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How do multi-modality strategies affect outcomes in T2D using a randomized control trial?

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ABSTRACT

Objective: A randomized clinical trial to examine the levels of body mass index, fasting blood glucose, blood pressure and glycemic control using multi-modality strategies among adults with type 2 diabetes.
Methods: A randomized control trial (RCT), two-arm, prospective, and an interventional was designed with an intervention group (IG) and a control group (CG) using stratified block randomization and triple-blinding. Adults with T2D (N = 200) were randomly assigned to an intervention group (IG, n = 100) and a control group (CG, n = 100) in a single site trial. The adults with T2D in the IG were exposed to multi-modality strategies using an animated digital video, motivational interviewing, telephone counseling and the structured diabetes education by the diabetes nurse educator. Adults in the CG were only exposed to the structured diabetes education. Body mass index (BMI), fasting blood glucose (FBG), blood pressure (BP), and glycosylated hemoglobin (HbA1c) were measured as primary outcomes.
Results: The adults with T2D in the IG had significant improvements in the HbA1c (2.4%), BMI (2.8 kg/m^2), and a FBG (1.8 mmol/L); and they achieved lower HbA1c levels compared to the CG.
Conclusion: Multi-modality strategies were effective for lowering HbA1c and reducing BMI among adults with T2D. Implications. Integration of cognitive behavioural educational using multi-modality strategies promoted better primary outcomes among adults with T2D.

1. Introduction

Diabetes Mellitus is a chronic disease that requires life-long management and continuous monitoring to prevent complications. An individual is diagnosed with diabetes mellitus (DM) every seventh second resulting in about 4 million deaths in a year across the globe.[1] About 387 million people around the globe have DM, and 179 million people with DM are undiagnosed.[2] These figures are expected to rise to 592 million in 2035.[3] Nearly 3.4 million die due to complications of DM and of which 80% of the deaths occur in the low and middle-income countries.[4] Type 2 diabetes (T2D) is expected to rise to 350 million cases by 2030. DM has increased dramatically in the Middle East.[5] In 2013, the prevalence of diabetes in Oman was estimated to be 8.01% or 199, 780 people with diabetes and is expected to increase to 217,000 in 2025.[6] This significant increase is attributed to rapid economic prosperity and urbanization,[7] lifestyle and sedentary behaviours.[8]

Diabetes mellitus is a challenge to health professionals, including nurses as the adults need to be empowered for a lifelong self-care management. Socio-cultural factors influence an individual's actions towards goal attainment and outcomes like body mass index, fasting blood glucose, blood pressure and glycemic control. Telephone counseling[9,10] and motivational interviewing[11] have increased activities of daily living and follow up. The study aimed to examine the clinical primary outcomes using cognitive behavioural multi-modality strategies among Omani adults with T2D.

2. Methods

2.1. Aim

A randomized clinical trial to examine the levels of body mass

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index, fasting blood glucose, blood pressure and glycemic control using multi-modality strategies (MMS) among Omani adults with type 2 diabetes.

2.2. Research question

How does multi-modality strategies affect outcomes in T2D using a randomized control trial?

2.3. Design

A randomized control trial (RCT) prospective interventional design, clustered by use of multi-modality strategies with an intervention group (IG) and control group (CG) was used in the study. The two-arm (intervention vs control) RCT was used to evaluate the effects of the multi-modality strategies in reducing the primary outcomes (body mass index, fasting blood glucose, blood pressure and glycosylated hemoglobin) among adults with T2D.

2.4. Randomization and assignment

A stratified block randomization system was created using Stata's ralloc procedure[12] to generate the blocks and later a random allocation sequence. The ralloc procedure was used to create balanced sequences of group assignments randomly permuted in blocks of size 2 and four within each stratum. This was achieved was generating two separate blocks for gender (male and female), and body mass index (< 24.9 and $> 25\,kg/m^2$) as a criterion for stratification to balance the number of adults within each stratum. An adult was assigned to the appropriate stratum and then assigned to a group based on the random sequence of group assignments. After the adults were assigned into blocks, a simple randomization using a random number table was performed within each block to allocate the adults to the intervention and the control group (two arms).

2.5. Sample size

The medium effect size was substantial to be detected by the naked eye to detect a 0.6% difference in individual HbA1c between the intervention group (IG) and the control group (CG).[13] A repeated measures ANOVA design required two groups of 64 adults each for a total of 128 adults. This design achieved 80% power when an F-test was used to test the group factor at a 5% significance level (two-tailed). The sample size was calculated using the formula,

$$n = \frac{z^2 p(1-p)}{\varepsilon^2}$$

Where, n = sample size, z = Value for the z distribution (1.96) based on the desired level of confidence (95%), p = The estimated proportion of a parameter from earlier studies. In this case, it is the proportion of the population that fall into a specific category that needs to be estimated. For this kind of study, it is recommended to used 14.5%,[14] ε = error of the estimate and it was assumed 0.05.

