



**EFFECTIVENESS OF MEDITERRANEAN DIET PYRAMID ON DIABETIC
CONTROL AND CARDIOVASCULAR RISK MODIFICATION AMONG
PATIENTS WITH TYPE 2 DIABETES MELLITUS AT A HOSPITAL IN
MUSCAT, OMAN**

By

AL-AUFI NAJWA SALIM KHALFAN NASSER

**Thesis Submitted to the School of Graduate Studies, Universiti Putra Malaysia in
Fulfilment of the Requirements for the Degree of Doctor of Philosophy**

November 2022

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Abstract of thesis presented to the Senate of Universiti Putra Malaysia in fulfilment of the requirement for the degree of Doctor of Philosophy

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November 2022

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Adoption of the Mediterranean Diet (MedDiet) has been shown to be effective on glycaemic control and decrease cardiovascular risk among individuals with diabetes mellitus in different populations. However, little compelling evidence is available on the effectiveness of MedDiet among Omanis. The general objective of this study is to determine the effectiveness of the Mediterranean Diet on glycaemic control and cardiovascular risk among type 2 diabetes patients in Muscat, Oman. This wait-list, open-labelled, randomized control trial aimed to assess if the provision of a 6 month MedDiet intervention is effective on cardiovascular risks and diabetic control. A total of 134 patients with Type 2 Diabetes Mellitus (T2DM) from the Nutrition Clinic of National Diabetes and Endocrine Centre at the Royal Hospital, Muscat, Oman was recruited and assigned into standard low-calorie diet control (1200-1500 calorie per day for women and 1500-1800 calories per day for men) (n=73) or MedDiet (n=61) group. Follow-up assessments and data collection were conducted during baseline, three and six months after the intervention. All data was analysed using SPSS version 26, with mixed model ANOVA was used to delineate the effectiveness of Mediterranean Diet intervention as compared to standard low-calorie diet. At baseline, average age of study participants was 44 years old. A higher proportion of them were female (56.3%), married (66.7%), have above primary education (69.4%), working (54.0%) and lower-income (< 800 rials; 50.8%). Total calories, carbohydrates, and fats intake were comparable between the two groups, while participants in the control group had significantly higher protein intake (17.5 ± 4.5 g vs. 15.5 ± 3.7 , $t = 2.660$, $p = 0.009$) compared to intervention group. Trans fat intake was significantly higher in intervention group (2.3 ± 2.4 g vs. 1.3 ± 1.7 g, $t = -2.501$, $p = 0.014$), while cholesterol intake was significantly higher in control group (270.1 ± 160.8 mg vs. 197.7 ± 133.7 mg, $t = 2.726$, $p = 0.007$). Approximately three-quarters of the participants had poor adherence to the MedDiet, especially in intervention group (88.1% vs. 62.7%; $\chi^2 = 10.72$, $p = 0.001$). There was a significant difference in the mean score of the MedDiet between study groups (control: 4.82 ± 2.18

vs. intervention: 3.78 ± 1.40 ; $t=3.217$, $p=0.002$). For the food groups, the cohesion for the usage of olive oil as the main cooking or culinary fat (0.10 ± 0.31 vs. 0.02 ± 0.13 ; $t=2.120$, $p=0.045$), commercial sweets or pastries (not homemade) (0.49 ± 0.50 vs. 0.31 ± 0.46 ; $t=2.173$, $p=0.032$), vegetables (0.33 ± 0.47 vs. 0.08 ± 0.28 ; $t=3.561$, $p=0.001$) and butter, margarine or cream (0.10 ± 0.31 vs. 0.01 ± 0.13 ; $t=2.120$, $p=0.037$) were higher among the control group compared to the intervention group. There were comparable self-perceived to healthy eating between the two groups such as personal and environmental barriers (11.40 ± 1.71 vs. 11.42 ± 1.85 ; $\chi^2=0.065$, $p=-0.948$), social and environmental barriers (7.70 ± 1.24 vs. 8.12 ± 1.53 ; $\chi^2=1.686$, $p=-0.094$) and level of perceived barrier to healthy eating (Low (<17); 5(7.5) vs. 7(11.9); $\chi^2=3.689$, $p=0.158$), Moderate (17 – 22); 60(89.6) vs. 46(78.0), High (>22); 2(3.0) vs. 6(10.2)). Moreover, the control participants have higher self-efficacy to healthy eating and diabetes management (19.91 ± 2.53 vs. 19.49 ± 2.38 ; $t=0.953$, $p=0.343$) compared to the intervention group. About 6% of the study participants have a high perceived barrier to healthy eating while almost 70% have low self-efficacy to healthy eating and diabetes management. There were 26% of the participants had low physical activity and 30% have a risk of dozing off. The control and intervention participants have comparable vigorous physical activity (65.07 ± 143.69 vs. 48.14 ± 139.71 ; $t=0.669$, $p=0.505$), moderate physical activity (113.13 ± 106.66 vs. 101.69 ± 111.50 ; $t=0.588$, $p=0.558$), walking (740.28 ± 240.82 vs. 678.73 ± 179.48 ; $t=1.608$, $p=0.110$) and total intensity of physical activity (918.49 ± 377.93 vs. 828.57 ± 307.63 ; $t=1.452$, $p=0.149$). With regards to daytime sleepiness, male participants from the intervention group and female participants from the control group have higher daytime sleepiness. The anthropometry parameters namely weight (108.9 ± 23.6 kg vs. 118.1 ± 23.2 kg; $t=-2.195$, $p=0.030$) and Body Mass Index (41.6 ± 7.9 kg/m² vs. 44.6 ± 7.7 kg/m²; $t=-2.182$, $p=0.031$) were higher among the intervention participants. Dietary phosphorus was inversely associated with HbA1c concentration ($p=0.023$) among the study participants, while increased in calcium intake was associated with higher concentration of HbA1c ($p=0.007$). Higher score in barriers to healthy eating and self-efficacy were associated with higher concentration of HbA1c ($p=0.008$ vs. $p<0.001$). Higher fasting blood glucose and LDL cholesterol were also associated with increased HbA1c among the study participants ($p=0.003$ vs. $p=0.001$). There was no significant different in the mean or distribution of the metabolite traits between the intervention and control participants. On the other hand, there were 80-90% of the participants had sub-optimal glycaemic control, hypercholesterolemia, hypertriglyceridemia, and elevated low-density lipoprotein, with 77% of them had metabolic syndrome. Obesity was prevalent with about 65% were either severely or morbidly obese with 80% had central obesity. After 6 months intervention, adherence to MedDiet had increased significantly over time in the intervention group, with mean changes were significantly higher between baseline and 6 months follow-up. Using repeated measure ANOVA, MedDiet intervention has small to moderate but significant effects towards reducing metabolic profiles (additional reduction of 4.88%, 13.28%, 14.89% and 23.18% for total cholesterol, HbA1c, triglycerides and fasting blood glucose, respectively) and anthropometrics parameters (additional reduction of 12.07%, 12.01% and 4.77% for body weight, body mass index and waist circumference, respectively). In addition, there was significant increase in physical activity intensity but lesser daytime sleepiness in the intervention participants as compared to their control counterparts. The current study revealed that carefully plan nutritional education emphasizing MedDiet was effective and superseded the conventional nutrition counselling in the improvement of metabolic control (glycaemic control and reduction of cardiovascular risk), dietary intake, psychosocial factors, daytime sleepiness, physical activity of T2DM patients. The current educational module can be incorporated in the existing diabetic control program

for optimising metabolic control of T2DM patients from non-Mediterranean countries or populations like Oman.



