

## The Effectiveness of an Education Intervention on the Health-Related Quality of Life of Adolescents with Type 1 Diabetes Mellitus

Sherry Oluchina

Department of Nursing Education Leadership Management and Research, School of Nursing, Jomo Kenyatta University of Agriculture and Technology, (JKUAT), Nairobi, Kenya

**Correspondence:** Sherry Oluchina. Email address: soluchina@jkuat.ac.ke **DOI:** <u>https://dx.doi.org/10.4314/ajhs.v37i1.5</u>

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## Abstract

#### INTRODUCTION

The increasing prevalence rate has made diabetes a world epidemic. Type 1 diabetes mellitus has an impact on everyday life and in general, it reduces the health-related quality of life (HRQoL) of adolescents. Considering diabetes and its associated effects on patients' health-related quality of life, this interventional study was performed to promote the health-related quality of life using education based on the self-care model in Kiambu County, Kenya.

METHODOLOGY

The study was conducted from January to August 2021 at diabetic clinics of Thika Level 5 Hospital (TL5H) and Kiambu Level 5 Hospital (KL5H). The study employed a pre-test post-test non-equivalent quasi-experimental study design. There were 96 adolescents with Type 1 Diabetes Mellitus (T1DM) obtained by stratified random sampling technique, and assigned into experimental (48 respondents) and control group (48 respondents). Health-related quality of life (HRQoL) was evaluated in the first and seventh months using a Short Form health survey (SF-12) questionnaire. A paired sample T-test and an Independent T-test were used to analyze data. RESULTS

Paired sample T-test statistics revealed a significant difference in increasing HRQoL (p<0.05) before and after the intervention; Independent T-test discovered a significant difference in HRQoL (p<0.05) between the intervention and control group at post-intervention.

CONCLUSIONS

Education intervention based on a self-care model is an effective program that can improve HRQoL. In addition, the education intervention based on the self-care model needs to be implemented continuously to prevent diabetes-related complications and improve HRQoL for diabetic patients.

Keywords: Adolescents, Education, Health-Related Quality of Life, Self-Care Model, Type 1 Diabetes Mellitus

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#### Introduction

Type 1 diabetes mellitus (T1DM) is a serious and life-threatening disease. Type 1 diabetes mellitus, previously known as juvenile diabetes, is an autoimmune disease that originates when very little or no insulin is produced by the islets of Langerhans in the pancreas (1). Insulin is a hormone required for the cells to use blood sugar for energy and it helps regulate normal glucose levels in the bloodstream (1). Before treatment, this results in high blood sugar levels in the body. The common symptoms of this elevated blood sugar are frequent urination, increased thirst and hunger, weight loss, and other serious complications. Additional symptoms may



include blurry vision, tiredness, and slow wound healing (1).

Type 1 diabetes mellitus global and African incidence rates are increasing at approximately 3–4% and 2-3% per year respectively (2), but the reason for this is not yet clear (3). It was estimated in 2010, that 37,500 children under 14 years of age in Africa had T1DM (4). In Kenya, diabetes mellitus prevalence is 3.3%, and T1DM accounts for 10% of this. There were approximately more than 5,000 children under the age of 18 years with T1DM in 2015 in Kenya, which is expected to exceed 10,000 by 2030 (5).

Diabetes is among the costliest diseases all over the world charging high expenses to society (6). Because of its high burden, lasting effects, direct and indirect expenses on the health system, and the great influence on health-related quality of life, treating diabetes is of great importance. About 2.5 to 15 % of the health budget in countries is devoted to diabetes (7). Diagnosis of T1DM and its treatment results have a strong emotional impact on adolescents. Psychosocial problems such as anxiety, depression, suicidal tendencies and eating disorders have been documented among adolescents with T1DM attending Thika level 5 hospital (8). The chronic nature of T1DM, along with its associated complications, often leads adolescents to feel discomfort and a sense of losing control over their lives.