Hence,

$$n = \frac{1.96^2 \times 0.14(1-0.14)}{0.05^2} = 185$$

A total sample size of 200 adults with T2D was considered adequate to take into account possible attrition (5%) (Fig. 1). The selected adults were randomly assigned to the intervention group [IG = 100] and the control group [CG = 100] from the two outpatients' clinics in a selected public hospital after the baseline assessment.

2.6. Inclusion criteria

Omani adults were eligible for the study if they were aged ≥18 years and above met the medical diagnosis of T2D, were treated by anti-diabetes medications, spoke and understood Arabic or English, had access to a telephone in residence that they were able to use effectively, and who were able to travel to the clinic.

2.7. Exclusion criteria

Omani adults were excluded from the study if they had complexity health problems (e.g. sensory illness, stroke, heart, liver, kidney, foot ulcer, advanced cancer, visual or cognitive impaired), or taking medications indicated for weight loss, systemic or autoimmune that may confound the outcomes or impact their participation in the study.

2.8. Primary outcomes

The primary clinical outcomes measured were fasting blood glucose (FBS in mmol/L), glycosylated haemoglobin (HbA1c in %), systolic and diastolic blood pressure (SBP/DBP in mm Hg), and body mass index (BMI in kg/m^2) in ISI units. Demographic and clinical data used were age, gender, education, income, duration of diabetes, diabetes education and medication with the identifiers name, address, phone numbers, and occupation. Five clinical nurses and physicians evaluated the content validity of demographic and clinical instruments. The instruments were translated into Arabic and back-translated and were administered face to face by the research assistants.

2.9. Data collection procedure

Announcements about the research study were projected on the television in the waiting rooms, hospital bulletin boards, local newsletters, and brochures were distributed in the outpatient clinics of the selected hospitals. Adults who were interested in voluntary participation in the study approached the study team for the information sheet and enrollment in the study. The study protocol included a cover letter describing the study's risks and benefits, the incentives, and the 3-page survey questionnaire was given to all the adults who met the eligibility criteria. These adults were drawn into a common pool to form the sampling framework during the study period between 2 January 2015 and 30 July 2016. Research assistants were provided training in conducting a review of literature, data collection, monitoring the interventions, bioethics, interventions protocols, data entry, and data coding.

Baseline assessment was collected from the adults who met the eligibility criteria. After the baseline assessment, the adults were randomly assigned to either the control or intervention group and were assessed at the end of 3 months (T2) after 90 days and the end of 6 months (T3) after 180 days to assess the maintenance or an effect of all the measures. Before the end of the 3 months and at the end of the 6 months, the adults were contacted via telephone, a post-card reminder, and a postal letter reminding of them of the study protocol. The adults in the intervention group were provided the intervention protocol and did not disclose the intervention to the control group. The randomized control group was offered the intervention protocol on completion of the study.

Confidentiality was maintained with the use of study codes to protect the identifying information (e.g. name, address, phone number, education, occupation) of the adults. Study codes or identification numbers (IDs) were used on the surveys to protect the adult's responses and prevent anyone viewing the data from determining the adult's identity. The adult's responses/data was linked by assigning each adult to a study ID (e.g. 0001) prior to collecting the data. On a separate document, each adult's name and their unique study ID was recorded. This document was stored separately from the data survey. When the data was collected, each adult's unique study ID was inserted onto their data document. This study ID was used on all their survey forms and allowed to match the survey data to the primary outcomes. Data