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**KEBERKESANAN PIRAMID DIET MEDITERRANEAN TERHADAP
KAWALAN DIABETIS DAN PENGUBAHSUAIAN RISIKO
KARDIOVASKULAR DALAM KALANGAN PESAKIT DIABETES
MELLITUS JENIS 2 DI HOSPITAL DI MUSCAT, OMAN**

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Penggunaan Diet Mediterranean (MedDiet) telah terbukti berkesan terhadap kawalan glisemik dan meningkatkan risiko kardiovaskular dalam kalangan individu yang menghidap diabetes mellitus dalam kalangan populasi yang berbeza. Walau bagaimanapun, bukti keberkesanan MedDiet adalah kekurangan dalam kalangan rakyat Oman. Kajian ini merupakan kajian kawalan rawak senarai tunggu, berlabel terbuka bertujuan untuk menilai keberkesanan MedDiet terhadap risiko kardiovaskular dan kawalan diabetes, dengan perubahan faktor psikososial, kualiti tidur, aktiviti fizikal dan tingkah laku pemakanan sebagai hasil sekunder. Seramai 134 pesakit diabetes mellitus (T2DM) dari Klinik Pemakanan Pusat Diabetes dan Endokrin Kebangsaan di Royal Hospital, Muscat, Oman telah direkrut dan dibahagikan sebagai kumpulan kawalan diet rendah kalori (1200 – 1500 Kcal setiap hari) (n=73) atau kumpulan MedDiet (n=61). Pengumpulan data telah dijalankan untuk fasa awalan, dengan penilaian susulan dilakukan tiga dan enam bulan selepas intervensi. Pada peringkat kajian awalan, purata umur subjek kajian ialah 44 tahun. Majoriti subjek terdiri daripada wanita (56.3%), berkahwin (66.7%), mempunyai pendidikan rendah atas (69.4%), bekerja (54.0%) dan berpendapatan rendah (< 800 rial; 50.8%). Terdapat perbezaan yang signifikan dalam pendapatan isi rumah bulanan antara kumpulan intervensi dan kawalan ($\chi^2 = 9.424$, $p = 0.024$). Majoriti subjek tidak merokok (84.9%) atau mengambil alkohol (93.7%). Jumlah pengambilan kalori, karbohidrat dan lemak adalah setanding antara kedua-dua kumpulan, manakala subjek dalam kumpulan kawalan mempunyai pengambilan protein yang jauh lebih tinggi (17.5 ± 4.5 g vs. 15.5 ± 3.7 g, $t = 2.660$, $p = 0.009$). Pengambilan lemak trans (2.3 ± 2.4 g vs. 1.3 ± 1.7 g, $t = -2.501$, $p = 0.014$) adalah lebih tinggi dalam kumpulan intervensi berbanding kumpulan kawalan. Kira-kira tiga perempat daripada subjek mempunyai pematuan yang rendah kepada MedDiet, terutamanya dalam kumpulan intervensi (88.1% vs. 62.7%; $\chi^2 = 10.72$, $p = 0.001$). Terdapat perbezaan yang signifikan dalam skor min MedDiet antara kumpulan kajian (kawalan: 4.82 ± 2.18 ; intervensi: 3.78 ± 1.40 ; $t = 3.217$, $p = 0.002$). Dari aspek kumpulan makanan, kohesi

penggunaan minyak zaitun sebagai masakan utama atau lemak masakan (0.10 ± 0.31 vs. 0.02 ± 0.13 ; $t = 2.120$, $p = 0.045$), gula-gula atau pastri komersial (bukan buatan sendiri) (0.49 ± 0.50 lawan 0.31 ± 0.46 ; $t = 2.173$, $p = 0.032$), sayur-sayuran (0.33 ± 0.47 lawan 0.08 ± 0.28 ; $t = 3.561$, $p = 0.001$) dan mentega, marjerin atau krim (0.10 ± 0.31 lawan 0.01 ± 0.13 ; $t = 2.120$, $p = 0.037$) adalah lebih tinggi dalam kalangan subjek kawalan berbanding kumpulan intervensi. Terdapat persepsi diri yang setanding dengan pemakanan sihat antara kedua-dua kumpulan seperti halangan peribadi dan persekitaran (11.40 ± 1.71 vs. 11.42 ± 1.85 ; $\chi^2 = 0.065$, $p = -0.948$), halangan sosial dan persekitaran (7.70 ± 1.24 vs. 8.70 ± 1.24 vs. ± 1.53 ; $\chi^2 = 1.686$, $p = -0.094$) dan tahap halangan terhadap pemakanan sihat (Rendah (<17); 5(7.5) berbanding 7(11.9); $\chi^2 = 3.689$, $p = 0.158$), Sederhana (17 - 22; 60(89.6) berbanding 46(78.0), Tinggi (> 22); 2(3.0) berbanding 6(10.2)). Selain itu, subjek kawalan mempunyai efikasi sendiri yang lebih tinggi terhadap pemakanan sihat dan pengurusan diabetes (19.91 ± 2.53 vs. 19.49 ± 2.38 ; $t = 0.953$, $p = 0.343$) berbanding kumpulan intervensi. Kira-kira 6% daripada subjek kajian mempunyai halangan yang tinggi terhadap pemakanan sihat manakala hampir 70% mempunyai efikasi sendiri yang rendah untuk pemakanan sihat dan pengurusan diabetes. Terdapat 26% daripada subjek mempunyai aktiviti fizikal yang rendah dan 30% mempunyai risiko mengantuk. Berkenaan dengan mengantuk pada siang hari, subjek lelaki dari kumpulan intervensi dan subjek wanita dari kumpulan kawalan mempunyai rasa mengantuk pada siang hari yang lebih tinggi. Parameter antropometri iaitu berat (108.9 ± 23.6 kg lawan 118.1 ± 23.2 kg; $t = -2.195$, $p = 0.030$) dan Indeks Jisim Badan (41.6 ± 7.9 kg/m² lawan 44.6 ± 7.7 kg/m²; $t = -2.182$, $p = 0.031$) adalah lebih tinggi dalam kalangan subjek intervensi. Pengambilan fosforus dikaitkan secara songsang dengan kepekatan HbA1c ($p = 0.023$) dalam kalangan subjek kajian, manakala peningkatan dalam pengambilan kalsium dikaitkan dengan kepekatan HbA1c yang lebih tinggi ($p = 0.007$). Skor yang lebih tinggi dalam halangan kepada pemakanan sihat dan keberkesanan diri dikaitkan dengan kepekatan HbA1c yang lebih tinggi ($p = 0.008$ berbanding $p < 0.001$). Glukosa darah puasa yang lebih tinggi dan kolesterol LDL juga dikaitkan dengan peningkatan HbA1c dalam kalangan subjek kajian ($p = 0.003$ vs. $p = 0.001$). Tidak terdapat perbezaan yang signifikan dalam min atau taburan ciri-ciri metabolit antara subjek intervensi dan kawalan. Secara keseluruhan, terdapat 80-90% daripada subjek mempunyai kawalan glisemik yang sub-optimum, hiperkolesterolemia, hipertrigliseridemia, dan lipoprotein berketumpatan rendah tinggi, dengan 77% daripada mereka mempunyai sindrom metabolik. Prevalensi obesiti adalah tinggi di mana kira-kira 65% subjek mempunyai obesiti teruk atau morbid dengan 80% mempunyai obesiti berpusat Selepas intervensi selama 6 bulan, pematuhan kepada MedDiet telah meningkat dengan ketara dari semasa ke semasa dalam kumpulan intervensi, dengan perubahan min adalah lebih tinggi antara awalan dan susulan 6 bulan. Menggunakan ukuran ANOVA berulang, intervensi MedDiet mempunyai kesan kecil hingga sederhana tetapi ketara ke arah mengurangkan profil metabolik (pengurangan yang lebih tinggi sebanyak 4.88%, 13.28%, 14.89% dan 23.18% untuk jumlah kolesterol, HbA1c, trigliserida dan glukosa darah berpuasa, masing-masing) dan parameter antropometrik (pengurangan tambahan sebanyak 12.07%, 12.01% dan 4.77% masing-masing untuk berat badan, indeks jisim badan dan lilitan pinggang). Di samping itu, terdapat peningkatan ketara dalam intensiti aktiviti fizikal tetapi kurang mengantuk pada siang hari dalam subjek intervensi berbanding dengan rakan kawalan mereka. Kajian semasa membuktikan bahawa merancang pendidikan pemakanan yang menekankan MedDiet adalah lebih berkesan berbanding kaunseling pemakanan konvensional dalam kawalan metabolik (kawalan glisemik dan pengurangan risiko kardiovaskular), pengambilan diet, faktor psikososial,

