STUDY PROTOCOL

Effectiveness of Mediterranean Diet on Diabetic Control and Cardiovascular Risk Modification Among Patients With Type 2 Diabetes Mellitus in Oman: A Study Protocol

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ABSTRACT

Introduction: In the recent years, there is remarkable increased in the prevalence of Type 2 Diabetes Mellitus (T2DM) in Middle East countries including Oman. There is good evidence that Mediterranean Diet (MedDiet) is effective over diabetes control and several cardiovascular risk factors in different populations, with little compelling evidence among Omanis. This paper describes the protocol of a wait-list, open labelled, randomized control trial, with its main objective aimed to determine the effectiveness of Mediterranean Diet intervention on glycaemic control and cardiovascular risks among T2DM patients in Oman. **Methods:** A total of 140 eligible T2DM patients will be recruited. Participants in the intervention group will undergo a six-month MedDiet program comprising of different activities (individual dietary counseling, cooking classes, phone calls and social media messages) while the control group will continue with standard diabetes care. Data collection will be conducted at baseline, after three and six months. The 2 x 3 mixed-design ANOVA will be used to determine the mean changes in outcome variables over the full study period between the two groups. **Discussion:** Epidemiology studies on nutrition and health had focused on dietary pattern, which provides an opportunity to account for nutrient-nutrient interactions lately. Mediterranean Diet has produced consistent findings on its protective role in diabetes management, with little information on its effectiveness in population outside of Mediterranean basin, including Oman. The outcomes of current study will be used to inform community and health care professionals on the effectiveness and practically of MedDiet on diabetes management.
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INTRODUCTION

Like other developing countries, Oman has a high incidence of non-communicable diseases (NCDs), with increasing evidence that lifestyle-related NCDs have emerged as new health challenge to the Omani (1). Align with this, there has been a substantial increase in the prevalence of diabetes mellitus over the years, attributed to the epidemiological transition and socioeconomic development (2). More recently, the prevalence of diabetes and pre-diabetes among adults aged more than 18 years old were 15.7% and 11.8%, respectively (3), which is attributed to the steep increase of overweight and obese Omanis (4), tremendous lack of physical activity among T2DM patients (5) and poor diet. Omani has shifted from walking, biking, jogging to sedentary ways of transportation such as driving or using public transport. The use of technology has further enabled human communication through different forms of telecommunication, reducing the need for face-to-face interaction or meeting outdoors. On the other hand, nutrition transition that occurred in the country during the past few decades, with its characteristic shifts in diet and lifestyle partly attribute to the increasing numbers of T2DM as well (6). The traditional Omani diet, which is characterized with high fiber and low fat, has been replaced by westernized diet rich in saturated

fats, sodium, cholesterol, free and added sugars (7).

Type 2 diabetes mellitus and cardiovascular diseases (CVD) had been identified as a major and increasing workload for clinicians in Oman hospitals (2). Without any concerted action, Oman is expected to experience a substantial increase in its prevalence and associated macrovascular and microvascular complications, which give serious impact on socioeconomic, health and psychosocial to the people and nation. Evidence supports the effectiveness of lifestyle interventions across clinical and community settings and delivery formats (individual, group or technology-based) and implementers. Align with this, the World Health Organization has identified "best buys" with lifestyle interventions are important to mitigate NCDs including T2DM. Dietary treatment works alongside weight loss and lifestyle approaches (diet modification and increased physical activity) and is recognized as the cornerstone to the management of T2DM.

In recent years, compared to traditional approaches which used single food groups or nutrients, scientific communities have been focused on dietary pattern approaches which represent a comprehensive picture of an individual overall diet, allowing appreciation on the relationship between diet and disease (8). Mediterranean Diet defines as the traditional food intake of people living nearby the Mediterranean basin, and characterized by the intake of olive oil, fruits, vegetables, nuts, legumes, whole grains, with low consumptions of poultry and red meat and low to moderate amounts of fish besides a moderate consumption of dairy products such as yogurt, is one of the most studied dietary patterns.