There was a significant effect of education on the improvement of awareness, behaviour, quality of life, and Hemoglobin A1c (HbA1c) levels among diabetic patients (9). Another study showed an increased HRQoL in diabetic patients in terms of different constructs after an educational intervention (10).Education interventions aim to manage the disease and promote health-related quality of life imposed by patients themselves (11). Education plays an important role in healthrelated quality of life in diabetic patients utilizing theories and educational models designated to increase patients' awareness and change their attitudes through engaging patients in healthy behaviour (11). Chronic diseases,

because of their lasting effects, can affect the quality of life of patients. The use of educational models is a considerable approach to promoting the quality of life of the patients (12).

Self-care model is a program that aims to modify the lifestyle of diabetes patients by combining seven components of behaviour as recommended by the American Association of Diabetes Educators (13). The AADE7 self-care behaviours provide an evidence-based framework for patient-centred diabetes selfmanagement, which is oriented to the active participation of diabetes patients with goals to increase their knowledge and self-care management. The seven essential self-care behaviours include healthy eating, being physically active, monitoring blood glucose, compliance with medications, good problemsolving, healthy coping and risk-reducing behaviours (13). By implementing the self-care model, diabetes patients can identify barriers, enhance problem-solving and increase awareness and skills to practice a healthy lifestyle to achieve a better and more productive life. This manuscript forms part of a larger study and aims to analyze the effectiveness of an education intervention based on the self-care model on HROoL.

## Materials and methods Study design, setting, and period

A pre-test post-test non-equivalent quasi-experimental study design was adopted. The study was carried out at the diabetic clinics of Thika Level 5 Hospital (TL5H) and Kiambu Level 5 Hospital (KL5H). A baseline survey was conducted from March to May 2021. Education intervention based on the self-care model was initiated in June 2021 and ended in November 2021. Finally, the end-line survey was conducted from December to February 2021.

# Study population and sample size calculation

The study population comprised of adolescents aged 10 to 19 years with T1DM attending diabetic clinics at TL5H and KL5H.



According to 2018/2019 diabetic statistics, an average of 60 and 55 adolescents with T1DM visited monthly diabetic clinics at TL5H and KL5H respectively. The study sample size was 96 adolescents with T1DM (48 each in the intervention and control arms).

#### Sampling

Simple random sampling was used to select the TL5H diabetic clinic as the intervention site among the two level 5 hospitals in Kiambu County. Stratified random sampling was used to sample participants from each study site to ensure equal representation.

#### Inclusion and exclusion criteria

The inclusion criteria were: adolescents aged 10 to 19 years diagnosed with T1DM at least three months living in Kiambu County and attending diabetic clinics of TL5H and KL5H and adolescents with T1DM who agreed to participate in a follow-up survey after six months. The exclusion criteria were: adolescents with T1DM with mental, visual, communication or learning disabilities and adolescents with T1DM with major medical illnesses.

#### Intervention

The intervention group was divided into three subgroups. The intervention group attended four diabetes self-management education (DSME) based on self-care model sessions, each lasting for approximately 90 minutes. The four DSME based on self-care model sessions were provided over four months. Each subgroup was instructed by the principal investigator. This was followed by monthly follow-ups for the next two months. The participants in the control group continued their usual care.

#### **Data collection**

Data were collected using an interviewer-administered structured questionnaire consisting of socio-demographic characteristics, diabetic-specific characteristics and HRQoL assessed using short form-12 (SF-12) which was adopted and permission to use it was granted by the Medical Outcomes Trust. The SF-12 investigates the patient's state of health via eight different dimensions namely: General Health, Physical Functioning, Role Physical, Role Emotional, Body Pain, Mental Health, Vitality and Social Functioning. The SF-12 yielded two summary measures, the physical composite scale (PCS-12) and the mental composite scale (MCS-12). The scores of SF-12 were linearly transformed on a 0–100 scale, with 100 indicating the highest level of HRQoL. The score cut-off point was 50%, where a score of  $\geq$  50% was categorized as better and < 50% as worse health status (14).

# Validity and reliability of data collection tools

The validity of the study tool was assured by pre-testing. Pre-testing of the study tool was conducted in the diabetic clinic at Mama Lucy Kibaki Hospital. The study tool was revised and corrections were made to some questions that were found to be ambiguous. The data collected was further cleaned, coded and analyzed using STATA version 14 and Cronbach's alpha computed to test the reliability of each study construct scale in the questionnaire. The results showed that the Cronbach's alpha for all the constructs was > 0.7 which indicated that all the items were reliable.