mengantuk siang hari, aktiviti fizikal pesakit T2DM. Modul pendidikan semasa boleh digabungkan dalam program kawalan diabetes sedia ada untuk mengoptimumkan kawalan metabolik pesakit T2DM dari negara atau populasi bukan Mediterreanean seperti Oman.



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TABLE OF CONTENTS

	Page
ABSTRACT	i
ABSTRAK	iv
ACKNOWLEDGEMENTS	vii
APPROVAL	viii
DECLARATION	x
LIST OF TABLES	xv
LIST OF FIGURES	xix
LIST OF ABBREVIATIONS	xxi
 CHAPTER	
 1 INTRODUCTION	 1
1.1 Background of the Study	1
1.1.1 Prevalence of Diabetes Worldwide	1
1.1.2 Prevalence of Diabetes in Gulf Countries	1
1.1.3 Risk factor of Diabetes	2
1.1.4 Sleep Quality vs. Diabetes	2
1.1.5 Psychological factors and Diabetes	3
1.1.6 Mediterranean Diet	4
1.2 Problem Statement	4
1.3 Significance of the Study	7
1.4 Study Objectives	7
1.4.1 General Objective	7
1.4.2 Specific Objectives	7
1.5 Research Hypotheses	8
1.6 Conceptual Framework	8
 2 LITERATURE REVIEW	 11
2.1 Overview of Diabetes Mellitus	11
2.1.1 Complications of Diabetes	11
2.2 Clinical Classification of Diabetes	12
2.3 Disease Burden and Healthcare Cost	12
2.3.1 Health Care Burden in Oman	13
2.4 Global Epidemiology	14
2.5 Prevalence of Diabetes Mellitus in Oman	14
2.6 Aetiology and Management	15
2.7 Glycaemic Control and Complications	17
2.8 Factors Associated with Glycaemic Control	17
2.8.1 Patients and Clinical Characteristics	18
2.8.2 Lifestyle Behaviours	19
2.8.3 Anthropometric Measures	22
2.8.4 Dietary Factors	24
2.9 Mediterranean Diet	25
2.9.1 Definition	25
2.9.2 Mediterranean Dietary Pattern	26

2.9.2	Effectiveness of Mediterranean Diet	29
2.10	Health Promotion Models and Theories	32
2.10.1	Importance of Theories in Intervention Programme	32
2.10.2	Health Belief Model (HBM)	33
2.10.3	Effectiveness of HBM	34
3	METHODOLOGY	36
3.1	Study Design	36
3.2	Study Location	38
3.3	Ethical Approval	38
3.4	Sampling	38
3.4.1	Study Participants	38
3.4.2	Sample Size Calculation	39
3.4.3	Allocation Concealment and Randomization	40
3.5	Study Instruments and Measurements	41
3.5.1	Participant's Characteristics	41
3.5.2	Clinical Characteristics	41
3.5.3	Cardiovascular Metabolite Traits	42
3.5.4	Anthropometric Assessment	42
3.5.5	Assessment on Physical Activity	43
3.5.6	Assessment on Daytime Sleepiness	44
3.5.7	Assessment of Dietary Intake and Adherence to Mediterranean Diet	45
3.5.8	Assessment on Psychosocial Domain	45
3.6	Design and Development of Intervention Educational Material	47
3.6.1	Mediterranean Diet Booklet	47
3.6.2	Leaflets	48
3.7	Implementation of Intervention	48
3.7.1	Intervention Group	48
3.7.2	Wait-list Control Group	51
3.7.3	Adherence to Intervention	51
3.8	Evaluation of Effectiveness of Intervention	52
3.8.1	Baseline (T ₀)	52
3.8.2	Post-intervention I (Three months after Baseline, T ₁)	52
3.8.3	Post Intervention II (Six months after Baseline, T ₂)	52
3.8.4	Post Evaluation	53
3.9	Statistical Analyses	54
4	RESULTS	55
4.1	Recruitment and Retention of Participants	55
4.2	Socio-demographic Characteristics of Participants	56
4.3	Clinical Factors	57
4.4	Dietary Assessment	59
4.4.1	Dietary assessment among participants	59
4.4.2	Dietary Adequacy among Participants	63
4.4.3	Adherence to Mediterranean Diet	68
4.5	Psychosocial Factors	69
4.5.1	Barriers to Healthy Eating	69
4.5.2	Self-Efficacy to Healthy Eating and Diabetes Management	71
4.6	Physical Activity	73

4.7	Daytime Sleepiness	74
4.8	Anthropometric Measurements	75
4.9	Metabolite Traits	77
4.10	Association between Study Variables and HbA1c among Study Participants	79
4.11	Effectiveness of Intervention	80
4.11.1	Effectiveness of Intervention on Dietary Intake	80
4.11.2	Changes in Psychosocial Factors	119
4.11.3	Changes in Physical Activity	123
4.11.4	Changes in Daytime Sleepiness	127
4.11.5	Changes in Anthropometry Measurements	130
4.11.6	Changes in Metabolic Traits	134
4.12	Process Evaluation	141
5	DISCUSSION	142
5.1	Participants Characteristics	142
5.2	Dietary Intake	142
5.2.1	Dietary Energy, Macronutrients and Micronutrients Intake	142
5.2.2	Dietary Adequacy	143
5.2.3	Adherence to Mediterranean Diet	146
5.3	Psychosocial Factors	147
5.3.1	Barriers to Healthy Eating	147
5.3.2	Self-Efficacy to Healthy Eating and Diabetes Management	148
5.4	Physical Activity	148
5.5	Daytime Sleepiness	149
5.6	Weight Status	149
5.7	Metabolite Traits	150
5.7.1	Glucose Metabolism	150
5.7.2	Lipid Metabolism	151
5.7.3	Blood Pressure	152
5.8	Factors Associated with Glycaemic Control	152
5.9	Effectiveness of Intervention	155
5.9.1	Dietary Intake	156
5.9.2	Physical Activity	157
5.9.3	Daytime Sleepiness	157
5.9.4	Weight Status	158
5.9.5	Metabolite Traits	159
5.10	Process Evaluation	162
6	CONCLUSIONS, LIMITATIONS AND RECOMMENDATION	164
6.1	Conclusion	164
6.2	Strengths	165
6.3	Limitations	166
6.4	Recommendations	167
	REFERENCES	168
	APPENDICES	196
	BIODATA OF STUDENT	278
	LIST OF PUBLICATIONS	279