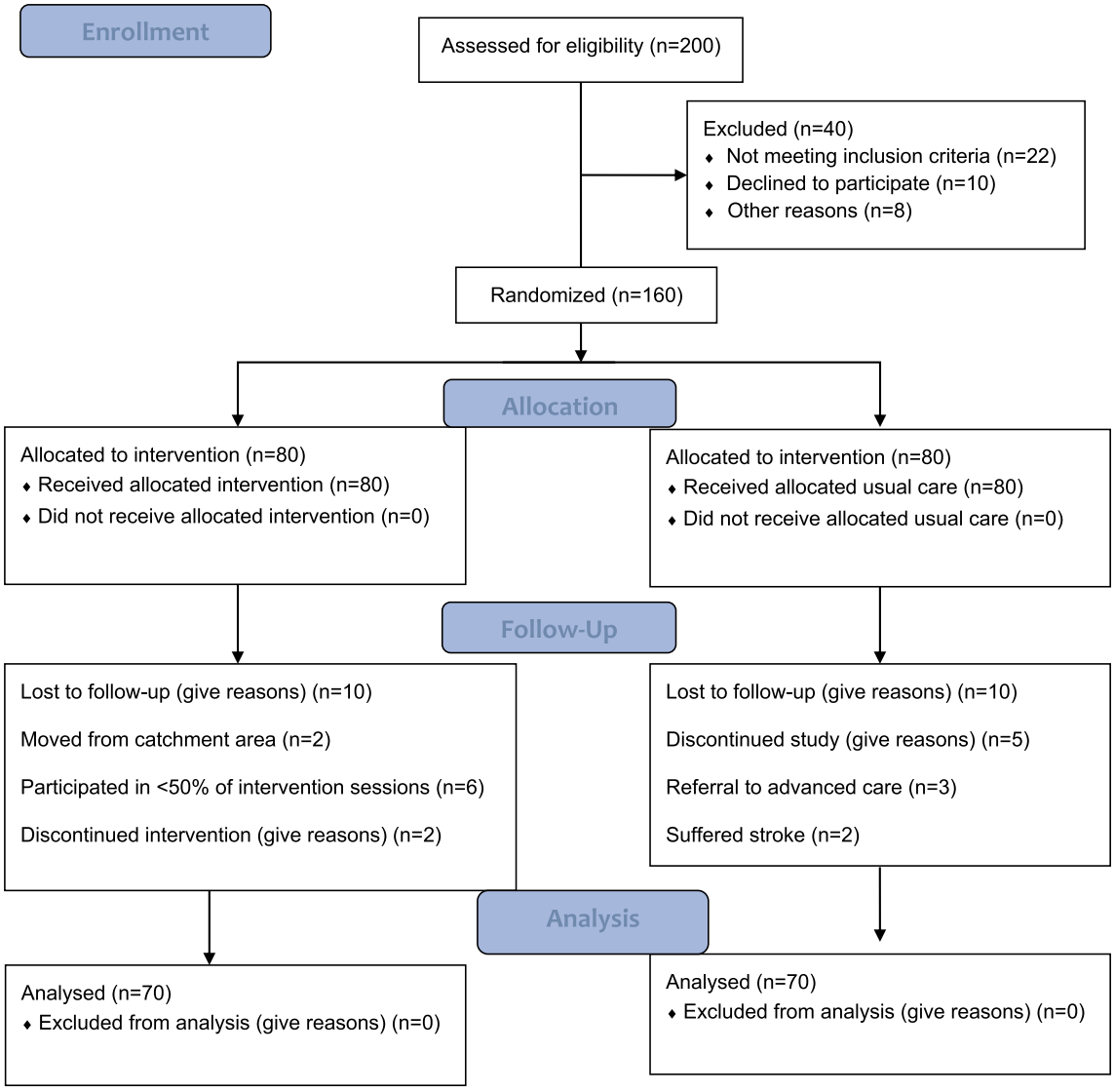

Fig. 1. CONSORT flow diagram.

information was anonymous, and the adult's name with the identifiers was removed from the cover sheet on the datasheet responses to protect the adults' identity after completion.

2.10. Development and validation of interventions

The intervention group (intent to treat) received the cognitive behavioural education using the multi-modality strategies (MMS) provided by the diabetes nurse educator (DNE) in the outpatient diabetes clinic in a selected hospital. The MMS included a structured diabetes education, an animated digital video, motivational interviewing, and a telephone counseling. The MMS contained skills enhancement, self-goal setting, and peer support aimed to encourage self-care behaviors, improve lifestyle, engage in problem-solving, and to enable an action plan. Adults in the control group (CG) received only the structured diabetes booklet as a routine and standard hospital information in the outpatient clinics performed by the nurse educator in the outpatient clinic in the selected hospital. The cognitive behavioural education using the MMS was evaluated by three diabetes nurses and physicians who validated the intervention protocols.

The intervention group (IG) consisted of 10 adults signed up a cognitive behavioural educational with the diabetes nurse educator for one weekly session (3 h each session). A total of 24 h of structured diabetes education using the animated digital videos was facilitated by a diabetes nurse educator (DNE) in the first two months. This interactive group session utilised a concept mapping and problem-solving on the hyper and hypoglycemia, lifestyle, management, blood glucose monitoring, dietary, physical activity, weight loss, foot care, medications, insulin, aerobic and resistance exercise, prevention of complications, being active, and stress management.

Motivational interviewing is an individual face-to-face and patient-centered individual counseling to facilitate cognitive behavioural change. This session was delivered by the DNE as the facilitator for 30 min for two sessions each month (every 2 weeks) in the consecutive four months (a total of 8 sessions). This interviewing session included an orientation, positive/supportive feedback, trust, and cooperation that focused on increasing performance, self-efficacy, sharing experience, using gentle verbal persuasion approach and a self-evaluation.

The telephone counseling was administered by the diabetes nurse educator in the allocated intervention sessions for one session each month (15 min) in the last three months until the end of the intervention (a total of 3 sessions). Telephone calls were structured by a computerized interview protocol consisting of cognitive behavioural modification (e.g. increase in call frequency, referral to the physicians/dietician or podiatrist as needed). E.g. Over the past week, how do you rate your physical health status, elaborate? The purpose of the call was

to foster continued performance accomplishment and goal-attainment via gentle verbal persuasion focused on self-care behaviors and self-care activities.