#### Data analysis

The questionnaires were cross-checked for errors, coded and entered into Statistical Package of Social Sciences (SPSS) version 26 software for data analysis. A T-test was used to analyze differences in continuous data between the mean scores of the intervention and control arms. Paired sample T-Test was used to determine whether there were statistically significant differences before and after the intervention, while Independent T-test was done to find the significant difference between the groups of study. A P-value of < 0.05 at a 95% confidence interval was considered significant in the study.

#### **Ethical consideration**

Ethical clearance to carry out the research was sought from the JKUAT Institutional Ethics Review Committee



(reference number: JKU/IERC/02316/0015). Permission to carry out the study was sought from the National Commission for Science Technology and Innovation (reference number: NACOSTI/P/20/7746/779807). Permission to carry out the study was also sought from Kiambu County Health Research Department, TL5H and KL5H administration. Participant's autonomy and privacy were maintained and any information shared with them was confidential. The principal investigator sought a signed informed assent and consent from participants who were 10 to 17 and 18 to 19 years old respectively. For the participants who were under 18 years old, informed consent was also obtained from their parents/guardians. The

#### Table 1:

Socio-Demographic Characteristics of Respondents

participants were not coerced to participate in the study. The privacy of participants was considered during the educational intervention and data collection. The filled study tools were kept in a secure place.

#### Results

# Socio-demographic characteristics of respondents

Most of the respondents in both groups were aged between 10-13 years old, female, in a primary level of education, and living together with two parents. The majority of respondents had the primary caregiver as their mother and their primary caregiver had reached tertiary level education (Table 1).

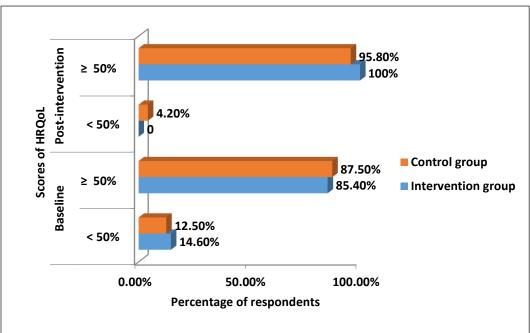
Variable	Category	Control n (%)	Intervention n (%)	Total n (%)
Age in years	10 -13	25 (52.1%)	18 (37.5%)	43 (44.8%)
	14-17	16 (33.3%)	17 (35.4%)	33 (34.4%)
	≥ 18	7 (14.6%)	13 (27.1%)	20 (20.8%)
Gender	Male	23 (47.9%)	20 (41.7%)	43 (44.8%)
	Female	25 (52.1%)	28 (58.3%)	53 (55.2%)
Education level	None	1 (2.1%)	2 (4.1%)	3 (3.1%)
	Primary	24 (50.0%)	20 (41.7%)	44 (45.8%)
	Secondary	18 (37.5%)	20 (41.7%)	38 (39.6%)
	Tertiary	5 (10.4%)	6 (12.5%)	11 (11.5%)
Family structure	2 parents living together	35 (72.9%)	33 (68.7%)	68 (70.8%)
	Single parent	10 (20.8%)	12 (25.0%)	22 (22.9%)
	Not living with parents	3 (6.3%)	3 (6.3%)	6 (6.3%)
Primary caregiver	Mother	38 (79.2%)	38 (79.2%)	76 (79.2%)
	Father	7 (14.5%)	8 (16.7%)	15 (15.6%)
	Others (relatives, friends)	3 (6.3%)	2 (4.1%)	5 (5.2%)
Primary caregiver	None	3 (6.3%)	2 (4.1%)	5 (5.2%)
education level	Primary	3 (6.3%)	5 (10.5%)	8 (8.3%)
	Secondary	18 (37.4%)	24 (50.0%)	42 (43.8%)
	Tertiary	24 (50.0%)	17 (35.4%)	41 (42.7%)