LIST OF TABLES

Table	Page
2.1 Summary of Studies on the Effectiveness Mediterranean Diet Intervention	28
2.2 Summary of Studies on the Effectiveness of Mediterranean Diet and Glycaemic Control	29
3.1 Eligibility of Participants	39
3.2 Participants' Characteristics	41
3.3 Recommendations for Treatment Targets for Patients with Diabetes	42
3.4 Classification of Body Mass Index	42
3.5 Classification of Waist Circumference	43
3.6 Classification of Physical Activity Level of Participants	44
3.7 Questionnaire Items Measuring Perceived Barriers to Healthy Eating	46
3.8 Question Items Measuring Self-efficacy for Diabetes	47
3.9 Measurements Performed According to Visits	53
4.1 Baseline Comparison of Socio-demographic Characteristics between Intervention (n = 59) and Control (n = 67) Participants	56
4.2 Baseline Comparison of Clinical Factors of Between Intervention (n = 59) and Control (n = 67) Participants	58
4.3 Baseline Comparison in Macronutrients and Micronutrients Intakes among Intervention (n = 59) and Control (n = 67) Group	61
4.4 Dietary Adequacy Among the Participants was Compared to Recommended Nutrient Intakes for Omani	64
4.5 TDietary Adequacy Among the Participants was Compared to USDA Reference	66
4.6 Distribution of Intervention (n = 59) and Control (n = 67) Participants According to Adherence to Mediterranean Diet	69

4.7	Distribution of Participants According to Barriers for Healthy Eating	70
4.8	Comparison of Perceived Barrier to Healthy Eating Among Intervention (n = 59) and Control (n = 67) Participants	71
4.9	Distribution of Participants According to Self-efficacy to Healthy Eating and Diabetes Management	72
4.10	Baseline Comparison on Self-efficacy to Healthy Eating and Diabetes Management Among Intervention (n = 59) and Control (n = 67) Participants	72
4.11	Baseline Comparison on Physical Activity among Intervention (n = 59) and Control (n = 67) Participants	73
4.12	Distribution of Participants According to Daytime Sleepiness	74
4.13	Baseline Comparison in Daytime Sleepiness Among Intervention (n = 59) and Control (n = 67) Participants	75
4.14	Comparison of Anthropometry Parameters Between Intervention (n = 59) and Control (n = 67) Participants	76
4.15	Comparison of Metabolic Traits Between Intervention (n = 59) and Control (n = 67) Participants	78
4.16	Univariate Analysis for Association Between Study Variables and HbA1c Among Study Participants	79
4.17	Multivariate Analysis for Associations Between Study Variables and HbA1c Among Participants	80
4.18	Comparison of Mean Changes of Dietary Energy Intake Within and Between the Intervention (n = 59) and Control Participants (n = 67) Across Three Different Time Points	82
4.19	Mixed Model ANOVA Multivariate Analysis on Effectiveness of Intervention on Calories Intake	83
4.20	Comparison of mean Changes of Dietary Macronutrients Intake Within and Between the Intervention (n = 59) and Control Participants (n = 67) Across Three Different Time Points	86
4.21	Mixed Model ANOVA Multivariate Analysis on Effectiveness of Intervention on Macronutrients Intake.	88
4.22	Comparison of mean Changes of Dietary Other Carbohydrate and Lipid Sources Intake Within and Between the Intervention (n = 59)	91

	and Control Participants (n =67) Across Three Different Time Points	
4.23	Mixed Model ANOVA Multivariate Analysis on Effectiveness of Intervention on Other Carbohydrate and Lipids Intake.	97
4.24	Comparison of Mean Changes of Dietary Vitamins Intake Within and Between the Intervention (n =59) and Control Participants (n =67) Across Three Different Time Points	101
4.25	Mixed Model ANOVA Multivariate Analysis on Effectiveness of Intervention on Dietary Vitamins Intake	106
4.26	Comparison of Mean Changes of Dietary Minerals Intake Within and Between the Intervention (n =59) and Control Participants (n =67) Across Three Different Time Points	110
4.27	Mixed Model ANOVA Multivariate Analysis on Effectiveness of Intervention on Mineral Intakes	114
4.28	Comparison of Mean Changes of Mediterranean Dietary Intake Within and Between the Intervention (n =59) and Control Participants (n =67) Across Three Different Time Points	117
4.29	Mixed Model ANOVA Multivariate Analysis on Effectiveness of Intervention on Mediterranean Diet Intake.	118
4.30	Comparison of Mean Changes of Psychosocial Factors Within and Between the Intervention (n =59) and Control Participants (n =67) Across Three Different Time Points	120
4.31	Mixed Model ANOVA Multivariate Analysis on Effectiveness of Intervention on Psychosocial Factors	121
4.32	Comparison of Mean Changes of Various Physical Activities Within and between the Intervention (n =59) and Control Participants (n =67) Across Three Different Time Points	124
4.33	Mixed Model ANOVA Multivariate Analysis on Effectiveness of Intervention on Physical Activity Intensity	126
4.34	Comparison of Mean Changes of Daytime Sleepiness Within and Between the Intervention (n =59) and Control Participants (n =67) Across Three Different Time Points	128
4.35	Mixed Model ANOVA Multivariate Analysis on Effectiveness of Intervention on Sleep Quality	129

4.36	Comparison of Mean Changes of Anthropometry Measurements within and Between the Intervention (n =59) and Control Participants (n =67) Across Three Different Time Points	131
4.37	Mixed Model ANOVA Multivariate Analysis on Effectiveness of Intervention on Anthropometry Assessments	133
4.38	Comparison of Mean Changes of Metabolic Profile Within and Between the Intervention (n =59) and Control Participants (n =67) Across Three Different Time Points	135
4.39	Mixed Model ANOVA Multivariate Analysis on Effectiveness of Intervention on Metabolite Traits	138
4.40	Process Evaluation for the Study	141
4.41	Feedback on Intervention Materials and Conduct	141

LIST OF FIGURES

Figure	Page
1.1 Conceptual Framework	10
2.1 Progress of Type 2 Diabetes Mellitus.	15
2.2 The Original Mediterranean Diet Pyramid	26
2.3 The Mediterranean Diet Pyramid Today	27
3.1 Consort Diagram: Flow of Study	37
3.2 Various Activities during Intervention	50
4.1 Recruitment and Retention of Participants Throughout the Study	55
4.2 Mixed model ANOVA interaction effect between group (intervention vs. control) and time (baseline vs. 3-month follow up vs. 6- months follow up)	89
4.3 Mixed model ANOVA interaction effect between group (intervention vs. control) and time (baseline vs. 3-month follow up vs. 6- months follow up)	98
4.4 Mixed model ANOVA interaction effect between group (intervention vs. control) and time (baseline vs. 3-month follow up vs. 6- months follow up)	99
4.5 Mixed model ANOVA interaction effect between group (intervention vs. control) and time (baseline vs. 3-month follow up vs. 6- months follow up)	108
4.6 Mixed model ANOVA interaction effect between group (intervention vs. control) and time (baseline vs. 3-month follow up vs. 6- months follow up)	116
4.7 Mixed model ANOVA interaction effect between group (intervention vs. control) and time (baseline vs. 3-month follow up vs. 6- months follow up)	119
4.8 Mixed model ANOVA interaction effect between group (intervention vs. control) and time (baseline vs. 3-month follow up vs. 6- months follow up)	122