2.11. Quality and rigour of the interventions

A pilot intervention was conducted to evaluate the use and feasibility of the multi-modality strategies (MMS) among ten Omani adults with T2D. The pilot study showed appropriateness of the content, credibility, user-friendliness, easy features and functionalities of the technology pedagogy. The two-arm RCT in the main study was a prospective 6-month study among adults with T2D implemented in the two outpatient clinics of a selected public hospital.

A computerized minimization combined with allocations kept in a locked encrypted computer file sequentially numbered was undertaken by a statistician blind to practice identity to conceal randomization sequence. Triple-blinding was used by which the intervention was unknown to the participating adults, the nurse educators administering the intervention, and the research assistants and investigators who evaluated the response to intervention, managed the data and outcome assessors and statisticians who analyzed the outcomes did not know which adults were exposed to the intervention.

To enhance the fidelity and rigor of the intervention delivery the diabetes nurse educators participated in the intensive self-care management (SCM) training with a systematic protocol, the theoretical framework of the intervention, group management skills, and training in implementing the intervention protocol. The SCM training program incorporated didactic, interactive sessions using the multi-modality strategies, simulated demonstrations using human standardised patients and videos with feedback, skills enhancement, teaching-learning process, interviews, and in-vivo observation followed by debriefing. Quality control checklists served to monitor delivery or omissions of intervention components. Intervention protocols, timing, feedback and evaluation were monitored by the research assistants at every visit of the adult to ensure the accuracy of content and the intervention to enhance treatment fidelity and rigor.

2.12. Ethical considerations

Human and research ethics approval was granted by the Institutional, College, and the Hospital Ethics Review Board for a single site trial in a selected hospital. Participation was voluntary, and withdrawal from the study was permitted without any consequences to personal and health care in the study. The two-arm RCT was registered in the International Standard Randomized Controlled Trial Number Trial ID: ISRCTN14410756.

2.13. Data management and analysis

An alpha-numeric code (e.g. 517 T) was provided for each study ID (e.g. 0001), which corresponded to key administrative data associated with each adult in the study. When the survey was completed, so was the administrative data was merged, e.g., a code such as “517 T", indicating an adult was aged 51 years, had 7 years of diabetes, and worked as a teacher. Two separate interrelated computerized files: an administrative file containing the adults' name and administrative codes (e.g. 517 T), which were used to generate the codes and a tracking file containing their names and study ID (e.g. 0001). When the confidential surveys were collected by the research assistants, the study ID was entered into the tracking file. The completed data entry of the adults automatically deleted their name and ID from the tracking file and triggered a simultaneous deleting of their name and administrative code from the administrative file. The unique study and the alpha-numeric codes were kept as separate documents locked in a separate location with a restricted access to these surveys and were properly destroyed after the study.

Data coding, data entry, and double checking were carried out on an encrypted identifiable database. Security codes were assigned to these computerized records. Data was double entered, and discrepancy checks carried out with the participant surveys. Range and consistency checks were performed to find erroneous or inconsistent values, which were then corrected according to the original questionnaire. Missing data were replaced with the last value carried forward. There were no significant differences between the analysis with and without missing data.

Data analysis was performed using SPSS version 25.0 software package. Descriptive statistics were used to examine the demographics and clinical characteristics, establish the frequency and percentage for the dichotomous variables, and the mean and SD for the continuous variables. T-tests were used to analyze differences in continuous data between the mean score for the two groups. To assess the group differences independent variable changes, repeated ANOVA/ANCOVA for repeated measures, the Multivariate General Linear Model and General Linear Model were used.

3. Results

3.1. Demographic and clinical characteristics

The experimental and control groups did not significantly differ in demographic and clinical characteristics (Table 1 and Table 2) before the intervention. This shows the homogeneity between the two groups. These characteristics were not adjusted in the inferential statistics. Both the groups did not significantly differ in the HbA1c, FBG, BMI, and BP levels. There were 65.71% and 58.57% men in the IG and CG compared to the women (34.29% and 41.43%) (Table 1). 41.43% and 57.14% had $\geq$8% HbA1c in the IG and CG compared to the adults with Hb1c between 7.01 and 7.99% (41.43% and 28.57%) respectively in the IG and CG respectively (Table 2).

3.2. Differences between the intervention vs control groups

At the T2 (end of 3 months) and the T3 (end of 6 months) phases, the mean HbA1c, FBG, BMI, and BP levels were reduced significantly in the IG group than in the control group (Table 3). Adults in the IG significantly improved their mean HbA1c levels from the T1 (baseline) to the T2 and from the T2 to the T3 phase. In the CG there was no significant improvement from the T1 to the T3 phases. The HbA1c level of Omani adults with T2D decreased from 8.7% to 7.4% at baseline to the end of three months and 7.4%–6.3% at the end of 6 months, corresponding to a decrement of 2.4% compared with a 1.2% decrement in the IG (Table 3). The mean FBG level for the IG and the CG was similar at the baseline 9.5 mmol/dl respectively. In the IG, the FBG reduced at the end of 3 and the end of 6 months post-intervention respectively (7.7 mmol/L and 8.8%). The mean FBG value decreased in IG more than CG (mean difference of 1.8 mmol/dl vs 0.7 mmol/dl) and was significantly higher. A decrease or improvement of FBG in the IG was more significant than that in the control group (a difference in change of 1.8 mmol/l).