#### Table 2:

Diabetic-Specific Characteristics of the Respondents

Variable	Category	Control n (%)	Intervention n (%)	Total n (%)
Duration of T1DM in	1-5	37 (77.1%)	39 (81.2%)	76 (79.2%)
Years	6-10	11 (22.9%)	9 (18.8%)	20 (20.8%)
Body mass index	Underweight (< 18.5)	7 (14.6%)	6 (12.5%)	13 (13.5%)
(kg/m <sup>2</sup> )	Normal (18.5 - 25.0)	37 (77.1%)	39 (81.2%)	76 (79.2%)
	Overweight (> 25.0)	4 (8.3%)	3 (6.3%)	7 (7.3%)
Family history of	None	4 (8.3%)	5 (10.4%)	9 (9.4%)
Diabetes	Present	44 (91.7%)	43 (89.6%)	87 (90.6%)
Insulin regime	2 daily injections	33 (68.8%)	32 (66.7%)	65 (67.7%)
-	Multiple daily injections	15 (31.2%)	16 (33.3%)	31 (32.3%)





#### Figure 1:

Percentage of Respondents According to Scores of HRQoL in the Intervention and Control Groups of the Study at Baseline and Post-Intervention

#### Table 3:

Independent Samples T-Test on Pre-Test scores for HRQoL in the Intervention and Control Arms of the Study

HRQoL scores										
Variable	Group	Ν	Mean	SD	Mean	T-test	Df	p-	<u>95%</u>	<u>C.I.</u>
					difference	value		value	Lower	Upper
Physical Functioning	Intervention	48	75.52	29.40	-1.56	-0.277	94	0.782	-12.75	9.627
	Control	48	77.08	25.70						
Physical role	Intervention	48	80.47	16.49	5.99	1.707	94	0.091	-0.977	12.96
	Control	48	74.48	17.86						
Bodily pain	Intervention	48	71.35	23.63	4.17	1.037	79	0.302	-3.833	12.17
	Control	48	67.19	14.73						
General Health	Intervention	48	55.73	23.77	0.52	0.106	94	0.915	-9.193	10.23
	Control	48	55.21	24.17						
Vitality	Intervention	48	59.17	25.75	4.17	0.858	94	0.393	-5.472	13.81
	Control	48	55.00	21.64						
Social role	Intervention	48	71.88	26.11	7.29	1.601	83	0.113	-1.770	16.35
	Control	48	64.58	17.74						
Emotional role	Intervention	48	58.33	39.05	-5.21	-0.608	92	0.544	-22.21	11.79
	Control	48	63.54	44.65						
Mental health	Intervention	48	64.79	19.46	-5.63	-1.498	94	0.137	-13.08	1.828
	Control	48	70.42	17.25						
PCS-12	Intervention	48	70.77	14.44	2.28	0.711	92	0.479	-4.084	8.641
	Control	48	68.49	16.86						
MCS-12	Intervention	48	63.54	18.75	0.15	0.039	94	0.969	-7.899	8.212
	Control	48	63.39	20.94						
HRQoL	Intervention	48	67.15	13.64	1.21	0.373	88	0.710	-5.266	7.701
	Control	48	65.94	18.03						



#### **Diabetes-specific characteristics**

Most of the respondents in both groups had T1DM between 1-5 years, a normal body mass index (18.5 -25.0 kg/m<sup>2</sup>), and a positive history of diabetes in the family. Regarding the insulin regime, the majority of the respondents were using 2 daily injections (Table 2).

# Health-Related QoL (HRQoL) in the intervention and control arms of the study

The proportion of participants who had a score of < 50% decreased from 14.6% (n=7) and 12.5% (n=6) at baseline to 0.00% and 4.2% (n=2) at post-intervention in the intervention and control groups respectively. The proportion of participants who had a score of  $\geq$  50% increased from 85.4% (n=41) and 87.5% (n=42) at baseline to 100% (n=48) and 95.8% (n=46) at post-intervention in the intervention and control groups respectively (Figure 1). As presented in Table 3 after the independent-samples t-test there was no statistically significant difference in the mean score difference of all domains and sub-domains of HRQoL between the pre-test scores for the intervention and control groups.

After the independent-samples t-test, there was a statistically significant difference in the mean score difference of bodily pain, vitality, social role, emotional role, mental health, PCS-12, MCS-12 and HRQoL between the post-test scores for the intervention and control groups. (Table 4).

Table 5 revealed that after the pairedsamples t-test, there was a statistically significant difference in the mean score difference of physical functioning, general health, social role, emotional role, mental health, PCS-12, MCS-12 and HRQoL between the pre and post-test scores for the intervention group.