4.9	Figure 4.9 Mixed model ANOVA interaction effect between group (intervention vs. control) and time (baseline vs. 3-month follow up vs. 6- months follow up) for physical activity	127
4.10	Mixed model ANOVA interaction effect between group (intervention vs. control) and time (baseline vs. 3-month follow up vs. 6- months follow up)	129
4.11	Mixed model ANOVA interaction effect between group (intervention vs. control) and time (baseline vs. 3-month follow up vs. 6- months follow up)	133
4.12	Mixed model ANOVA interaction effect between group (intervention vs. control) and time (baseline vs. 3-month follow up vs. 6- months follow up)	139

LIST OF ABBREVIATIONS

ACLS	Aerobics centre longitudinal study
ADA	American Diabetes Association
BMI	Body mass index
CARDIA	Coronary artery risk development in young adults
CDC	Center of diabetes control
CHD	Coronary heart disease
CHO	Carbohydrate
CI	Confidence intervals
CRP	C-reactive protein
CVD	Cardiovascular diseases
DASH	Dietary Approaches to Stop Hypertension
DBP	Diastolic blood pressure
DCCT	Diabetes control complications trial
DM	Diabetes mellitus
EMR	Eastern mediterranean region
EPIC	European prospective investigation into cancer and nutrition
ESS	Epworth sleepiness scale
EVOO	Extra virgin olive oil
FBG	Fasting blood glucose
FFQ	Food frequency questionnaire
FHSOC	Framingham heart study offspring cohort
GABA	Gamma-aminobutyric acid
GCC	Gulf cooperation council
GDM	Gestational diabetes mellitus
HBM	Health belief model

HDL	High density lipoprotein cholesterol
IDF	International diabetes federation
IPAQ	International physical activity questionnaire
IR	Insulin resistance
LDL	Low density lipoprotein cholesterol
MedDiet	Mediterranean diet
MENA	Middle East and North Africa
MI	Myocardial infarction
MOH	Ministry of health
MUFA	Monounsaturated fatty acids
NCDs	Non-communicable diseases
NDEC	Natioanl Diabetes and Endocrine Centre
NDNS	National diet and nutrition survey
PA	Physical activity
PCC	Patient-centred care
PREDIMED	PREvención con Dieta MEDiterránea
PUFA	Polyunsaturated fatty acids
RBG	Random blood glucose
RCT	Randomized controlled trial
RDA	Recommended Dietary Allowance
RLS	Restless leg syndrome
RNI	Recommended nutrient intake
SBP	Systolic blood pressure
SD	Standard deviation
SED	Self-efficacy for diabetes
SFA	Saturated fatty acids
T0	Baseline

T1	Post intervention 1
T2	Post intervention 2
T2DM	Type 2 diabetes mellitus
TC	Total cholesterol
TG	Triglyceride
TTM	The transtheoretical model
UKPDS	UK prospective diabetes study
WC	Waist circumference
WHO	World health organization
WHR	Waist-to-hip ratio
WHtR	Waist-to-height ratio

CHAPTER 1

INTRODUCTION

1.1 Background of the Study

1.1.1 Prevalence of Diabetes Worldwide

Diabetes mellitus is considered as a metabolic disorder primarily characterized by hyperglycemia, which is caused by either a disturbed insulin secretion (Type 1 diabetes mellitus) or insulin insensitivity (Type 2 diabetes mellitus) or both (WHO, 2019; American Diabetes Association, 2020). Type 2 diabetes mellitus (T2DM) is the most common type of diabetes, accounting for around 90% of all diabetes worldwide (International Diabetes Federation (IDF), 2020). It is confirmed as one of the fastest growing global health emergencies of the 21st century (IDF, 2020). Globally, the estimated prevalence of diabetes (in people aged 20–79 years) has affected 463 million (9.3%) people as of 2019. Without sufficient action to address the pandemic, it is predicted that a total of 578 million people, representing 10.2% of the population, will have diabetes by 2030 and further jump to a staggering 700 million (10.9% of the population) by 2045 (IDF, 2020). Diabetes Mellitus has a large worldwide economic impact, with an expected annual expenditure of USD 760 billion in 2019 and a predicted increase of 11.2% to USD 845 billion by 2045 (IDF, 2019).

1.1.2 Prevalence of Diabetes in Gulf Countries

According to recent literature, the prevalence of type 2 diabetes in the Gulf Cooperation Council (GCC) is high, has risen significantly in the last two decades, and is anticipated to rise by 96.5 percent by 2045 (Al Slamah et al., 2017; Morgan et al., 2019). Like other developing countries, Oman has a high incidence of non-communicable diseases (NCDs), with increasing evidence that lifestyle-related NCDs have emerged as a new health challenge to the Omani (Al Riyami 2010; Al Riyami & Afifi, 2003; Al-Shookri et al., 2011; Asfour et al., 1995; Ganguly et al., 2009; Hassab, Jaffer & Hallaj, 1995; Khatib 2004). Align with this, there has been a substantial increase in the prevalence of T2DM over the years, attributed to the epidemiological transition and socioeconomic development (Al-Lawati et al., 2015; Al-Riyami et al., 2012). More recently, the prevalence of pre diabetes and diabetes among adults aged more than 18 years old were 15.7% and 11.8%, respectively (Al Mawali et al., 2021). Generally, the prevalence of T2DM in Oman as well as in other Eastern Mediterranean (EMR) region is higher than the prevalence reported in other Asian countries (Akter et al., 2014; Pham & Egglesten, 2016; Tripathy et al., 2017; WHO, 2020). The World Health Organization (WHO) has designated Oman as a country with low child and adult mortality rates (crude death rate: 2.4 per 1000). Particularly, diabetes mellitus is the sixth major cause of premature death and the fifth leading source of disability-adjusted life years lost in Oman (Knudsen, 2019) which have been identified as the fastest growing health crisis in Oman (Al Mawali et al., 2021). The prevalence of type 2 diabetes in the Gulf Cooperation Council (GCC)

is high with a considerable increase in the past two decades and is foreseen to increase by 96.5 % by 2045 (Al Slamah et al., 2017; Morgan et al., 2019). The reported prevalence of diabetes among the Omanis is 15.7 % accompanied with other chronic diseases, resulting death of 187.75 people per 100 thousand in Oman each year (Al- Mawali et al., 2021).

In Oman, the majority of diabetic patients are poorly controlled and are prone to complications, putting the country under greater financial strain (Al Mawali et al., 2021). T2DM and cardiovascular diseases (CVD) had been identified earlier as a main and increasing workload for clinicians in Omani clinics and hospitals (Al-Lawati et al., 2015). Without concerted action, Oman is expected to experience substantial increase in its prevalence and associated macrovascular and microvascular complications, as such give serious impact on socioeconomic, health and psychosocial to the people and nation. The WHO has identified “best buys” with lifestyle interventions are important to mitigate NCDs including T2DM. The Omani Ministry of Health (MOH) recommended the initiation of patient- centred care (PCC) model as a model of care delivery into its health care system to address the chronic conditions , implying nurses as the primary care team to deliver health promotion and patient education (Ministry of Health, 2015).

1.1.3 Risk factor of Diabetes

The most common factors of diabetes are metabolic and behavioural risk factors and can be largely preventable by several available means. Among all, genetic susceptibility and environmental influences are factors responsible for the development of T2DM and its complications (Asif, 2014). Physical inactivity and poor diet quality however make up the main basis of the environmental factors which are largely modifiable. research supports the effectiveness of lifestyle interventions across community and clinical research and delivery formats (groups, personals, or technology-based) and implementers. Studies conducted in Oman revealed that, there were many factors linking or contributing to the impending prevalence of type 2 diabetes, including the high prevalence of sedentary lifestyles, obesity and physical inactivity (Al-Haifi et al., 2013; Al-Lawati & Jousilahti, 2004; Al Riyami et al., 2012; Mabry, Owen & Eakin, 2014), which are not new to researchers.