3.3. Effectiveness of multi-modality strategies

The mean body mass index, fasting blood glucose, blood pressure, and HbA1c levels were significantly higher and positive at the end the three months ($p < 0.04$, $p < 0.00$ and $p < 0.00$) and at the end of 6 months ($p < 0.05$, $p < 0.00$ and $p < 0.00$) in the IG compared to the CG (Table 4).

3.4. Predictors of primary outcomes

Gender, education, and duration of diabetes were strongly higher and positively influencing the FBG, HbA1c, BMI and BP among adults

Table 1
Demographic and clinical characteristics among adults with type 2 diabetes N = 140.

Variables	Categories	Experimental n = 70, n (%)		Control group N = 70, n (%)		Total group N = 140		χ^2/t	p
		F	P	F	P	F	P		
Gender	Male	46	65.71	41	58.57	87	62.14	0.06	0.81
	Female	24	34.29	29	41.43	53	37.86		
Age (years)	30–39 years	6	8.57	11	15.71	17	12.14	0.21	0.64
	40–49 years	18	25.71	23	32.86	41	29.29		
	50–59 years	29	41.43	16	22.86	45	32.14		
	> 60 years	17	24.29	20	28.57	37	26.43		
Income (Omani Riyals/OR)	< 500 OR	14	20.00	17	24.29	31	22.14	0.3	0.46
	501-1000 OR	22	31.43	27	38.57	49	35.00		
	1001-1500 OR	23	32.86	12	17.14	35	25.00		
	1501-2000 OR	11	15.71	14	20.00	25	17.86		
Education	No schooling	11	15.71	17	24.29	28	20.00		
	Primary/High school	32	45.71	34	48.57	66	47.14	1.52	0.47
	Bachelors/Master degree	27	38.57	19	27.14	46	32.86		
Duration diabetes	< 4 years	15	21.43	19	27.14	34	24.29	0.53	0.43
	5–10 years	25	35.71	17	24.29	42	30.00		
	10–15 years	19	27.14	23	32.86	42	30.00		
	> 15 years	11	15.71	11	15.71	22	15.71		
Diabetes education	No	40	57.14	46	65.71	86	61.43	0.56	0.38
	Yes	30	42.86	24	34.29	54	38.57		
Medication	Insulin and OHA	22	31.43	19	27.14	41	29.29	0.73	0.51
	Oral hypoglycemic	48	68.57	51	72.86	99	70.71		

with T2D (Table 5). Gender, education, diabetes education and duration of diabetes was significantly correlated with FBG, HbA1c, BMI and BP levels (Table 6). Adults who perceived FBG and HbAc1 to be highly significant were more likely to report increase diet, exercise, adherence to medications and self-monitoring of blood glucose. 23.2% of the variance of FBG and 32.7% of the variance of the HbA1c levels was positively explained by gender, education, diabetes education and duration of diabetes (Table 5).

4. Discussion

4.1. Demographic and clinical characteristics

Omani adults with higher age, education, and income reported increased physical activity and monitoring more frequently than adults with less education and income. Advancing age and complexity of problems exposed these adults to follow up visits and information awareness promoting better adherence. In this study, education, and income motivated men to engage in conditioning exercises and fitness outdoors. Employed Omani adults reported higher performance of exercises more habitually than the unemployed adults in this study. Despite the findings that employment is a constraint to perform self-care behaviours[15,16] age, duration of diabetes, education and increased intensity of exercises influenced self-care behaviors among adults with T2D.[17]

4.2. Differences between the intervention vs control groups

A gradual reduction in glycemic control has been observed with a longer duration of diabetes and an exposure to diabetes education, which is attributed to medication adherence. In this study, the absence of improvements in glycemic control in the subsequent three months reflects a lack of continuity of care for reducing an absolute HbA1c levels. Higher education and longer duration of DM significantly predicted foot care behaviours.[18,19] Age, education, duration of DM and diabetes education were significant determinants of glycosylated hemoglobin.[20]

Omani adults with longer duration of diabetes may have developed better adaptation strategies to self-manage diabetes compared to those with shorter duration of diabetes. Healthy BMI showed a controlled HbA1c with diabetes education among adults with T2D.[21] Omani adults have embraced the concept of self-efficacy and adapted to the experiences living with diabetes which makes them better able to understand the self-management. They would have received more self-care management compared with those with shorter duration of diabetes, increasing their self-efficacy to understand self-management. Omani

Table 2
Clinical parameters among adults with type 2 diabetes N = 140.

