervention 21.29 ±0.89, and the usual group at base line was7.14 ±2.93 and at post intervention to be 8.00 ±1.53, with a p value of 0.62 at base line and <0.001at post intervention which is significant. This showed that improvement was noticed more in the intervention group than the usual group. This finding shows that intense diabetes education using the DSME significantly improved diabetes knowledge of type 2 diabetes.

The diabetes knowledge score/education programmed was carried out in an actual clinical setting where participants were allowed to take control of the management of their illness using the instructions given by the researcher. It can be ascribed to self-efficacy theory which is the foundation for DSCE. This theory is also reflected in the active group dialogue during which the researcher asked open-ended questions which encouraged participants to reflect on their experience in self-care, attitude changes, and overcoming psychosocial and environmental barriers to encourage the participants to find the answer by themselves.[5],[14],[22] By exploring instead of being taught, participants had more confidence in changing their behavior. Improvement in diabetes-related knowledge score were seen in similar studies reported that program length may change the effectiveness of educational interventions in Diabetes. He reported that achieving sustained improvements in patients' HbA1C levels will require long-term intervention compared to short term intervention.[7],[12],[25],[27] These studies reviewed some randomized controlled trials, with 64.0% reporting significant changes in HbA1C, reported that those with educational intervention who practiced DSCE in adults lasting one year and above had a better HbA1C as compared to those less than a year. With a statistically significant (87.5% significant vs. 12.5% non-significant) differences in changes in HbA1C between the intervention and the control subjects, recording an overall between-group HbA1C mean difference of 0.6+-0.3% (range = 0.2-1.2). This study only lasted for 5 months as against one year reported by Kumah and colleagues however statistical significance was still noticed in all the parameters mentioned in this study both after 12 weeks post intervention. One other study reported that there was no difference between participants who had self-management interventions and those who had usual care, when tested for HbA_{1c} levels, BMI, depression, diabetes-related distress, overall self-care diabetes knowledge and self-efficacy at the post intervention[17],[20],[24]This is in contrast to this study that reported a mean p value for glycosylated hemoglobin among the intervention and the usual group of <0.001 which is significant, and diabetic knowledge score with a p value of <0.001 both after 12 weeks, other parameters also checked included FBG, DSCBS, level of satisfaction all checked after 12 weeks all having a p value of <0.001 which were all statistically significant.

The mean summary of diabetes self-care activities (SDSCA) which evaluated the number of days participants adhered to personalized physician recommended activities was low among study participants at baseline. Self-Care Behavior Self-care behavior was measured by asking the participants to report which recommended activities for diabetes self-management they performed during the past

seven days. These activities included their general diet, specific diet, exercise, foot care, blood glucose monitoring, and smoking.

Majority of the parameters assessed after the interventions at 12weeks follow-up to ascertain the sustainability of the intervention revealed either no change or a diminished level. Overall, the mean Glycosylated Hemoglobin scores at baseline was10.18 ±1.79. The score decreased to 6.96 ±1.50 at the end of the intervention (12^{th} week). This was the pattern in most studies that have employed the use of any form of diabetes self-management education. [4],[25] In this study, the effect of DSCE was same for all parameters after 12 weeks. This can be explained by the fact that DSCE is effective for improving clinical outcomes at least in the short term. DSCE is therefore encouraged in the management of patient with type 2 diabetes.

Conclusion

DSCE is an important tool in the management of patients with type 2 diabetes mellitus. Although it is generally valued tool in the care of diabetic patients, it is often not used as an integral part of diabetes management in our clinics. Hence, the need for this study. The study demonstrated that people with type 2 diabetes experienced improved glycosylated hemoglobin. The mean difference (2.04) between the intervention and the usual care groups was statistically significant (95% CI = 2.35 – 3.73; p = <0.0001).

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Ethical consideration: Ethical approval for the study was obtained from the Ethical Committee of FMC Keffi. Informed consent was also obtained from each participant prior to the study. Confidentiality of all the data obtained during the study was masked. Participants had the rights to withdraw from the study at any point in time, without prejudice to their care

Limitations: The study used data from a single hospital. Therefore, our results may not apply to other hospitals.

Declarations: The authors have no competing interests to declare.

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