1.1.4 Sleep Quality vs. Diabetes

Sleep problems are defined as difficulties falling or staying asleep, as well as sleep that is not restful. Sleep disturbances appear to be frequent in society, according to epidemiological studies. Sleep disturbances can have serious implications, such as weight-related problems, hypertension, dyslipidaemia, type 2 diabetes, metabolic syndrome and cardiovascular disease. Sleep difficulties are found in around 50–70% of diabetes patients, negatively affecting their lives by compromising school or business performance, marriage, and other aspects of life (Keskin et al., 2015; Zhu et al., 2017). Sleep disturbance, especially impaired sleep quality, could potentially influence glycaemic control in T2DM patients (Zhu et al., 2017). Sleep disturbance is a symptom that is defined by poor sleep quality and/or atypical sleep length, among other things.

Diabetes-related physiological changes and psychological well-being are two precursors. Daytime functioning, glycaemic management, and quality of life can all be impaired by sleep disruption (Zhu et al., 2018). Poor sleep and insomnia has been associated with decrease in gamma-aminobutyric acid (GABA). A decrease level of GABA is usually observed in depression patients. Moreover, it has been demonstrated to prevent the apoptosis of rodent beta cells. Type 1 DM has been associated with glutamate decarboxylase, the key enzyme (GAD) involved in the manufacture of GABA. At low level, GABA may play a role in the quality of sleep experienced by the diabetics. On the other hand, orexins have been implicated in glucose metabolism and linked to nutrition, arousal, sleep, and energy balance. Moreover, Nocturnal hypoglycemia can lead to sleep disruption and can be regarded as one of the many factors leading to poor sleep quality among diabetics. Studies showed diabetic patients with Restless Leg Syndrome (RLS) may also suffer from peripheral neuropathy. Diabetic patients who suffer from RLS are more likely to report worse sleep quality, have longer sleep latency and worse sleep efficiency, and experience more daytime dysfunction compared with diabetic controls without RLS (Allen et al., 2013; Surani et al., 2015; Winkelman et al., 2014).

1.1.5 Psychological factors and Diabetes

Several psychological factors were associated with glycaemic control among diabetes patients. Studies showed that perceived barriers have been associated with decreased medication use or adherence as well as low physical activities, which have been vastly linked with poor glycaemic control among T2DM patients (Adu et al., 2019; Sina, Graffy & Simmons, 2018). Beside self-care behaviours, lifestyle behaviours such as physical activity was found as one of modifiable behaviours which was consistently found to reduce the risk of diabetes development. Some studies have tried to assess the relationship between physical activity and diabetes management, yet the results are inconsistent (Baskerville et al., 2017; Rachmah et al., 2019).

Type 2 diabetes mellitus is a leading cause of microvascular issues such as retinopathy and macrovascular issues including cerebrovascular disease and coronary artery disease. People living with T2DM have higher rate of hospitalisation (Donnan et al., 2020; Harding et al., 2020; Pournaras et al., 2017) and high incidence of morbidity and mortality (IDF, 2020). In 2019, over four million people aged 20–79 years were estimated to die from diabetes-related causes (Pournaras et al., 2017). With approximately 75% are of working age (IDF, 2020), diabetes mellitus imposes a high economic effect on health systems, countries and, when healthcare needs to be funded ‘out-of-pocket’, for individuals with diabetes and their families (Care, 2017; Harding et al., 2020; Peter et al., 2017; Yang et al., 2012).

The majority of uncontrolled cases, which account for more than two-thirds of cases with elevated blood glucose, are extremely alarming. This pool of uncontrolled diabetes mellitus cases would become more prone to complications, putting a greater financial pressure on the country. When only the Omani national population treated by free primary healthcare was examined, approximately half of those taking medication were found to have a regulated blood glucose condition. This indicates that only 17% patients who received treatment under health system had their blood glucose levels under control,

which is a concerning figure (Al-Mawali et al., 2021). To address unsafe behaviours and subsequent health-related interventions, the challenges of health promotion must be addressed as part of Oman's Health Vision 2050 (Al-Hinai et al., 2020). Further research into the underlying issues is critical (Al-Mawali et al., 2017).

1.1.6 Mediterranean Diet

Recently, research in health and nutrition has begun to focus on dietary pattern approaches instead of the evaluation of one nutrient or food (Koloverou et al., 2014; Freeland-Graves & Nitzke., 2013; Dinu et al., 2018; Koloverou et al., 2014; Shen et al., 2015; Esposito et al., 2014) in mitigate NCDs including diabetes mellitus. Based on this holistic approach, many dietary patterns have been identified and some play a significant role in the prevention and/or management of chronic diseases such as blood pressure, coronary heart disease and cancer. One of the most studied patterns is the Mediterranean diet, first characterized in the late 1970s (Keys et al., 1986).

The traditional Mediterranean diet describes the traditional dietary habits of people living around the Mediterranean basin, specifically in the olive tree growing regions in a time before globalization expanded also to the food culture. Mediterranean Diet (MedDIET) is characterized by abundant plant foods, mainly fruit, vegetables, nuts, seeds, bread, beans, cereals and legumes, in addition to include olive oil as a main source of healthy fat and highlight the use of spices and herbs. The diet also consists of a moderate amount intake of dairy products such as yoghurt and cheese, low to moderate amounts of fish and low amounts intake of red meat and poultry (Kafatos et al., 2000; Willett et al., 1995; Bach-Faig et al., 2011; Estruch et al., 2018; Raddetto, 2012; Trichopoulou et al., 2003 and Davis et al., 2015). In general, the Mediterranean Diet (MedDiet) is characterized by high amounts of antioxidants and fibre, a balanced ratio of (n-6):(n-3) essential fatty acids and rich in monounsaturated fatty acids (Simopoulos, 2001). The MedDiet has been shown to successfully mitigate against CVD risk factors such as hypertension, hypercholesterolemia, obesity and metabolic syndrome (Hosseini-Esfahani et al., 2010, Rossi et al., 2013, Salas-Salvado et al., 2014; Tobias et al., 2012).

1.2 Problem Statement

The Sultanate of Oman is located on the southeast corner of the Arabian Peninsula is a high-income oil-producing country. In the last few decades, there has been rapid socioeconomic development which has resulted in epidemiological and demographic transitions, with alarming rise in the incidence of NCDs including T2DM and CVD. The later had imposed a great challenge on the health care system in Oman and signify the need for appropriate lifestyle intervention (Ministry of Health of Oman, 2016; Khan., 2012). Estimating diabetes prevalence and identifying high-risk groups is critical for monitoring, policy creation, and clinical intervention. In the Sultanate of Oman, there is currently insufficient, up-to-date information on the prevalence of type 2 diabetes and its risk factors. Most of the studies focused on general community yet studies in Oman were restricted, and they did not accurately represent all of the risk factors and their

correlations with diabetes in the Oman population (Al-Lawati et al., 2015; Al-Lawati, 2017; Majeed et al., 2014). There is a need for a clinical-setting base study for a focused and personalised risk assessment and intervention.