Variables	Categories	Experimental n = 70		Control group N = 70		Total group N = 140		χ^2/t	p
		F	P	F	P	F	P		
Body mass index (kg/m2)	< 18.5 kg/m2	14	20.00	13	18.57	27	19.29	0.63	0.34
	18.5–24.9 kg/m2	18	25.71	20	28.57	38	27.14		
	> 25 kg/m2	27	38.57	22	31.43	49	35.00		
	> 30 kg/m2	11	15.71	15	21.43	26	18.57		
Blood pressure (mm Hg)	< 119/80 mm Hg	9	12.86	11	15.71	20	14.29	0.76	0.37
	120-139/80–89 mm Hg	34	48.57	27	38.57	61	43.57		
	140-159/90–99 mmHg	18	25.71	22	31.43	40	28.57		
	> 160/100 mm Hg	9	12.86	10	14.29	19	13.57		
Fasting blood glucose (mmol/L)	< 7.2 mmol/L	14	20.00	5	7.14	19	13.57	0.43	0.45
	> 7.2 mmol/L	56	80.00	65	92.86	121	86.43		
HbA1c (%)	≤7%	12	17.14	10	14.29	22	15.71	1.54	0.65
	7.01–7.99%	29	41.43	20	28.57	49	35.00		
	≥8%	29	41.43	40	57.14	69	49.29		

Table 3
Comparison of mean differences between and within the two groups at T1, T2 and T3.

Clinical Char	Baseline	End 3 months	End 6 months	Effect 1	Effect 2	Effect 3	T2-T1	T3-T1	T3-T2
Mean + SD	T1	T2	T3	T1-T2	T2-T3	T1-T3	t-value (p)	t-value (p)	t-value (p)
HbA1c < 7%									
IG n = 70	8.7 + 0.8	7.4 + 0.7	6.3 + 0.8	1.3	1.1	2.4	9.23 (0.23)	7.34 (0.04)	5.91 (0.01)
CG n = 70	8.2 + 0.7	8.3 + 1.1	7.0 + 1.7	−0.1	1.3	1.2	5.34 (0.45)	3.45 (0.67)	1.82 (0.76)
t-value (p)	1.34 (0.12)	−1.23 (0.03)	1.34 (0.04)						
BMI 18–24 mg/kgm2							8.23 (0.34)	6.53 (0.03)	4.64 (0.05)
IG n = 70	29.4 + 4.7	28.1 + 1.4	26.6 + 2.7	1.3	1.5	2.8	3.45 (0.34)	2.13 (0.43)	1.93 (0.53)
CG n = 70	29.7 + 4.5	29.8 + 3.3	28.4 + 3.3	−0.1	1.4	1.3			
t-value	0.71 (1.2)	−4.23 (0.02)	5.34 (0.03)						
FBG 80–120 mg/dl							9.45 (0.97)	9.34 (0.34)	8.89 (0.34)
IG n = 70	9.5 + 3.6	8.8 + 0.3	7.7 + 0.7	0.7	1.1	1.8			
CG n = 70	9.5 + 0.8	9.3 + 1.2	8.8 + 2.3	0.2	0.5	0.7			
t-value	1.56 (0.47)	3.96 (0.01)	4.67 (0.04)				10.34 (0.34)	9.23 (0.23)	8.34 (0.34)
SP mm Hg									
IG n = 70	152.2 + 8.3	149.4 + 2.2	146.3 + 2.3	2.8	3.1	5.9			
CG n = 70	156.3 + 6.3	155.2 + 6.4	153.1 + 7.3	1.1	2.1	3.2	8.34 (0.25)	7.34 (0.45)	6.56 (0.45)
t-value	0.5 (0.75)	4.65 (0.02)	1.83 (0.01)				9.34 (0.45)	9.67 (0.76)	8.88 (0.82)
DP mm Hg									
IG n = 70	92.3 + 2.3	89.2 + 1.8	87.2 + 3.3	3.1	2	5.1			
CG n = 70	94.2 + 1.3	93.1 + 3.2	92.3 + 1.3	1.1	0.8	1.9			
t-value	0.5 (0.45)	4.35 (0.05)	5.64 (0.05)						

Baseline T1, the end of 3 months T2, end of 6 months T3.

adults with shorter duration of diabetes have to learn to cope with physiological, psychological and social concerns related to the diagnosis, adjustment to and managing diabetes.

4.3. Effectiveness of multi-modality strategies

The social cognitive model explained 23.2% of the variance of FBG and 31.6% of The variance of HbA1c. 30.6% of the variance in the total QOL and 14% of the variance in health state was explained by demographic and clinical characteristics.[22] Gender differences in diabetes process of care have also been observed in a few studies.[23,24] More women tend to adhere to self-care (healthy diet, glucose monitoring, and self-foot examination) compared to men. However, women tend to be inactive due to gendered differentiated roles and socio-cultural norms compared to their counterparts.[24] Men were less likely to have inappropriate dietary practices than women with family support.[23] In this study, gender, education, duration of diabetes and adult education favorably affected HbA1c, fasting plasma glucose, and body weight. The effect of predictors like men, aging adults, having a moderate-income group, and a higher education group, longer duration of diabetes and had a lower glycemic control benefited from the exposure to the multi-modality strategies by the diabetes nurse educators.