#### Table 4:

Independent Samples T-test On Post-Test Scores for HRQoL in the Intervention and Control Arms of the Study

HRQoL scores										
Variable	Group	Ν	Mean	SD	Mean	T-test	Df	p-	95% C.I.	
					difference	value		value	Lower	Upper
Physical Functioning	Intervention	48	90.10	14.35	7.29	1.855	78	0.067	-0.535	15.12
	Control	48	82.81	23.15						
Physical role	Intervention	48	80.73	13.63	2.34	0.765	94	0.446	-3.736	8.424
	Control	48	78.39	16.26						
Bodily pain	Intervention	48	77.60	14.80	15.10	5.198	94	<0.001	9.335	20.87
	Control	48	62.50	13.64						
General Health	Intervention	48	64.06	19.91	5.73	1.503	94	0.136	-1.842	13.30
	Control	48	58.33	17.36						
Vitality	Intervention	48	66.67	17.18	15.00	3.332	81	0.001	6.042	23.96
	Control	48	51.67	26.04						
Social role	Intervention	48	80.21	17.83	14.06	4.079	94	< 0.001	7.218	20.91
	Control	48	66.15	15.89						
Emotional role	Intervention	48	85.42	25.18	15.63	2.365	81	0.020	2.479	28.77
	Control	48	69.79	38.23						
Mental health	Intervention	48	83.33	10.98	11.45	4.811	94	<0.001	6.729	16.19
	Control	48	71.88	12.32						
PCS-12	Intervention	48	78.13	9.76	7.62	3.291	88	0.001	3.017	12.22
	Control	48	70.51	12.73						
MCS-12	Intervention	48	78.91	10.79	14.04	5.590	94	<0.001	9.051	19.02
	Control	48	64.87	13.65						
HRQoL	Intervention	48	78.52	9.11	10.83	5.099	94	<0.001	6.611	15.04
	Control	48	67.69	11.55						



Table 5:
Paired Samples T-Test On Pre and Post-Test Scores for HRQoL in the Intervention Arm of the Study

	HRQoL scores										
Variable	Group	Ν	Mean	SD	Mean	T-test	Df	p-value	959	% C.I.	
					difference	value			Lower	Upper	
Physical	Before	48	75.52	29.40	-14.58	-4.292	47	<0.001	-21.42	-7.748	
Functioning											
	After	48	90.10	14.35							
Physical role	Before	48	80.47	16.49	-0.26	-0.139	47	0.890	-4.041	3.520	
	After	48	80.73	13.63							
Bodily pain	Before	48	71.35	23.63	-6.25	-1.854	47	0.070	-13.03	0.530	
	After	48	77.60	14.80							
General Health	Before	48	55.73	23.77	-8.33	-3.483	47	0.001	-13.15	-3.520	
	After	48	64.06	19.91							
Vitality	Before	48	59.17	25.75	-7.50	-1.806	47	0.077	-15.85	0.854	
	After	48	66.67	17.18							
Social role	Before	48	71.88	26.11	-8.33	-2.318	47	0.025	-15.57	-1.100	
	After	48	80.21	17.83							
Emotional role	Before	48	58.33	39.05	-27.09	-4.869	47	<0.001	-38.27	-15.89	
	After	48	85.42	25.18							
Mental health	Before	48	64.79	19.46	-18.54	-6.716	47	<0.001	-24.10	-12.99	
	After	48	83.33	10.98							
PCS-12	Before	48	70.77	14.44	-7.36	-4.403	47	<0.001	-10.72	-3. 995	
	After	48	78.13	9.76							
MCS-12	Before	48	63.54	18.75	-15.37	-6.816	47	<0.001	-19.90	-10.83	
	After	48	78.91	10.79							
HRQoL	Before	48	67.15	13.64	-11.37	-8.371	47	<0.001	-14.09	-8.630	
	After	48	78.52	9.11							

#### Table 6:

Paired Samples T-test on Pre and Post-Test Scores for HRQoL in the Control Arm of the Study