Dietary management is often recommended as the first-line treatment of type 2 diabetes, prior to, or in parallel with initiation of pharmacological therapy (Johansen et al., 2017). Lifestyle interventions on T2DM have also produced favourable outcomes (Asaad et al., 2016; Johansen et al., 2017; Look AHEAD Research Group, 2007; Pot et al., 2018; Ried-Larsen et al., 2017; Gong et al., 2018). However, there have been conflicting results which may be explained by reliance on advice-based exercise interventions as opposed to supervision of exercise (Johansen et al., 2017) as well as poor adherence to dietary recommendations (Webb & Byrd-Bredbenner, 2015) and unavailability of healthy food choices (Asaad et al., 2016). Despite national dietary guidelines are available as early as 40 years ago, population dietary change has been slow, with many still fall short of current food-based dietary recommendations and poor adherence to dietary guidelines are evident. The Omani Food groups are categorised of all the food items consumed by the locals, Omanis which are further classified into groups based to their content of energy and nutrients. The Omani dietary guidelines are composed of six food groups namely whole grains and potatoes, fruits, vegetables, meats and alternatives, legumes, milk and dairy products. Moreover, the Omani dietary Guidelines encourages the consumption of a variety of food items from the six food groups on a daily basis in the recommended proportions that are consistent with the food guide for a healthy lifestyle and nutrition intake. Whole grains cereal and potatoes with their skin, 3 -5 servings of vegetables daily, 2-4 servings of fruits daily, fish, poultry, eggs or lean meat, 1 serving of legumes daily, milk or dairy products daily, limited intake of fat and wise choice of snacks consumed daily and be active, exercise regularly and drink plenty of water (The Omani Guide to Healthy Eating, 2009).

This is partially attributed to the difficulties of translating present dietary recommendations into food-based public health advice (Mozaffarian, 2019; Webb et al., 2015) and lacks of certain universally consistent recommendation across countries (Herforth et al., 2019). Adherence is further complicated with the expectation of certain level of health literacy such as calculation of calories and label reading among the socioeconomic deprived communities. Dietary guidelines which focus on dietary pattern rather than individual nutrient recommendations could help avoid confusion and avoid inadvertent increases in one nutrient of concern at the expense of another (Mozaffarian, 2019; Herforth et al., 2019; Gao et al., 2021).

Recent meta-analysis and systematic review reported that following the Mediterranean diet was linked with a 19-23% decreased risk of developing diabetes (Koloverou et al., 2014; Schwingshack et al., 2014). However, several cross-sectional and prospective epidemiologic studies suggested an inverse association between consumption of the Mediterranean diet and risk of metabolic syndrome (Panagiotakos et al. 2004; Babio et al., 2009; Viscogliosi et al., 2013; Tortosa et al., 2007; Rumawas et al., 2009; Kesse-Guyot et al., 2013). The majority of available studies were conducted among non-diabetics (Kesse-Guyot et al., 2013; Panagiotakos et al., 2004; Rumawas et al., 2009; Viscogliosi et al., 2013), with inconclusive evidence on the effect of the Mediterranean

diet in reducing risk of cardiovascular among diabetics. As cardiovascular disease is responsible for approximately one-third of all mortality among diabetics (Fuller et al., 2001), reducing the risk of cardiovascular among diabetics is potentially important for lowering the risk of CVD. Studies in non-Mediterranean countries such as Australia (Kouris-Blazos et al., 1999), Iran (Veissi et al., 2016) and US (Mitrou et al., 2007, Yang et al., 2014) and other countries (Martínez-González et al., 2015; Huo et al., 2015; Ben-Yacov et al., 2021; Mattei et al., 2019; Sleiman, Al-Badri & Azar, 2015; Milenkovic et al. 2021; Itsiopoulos et al. 2011) had shown that Mediterranean diet worked. This however has not been confirmed among Oman population, whom has experience tremendous nutritional transition including dietary intake, with growing evidence that diet of Omanis are high fat but low in fruits and vegetables (Al-Lawati et al., 2015; Al-Riyami et al., 2012).

Growing evidence from intervention studies on MedDiet demonstrated generally a good adherence with Mediterranean diet among the patients. The flexibility of MedDiet with the emphasize of encouraging positive behaviour change and improving dietary quality through displacement of discretionary items with healthy nutrient-dense foods instead of prohibiting of certain goods allow better adherence on MedDiet (Opie et al., 2018). As such, it is worth to investigate and delineate whether a universal-recognised, flexible and workable dietary pattern, namely Mediterranean Diet can improve the glycaemic control and other prominent complications among T2DM patients in Oman.

The prevalence of sleep disturbance is rising at an alarming rate, particularly among T2DM patients. According to reports, 39.4% and 55.0% of them have short sleep duration (6.5 hours per night) and poor sleep quality, respectively. Sleep disturbance and glucose regulation appear to form a cycle via multiple pathophysiological pathways, according to evidence. Sleep disruption is linked to an increased risk of T2DM. Despite growing concern about the effects of sleep disruption on health, few studies have examined the relationships between sleep disruption and diabetes-related health outcomes (Keskin et al., 2015; Zhu et al., 2017; Zhu et al., 2018), however, intervening sleep quality and its effect on glycaemic control in people with T2DM is still scattered.

Perceived barrier and low self-efficacy were found inversely associated with self-care behaviour and promote non-adherence to diabetes management procedures. However, their influence on glycaemic control is under-explored (Adu et al., 2019; Sina, Graffy & Simmons, 2018). Similarly, lifestyle behaviours especially physical activity, was previously assessed based on randomised controlled trial, but the effectiveness of counselling and education intervention on physical activities which predicted to enhance changes in lifestyle behaviours are yet to be assessed (Baskerville et al., 2017; Rachmah et al., 2019).

To date, there is a paucity of data available on how the Mediterranean diet may augment glycaemic control and cardiovascular risk in the Omanis, especially among T2DM patients. The aim of this study was therefore to assess the effects of a Mediterranean diet on glycaemic control and risk of cardiovascular among T2DM patients.

1.3 Significance of the Study

With growing literature that dietary pattern works better than single nutrient approach in NCDs, the findings of this study provided scientific evidence whether dietary pattern approach works for Omani. There were very few published studies on the effects of the Mediterranean diet and its effect on the risk of cardiovascular among T2DM in Arab countries, with no studies are currently being conducted in Middle East countries. Effectiveness of Mediterranean Diet is more profound in Mediterranean countries, with evidence is growing in non-Mediterranean countries (Kouris-Blazos et al., 1999, Veissi et al., 2016, Mitrou et al., 2007, Yang et al., 2014; Martínez-González et al., 2015; Huo et al., 2015; Ben-Yacov et al., 2021; Mattei et al., 2019; Sleiman, Al-Badri & Azar, 2015; Milenkovic et al. 2021; Itsiopoulos et al. 2011). It is expected this study can further inform the scientific communities and policy makers on the effectiveness of Mediterranean Diet in Oman.

Omani Guide to Healthy Eating and Diabetes Mellitus Management Guidelines were available in Oman since 2009 and 2015, respectively (Department of Nutrition, Ministry of Health Oman, 2009; Ministry of Health Sultanate of Oman, 2015). However, the incidences of Type 2 Diabetes Mellitus are increasing in an alarming rate, with poor glycaemic control was evidence among T2DM. This signifies the need for other dietary approach. Findings of this study served as scientific resource to inform the Omani Guide to Healthy Eating according to dietary pattern.

Last but not least, the current study can provide baseline data for future studies which could further explore the effects of the Mediterranean diet on glycaemic control and cardiovascular risk among Type 2 diabetic patients.

1.4 Study Objectives

1.4.1 General Objective

To determine the effectiveness of Mediterranean Diet on glycaemic control and cardiovascular risk among type 2 diabetes patients in Muscat, Oman.