Table 4
ANOVA between experimental and control groups adults with type 2 diabetes N = 140.

Experimental and control groups		Sum of Squares	df	Mean Square	F	Sig.
BMI baseline	Between Groups	0.33	1	0.33	0.01	0.90
	Within Groups	4329.19	198	21.86		
	Total	4329.52	199			
BMI three month	Between Groups	39.81	1	39.81	1.83	0.04
	Within Groups	4300.17	198	21.71		
	Total	4339.99	199			
BMI Six month	Between Groups	172.42	1	172.42	7.97	0.05
	Within Groups	4283.04	198	21.63		
	Total	4455.46	199			
FBS baseline	Between Groups	6.51	1	6.51	1.85	0.15
	Within Groups	695.66	198	3.53		
	Total	702.17	199			
FBS three month	Between Groups	59.01	1	59.01	16.06	0.00
	Within Groups	727.32	198	3.63		
	Total	786.33	199			
FBS Six month	Between Groups	210.33	1	210.30	56.82	0.00
	Within Groups	732.90	198	3.70		
	Total	943.23	199			
HB1Ac baseline	Between Groups	.41	1	0.41	0.35	0.50
	Within Groups	228.94	198	1.15		
	Total	229.35	199			
Hb1Ac three month	Between Groups	20.89	1	20.82	17.34	0.00
	Within Groups	238.42	198	1.20		
	Total	259.31	199			
Hb1Ac Six month	Between Groups	129.76	1	129.76	100.85	0.00
	Within Groups	254.75	198	1.28		
	Total	384.52	199			

Table 5
Multivariate general linear model (Wilk's lambda) for FBG and HbA1c N = 140.

Effect	Value	F	Hypothesis df	Error df	Sig.
Intercept	0.95	1.52[a]	2.00	121.00	0.26
Age	0.98	4.08[a]	2.00	121.00	0.61
Gender	0.94	0.31[a]	2.00	121.00	0.04
Income	0.96	0.26[a]	2.00	121.00	0.80
Education	0.90	2.54[a]	2.00	121.00	0.05
Duration diabetes	0.94	5.05[a]	2.00	121.00	0.05
Diabetes education	0.99	1.35[a]	2.00	121.00	0.27
Medication	0.95	2.25[a]	2.00	121.00	0.09

[a] Design: Intercept + age + duration + income + diabetes education + education + medication + gender.

Table 6
General linear model: Tests of between-subjects effects: FBG and HbA1c N = 140.

Source	Total scores	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	FBG	716.65[a]	15	44.44	4.42	0.00
	HBA1c	4865.89[b]	15	257.76	5.23	0.00
Intercept	FBG	59.61	1	59.61	3.10	0.08
	HBA1c	74.320	1	64.32	1.31	0.25
age	FBG	215.95	1	215.95	7.24	0.09
	HBA1c	275.83	1	275.83	5.57	0.08
gender	FBG	40.76	1	30.72	0.60	0.04
	HBA1c	5.77	1	2.77	0.05	0.05
income	FBG	6.18	1	7.18	0.38	0.53
	HBA1c	3.43	1	1.43	0.02	0.86
Education	FBG	55.62	1	35.63	1.60	0.02
	HBA1c	63.61	1	33.61	0.68	0.04
Diabetes education	FBG	7.45	1	7.44	0.34	0.05
	HBA1c	223.67	1	223.67	2.50	0.01
Duration diabetes	FBG	224.033	1	124.03	7.75	0.00
	HBA1c	506.63	1	506.63	8.22	0.00
Medication	FBG	50.57	1	70.53	3.78	0.06
	HBA1c	265.53	1	165.50	3.34	0.07
Corrected Total	FBG	3801.09	139			
	HBA1c	3996.33	139			

[a] .R Squared = 0.232 (Adjusted R Squared = .106).
[b] .R Squared = 0.327 (Adjusted R Squared = .213).

4.4. Predictors of primary outcomes

An effect size estimated a 2.4% reduction in HbA1c for adults with T2D. HbA1c improved by an average of 1.3% which is clinically significant. The significant difference in HbA1c change between the IG and CG demonstrated a beneficial effect of the multi-modality strategies. This finding was confirmed by the results in which the group factor accounted for a 2.4% reduction in the HbA1c level in the IG. The IG had significantly improved in HbA1c, and FBG at the T2 and the T3 levels compared to the control group. The multi-modality strategies can effectively improve primary outcomes like HbA1c, BMI, and SBP/DBP. In this study, adequate glycemic control is shown by an HbA1c of < 7% and a reduction of 2.4% in the IG which may explain these results. A higher proportion of adults in the family intervention group reached HbA1c values below 7% than adults in the CC group.[25] The study findings indicated that the multi-modality strategies were clinically significant to improve the outcomes and the glycemic control.