HRQoL scores										
Variable	Group	Ν	Mean	SD	Mean	T-test	Df	p-	95% C.I	•
	-				difference	value		value	Lower	Upper
Physical Functioning	Before	48	77.08	25.70	-5.73	-2.115	47	0.040	-11.18	-0.280
	After	48	82.81	23.15						
Physical role	Before	48	74.48	17.86	-3.91	-1.880	47	0.066	-8.086	0.273
	After	48	78.39	16.26						
Bodily pain	Before	48	67.19	14.73	4.69	1.770	47	0.083	-0.640	10.01
	After	48	62.50	13.64						
General Health	Before	48	55.21	24.17	-3.12	-1.430	47	0.159	-7.523	1.273
	After	48	58.33	17.36						
Vitality	Before	48	55.00	21.64	3.33	0.727	47	0.471	-5.894	12.56
	After	48	51.67	26.04						
Social role	Before	48	64.58	17.74	-1.57	-0.503	47	0.617	-7.810	4.685
	After	48	66.15	15.89						
Emotional role	Before	48	63.54	44.65	-6.25	-1.098	47	0.273	-17.70	5.203
	After	48	69.79	38.23						
Mental health	Before	48	70.42	17.25	-1.46	-0.655	47	0.516	-5.940	3.024
	After	48	71.88	12.32						
PCS-12	Before	48	68.49	16.86	-2.02	-1.628	47	0.110	-4.512	0.476
	After	48	70.51	12.73						
MCS-12	Before	48	63.39	20.94	-1.48	-0.635	47	0.529	-6.190	3.221
	After	48	64.87	13.65						
HRQoL	Before	48	65.94	18.03	-1.75	-1.131	47	0.264	-4.866	1.363
	After	48	67.69	11.55						



Table 6 revealed that after the pairedsamples t-test, there was a statistically significant difference in the mean score difference of physical functioning between the pre and post-test scores for the control group.

### Discussion

Health-related quality of life is a outcome measure patient-reported that evaluates the extent to which diseases, disability, and treatment affect the health status of patients (15, 16, 17). Several studies have demonstrated that diabetes harms the overall health-related quality of life (HRQoL) (18, 19, 20). The present study identified a better HRQoL. This finding was in line with studies that noted that participants with T1DM rated HRQoL scores as good (21, 22). Other studies done in Iran, India and Middle Eastern countries but used different measurement scales, also affirmed the findings (23, 24, 25). However, in studies done in Palestine, Nigeria and Uganda the HRQoL score of participants with T1DM was low (26, 27, 28). This was probably due to the demand for the disease.

The study revealed that the participants had a higher score on PCS-12 than MCS-12. This finding was similar to studies that found that MCS-12 was more severely affected than PCS-12 (29, 30, 31, 32). This consistency could be justified by patients with T1DM having lower rates of complications which do affect their physical ability. Contrary, a study conducted in Australia indicated that MCS-12 was better than PCS-12 (33). The MCS-12 was better because the patients had gained more experience in self-management of the disease. There was no statistically significant difference observed in the HRQoL of participants in the intervention and control groups at baseline. This finding agreed with findings from other studies (34, 35).

After six months of education intervention, HRQoL improved substantially in the intervention in comparison to the control group. These results were consistent with other studies (36, 37, 38). There was a significant difference between five sub-domains of SF-12 (physical functioning, general health, social role, emotional role, and mental health), PCS-12, MCS-12 and HRQoL of respondents of the intervention group before and after the intervention. Similarly, there was ample evidence from different interventional studies for the positive impact of educational programs on various aspects of HRQoL and overall wellbeing in the experimental arm at post-test (39, 40). The findings were inconsistent with diabetes self-management interventions offered to low-income diabetic patients (41), peer-led diabetes self-management support (DSMS) (42), and diabetes education supported with counselling and telephone follow-up sessions (43). The inconsistency in the findings was due to various factors that impacted the effect of the intervention on HRQoL.

#### Conclusion

Educational intervention based on the self-care model significantly increased HRQoL. The mean for HRQoL increased from  $67.15\pm13.64$  to  $78.52\pm9.11$  in the intervention arm and decreased from  $65.94\pm18.03$  to  $67.69\pm11.55$  in the control arm. The study recommends that education intervention based on a self-care model needs to be implemented continuously to improve the HRQoL of diabetic patients.

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