1.4.2 Specific Objectives

1. To determine the following characteristics of the patients with Type 2 Diabetes Mellitus at baseline:
 - a. Sociodemographic characteristics (age, education level, sex, marital status, income)

- b. Clinical factors (presence of disease, duration of illness, medication)
 - c. Dietary intake (macronutrients and micronutrients) and adherence to Mediterranean Diet
 - d. Lifestyle characteristics (smoking, alcohol consumption, physical activity level, daytime sleepiness)
 - e. Anthropometric measurements (weight, height, BMI, waist circumference)
 - f. Glycaemic control parameters (fasting plasma glucose, HbA1c)
 - g. Risk of cardiovascular (systolic and diastolic blood pressure, high density lipoprotein cholesterol, low density lipoprotein cholesterol, ratio of total cholesterol to high density lipoprotein cholesterol, and triglycerides level).
2. To compare the mean differences in Glycaemic control, risk of cardiovascular, dietary intake, physical activity, daytime sleepiness, anthropometric measurements, within and between control and intervention groups at three months (post-intervention 1) and six months (post-intervention 2) after intervention.

1.5 Research Hypotheses

- H1. There are significant mean differences between control and intervention groups in the following variables after 3- and 6-months intervention (glycaemic control parameters, risk of cardiovascular, dietary intake, physical activity, daytime sleepiness, anthropometric measurements).
- H2. The Mediterranean Diet is significantly associated in improving glycaemic control and reducing risk of cardiovascular among T2DM patients.

1.6 Conceptual Framework

As shown in Figure 1.1, the study aimed to determine the effectiveness of Mediterranean Diet on glycaemic control and cardiovascular risk among type 2 diabetes patients in Omani adults. Adherence to Mediterranean diet was associated with significant improvements in health status, with reduced risk of mortality, metabolic syndrome, diabetes and chronic disease. Earlier studies showed Mediterranean diet can improve risk of metabolic syndrome and may prevent or decrease the risk of metabolic syndrome among individuals with T2DM, which has significant impact on socioeconomic and health aspects of an individual.

In this study, a nutritional education program based on the concept of Mediterranean diet was developed. The Health Belief Model (HBM) is a universal recognised theoretical framework to guide the health education intervention and to improve the intervention efficacy. The focus of the intervention was to create awareness among participants and to help them develop an accurate perception of their own risk. Healthy eating is important in preventing diabetes-related complications and participants were reassured that healthy eating is achievable by adopting the Mediterranean diet. The Health Belief Model in this study assesses different components, firstly the perceived severity which indicates the belief of the participants that type 2 diabetes would have serious consequences, followed by perceived susceptibility highlighting that the participants perceived that they are likely to suffer from the type 2 disease. The modifying factors of this study were the demographic factors and social psychological variables. The cues to action was the intervention part which implies the intervention at baseline to follow-ups. Their likelihood of taking action was assessed during the follow-ups to determine the effectiveness of the intervention.

In this study, it is hope to delineate whether the effectiveness of the universal recognised Mediterranean Diet on glycaemic and cardiovascular risk factors which was shown in Mediterranean populations can be replicated in non-Mediterranean population. The effectiveness of the intervention was examined through the changes in surrogate measure of glycaemic control (HbA1c), and cardiovascular risk factors (systolic blood pressure, high density lipoprotein cholesterol HDL, low density lipoprotein cholesterol LDL, ratio of total cholesterol to high density lipoprotein cholesterol, triglyceride level) after a 6-month intervention. Secondary outcomes of the intervention were psychosocial factors, dietary behaviours and daytime sleepiness.

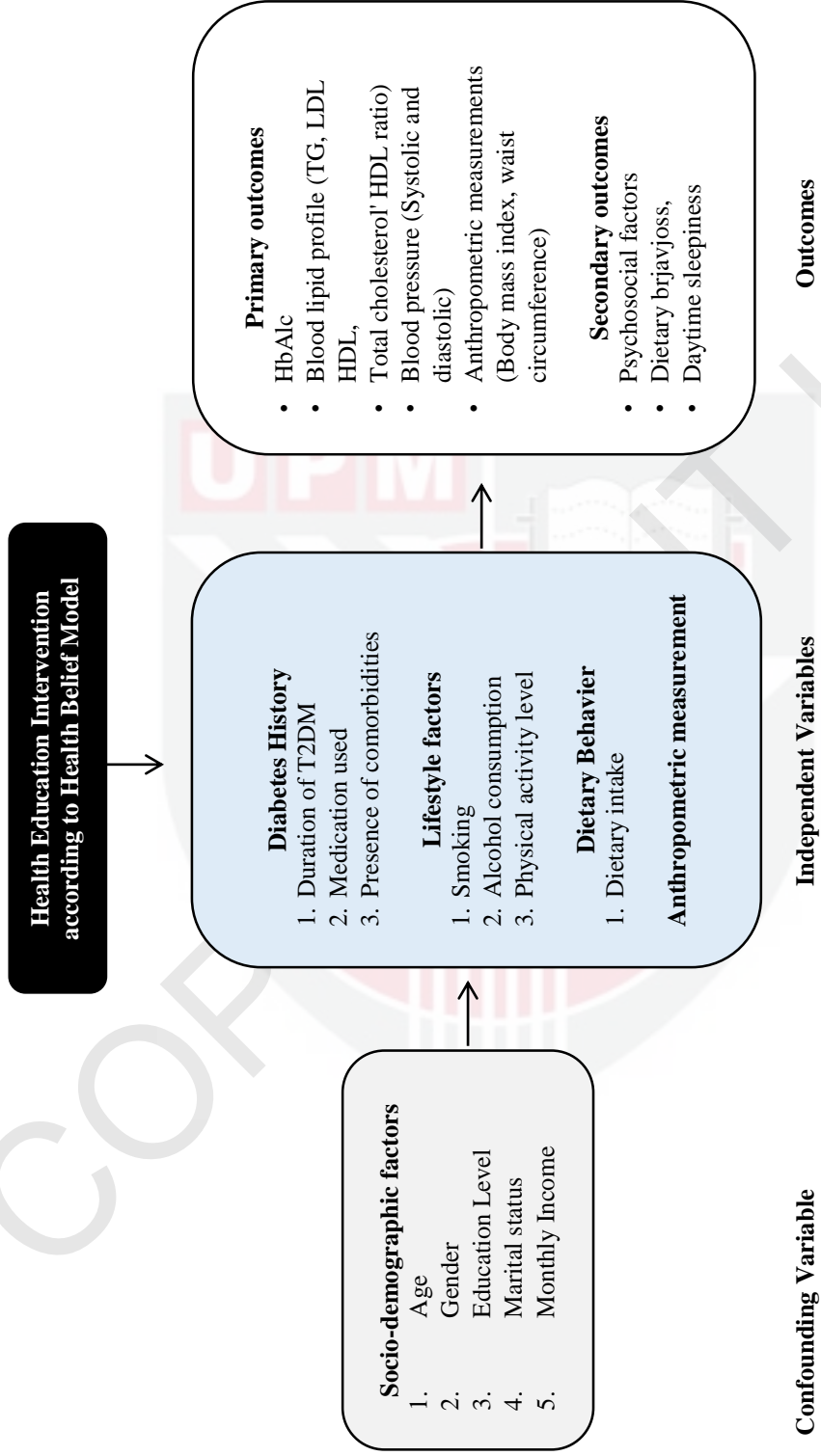


Figure 1.1: Conceptual Framework

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