The body mass index significantly decreased by 2.8 kg/m^2 from the T1 to the T3 phase. The study suggests that the positive effect of decreasing BMI at the end of 3 months to the end of 6-month decreases ranging from 1.5 kg/m^2 to 1.4 kg/m^2 in the IG. The mean BMI was lesser than 26 kg/m^2 at six months post-intervention indicating that the Omani adults in the IG had lower BMI compared to the CG (28.4 kg/m^2). There was a small reduction in BMI which was achieved in the IG, the differences were significant. For blood pressure, glycemic control reduced both systolic and diastolic blood pressure by decrements of 5.9 mmHg and 5.1 mmHg in the IG and influenced a reduced glycemic control by 2.4%. Decreases in SBP/DBP of 3.2 mmHg and 0.9 mmHg reduced glycemic control by 1.2%. Studies showed that supervised exercise improved blood pressure.[26] Omani adults in the IG showed more statistically significant improvement in FBG and HbA1c than adults in the CC group at a 6-month follow-up.

4.5. Limitations

Mediating factors like self-efficacy, self-care behaviors, lifestyle and psychological characteristics were not obtained by self-reporting. Omani adults were supervised for a period of 6 months which was not sufficient to examine the long-term and lasting effects of self-care behaviors. Significant risk factors of cardiovascular and renal reduction, metabolic control, waist-hip ratio, waist circumference, and insulin resistance were not estimated. Behavioural changes like dietary, exercises, and medications were not measured in the study.

5. Conclusion

Gender, education, diabetes education and duration of diabetes have a substantial effect and are strong predictors of glycemic control among Omani adults with T2D. In this study, the mean FBG and HbA1c were lower in the IG compared to the CG. The adults in the IG was satisfied with multi-modality to enhance physical activity and healthy diet which provided support and reinforce behavioural goals. This emphasized informed choices regarding monitoring and medications among Omani adults in the IG. The findings of this study suggest that Omani adults with T2D in the IG have an adequate level of glycemic control s for improving self-management. Omani adults' willingness to appreciate the change in self-care behaviors, is the 'goal-attainment' to achieving glycemic control and increasing adherence to self-care activities.

A structured diabetes education, an animated digital video, motivational interviewing and telephone counseling highlight the significance of adherence to medication, physical activity, a go-green diet, low glycemic diet, monitoring, active life and its contribution to the effective control of the T2D. Diabetes education and duration of diabetes contributed to a significant effect in increasing the amount of physical activity regardless of their age, gender, education, and income. Traditionally, the Omani physicians have higher authority and power, towards influencing self-care management to empower the desired behavioural changes that are required to improve adherence. This RCT study was proven influential in gauging varied styles of learning and engaging in the cognitive behavioural processes among Omani adults with T2D to facilitate an adherence to self-care behaviors compared with the control group.

5.1. Implications and recommendations

The RCT outcomes have important implications for patient education, nursing practice and clinical research regarding initiatives in tertiary prevention, chronic disease management, and health promotion. Gender, age, education, duration of diabetes, diabetes education and income are the main determinants of glycemic control among Omani adults with T2D. The cognitive behavioural education promoted health beliefs and an action plan for an active role in self-care management among adults with T2D. These informational strategies are recommended for integration in nursing practice to improve the outcomes like body mass index, fasting blood glucose, blood pressure, and glycemic control among adults with T2D.

Diabetes nurse educators are the front-line health care members responsible for knowledge mobilization for better self-care behaviors among adults with T2D. The cognitive behavioural education incorporated multi-modality technology for knowledge transfer to adults with T2D for improving client outcomes. These cognitive behavioural education have effects on the outcomes and transitioning the continuity of care through improving adherence and the quality of life among adults with T2D. The study recommends a cognitive behavioural education for diabetes care involving physicians, nurse educators, physiotherapists, podiatrists, dieticians, pharmacists, psychologists, and adults to facilitate an evidence-informed practice.

Authorship

MSD, KSN, LJL and AAAA have made substantial contributions on the conception, design, acquisition of data, and analysis and interpretation of data. MSD, KSN, LJ and AAAA have drafted the article and revised it critically for important intellectual content. All authors have agreed on the final version of the submitted paper. Melba Sheila D'Souza (MSD), Subrahmanya Nairy Karkada (KSN), Leodoro Jabien Labrague (LJL), and Ali Ahmad Ali Ammouri (AAAA).

Ethical approval of studies and informed consent

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Declaration of conflict of interest statement

There is no financial, personal or other conflicts of interest has been declared by the authors. ICMJE form for disclosure of potential conflicts of interest will be submitted by the authors. None.

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Human rights and ethical approval

The study has been approved by the College of Nursing Research and Ethics Committee, Sultan Qaboos University Hospital Board, the Sultan Qaboos University Review Board. The research conforms to the provisions of the Declaration of Helsinki in 1995 (as revised in Edinburgh 2000).

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.cegh.2019.01.004.

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