Despite full implementation of the National Treatment Diabetes Guidelines, there remains absence of strategy, action plan or operational policy for diabetes or its risk factors, including plans to reduce obesity and physical inactivity in Oman. When compared with other dietary patterns, MedDiet has consistently mitigates CVD risk factors and is associated with reduction in risk of fatal and non-fatal clinical events of CVD in Mediterranean and non-Mediterranean European countries such as Asia (9) and Australia (10). While western dietary pattern has been predominant among Omani adults with fewer adherences to the traditional diet, such as the Mediterranean diet (11), several recommendations of the food based dietary guidelines for Omani are in line with Mediterranean Diet recommendations (12), which are considered an affordable and accessible dietary pattern (13). Mediterranean Diet is renowned as easily adopted by different populations with various cultures as it is adjustable and flexible according to certain needs/ preferences. With the scarcity of data on effectiveness of MedDiet among Omani and the growing evidence that MedDiet works for non-Mediterranean countries, this study is designed to evaluate the effectiveness of MedDiet on diabetes control and cardiovascular risk among T2DM patients in Muscat, Oman.

METHODS

Study design

A parallel 1:1 group, randomized controlled trial with two cohorts, specifically, the intervention and control groups, will be used to determine the effectiveness of MedDiet on numerous results for participants with T2DM. This study aims to determine effectiveness of MedDiet on glycaemic control, metabolic profiles and other metabolic-related parameters in patients with T2DM. This study is trying to address the following research questions, namely (1) Is 6-month Mediterrenean Diet intervention able to improve glycaemic control and metabolic profiles of T2DM patients in Oman and (2) Can a 6-month Mediterranean diet intervention brings significant mean changes in anthropometric parameters, psychosocial factors, sleeping quality and dietary behaviors between the intervention and control groups? An overview of the study design and allocation of study participants is illustrated in Figure 1.

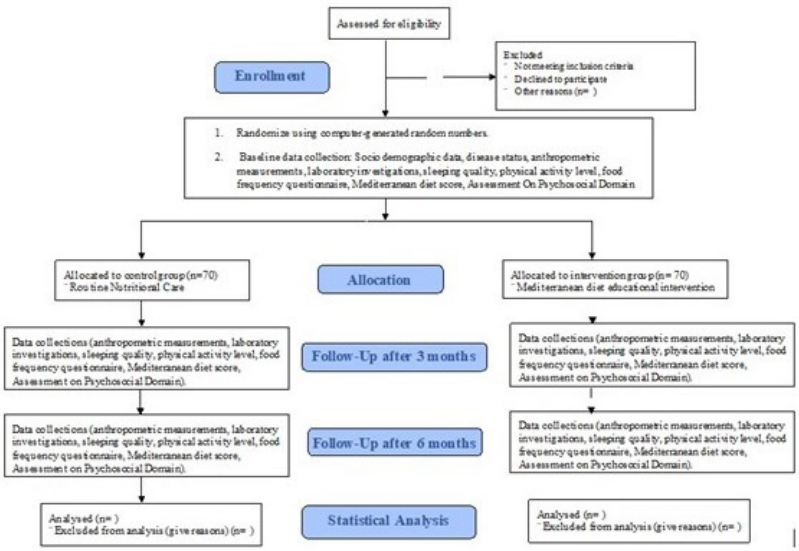

Figure 1: Study workflow

Setting, recruitment, and participants

Study participants will be recruited from the Outpatient Nutrition Clinic, National Diabetes and Endocrine Centre of Royal Hospital Muscat, Oman. Only new referrals for diet optimization will be recruited to avoid possibility of bias or contamination in the education and counselling sessions. Screening for eligibility will be performed by the same onsite researcher using pre-determined inclusion and exclusion criteria. Eligibilities are those between 18 – 75 years old, read and write, male or female adults diagnosed with T2DM, with a stable level of HbA1c at < 10% who are expected to have stabilized glycaemic control, and with no change in type and dosage of medications needed in the next six months. On the other hand, individuals who are pregnant or lactating, diagnosed with cardiac failure and/or severe renal disease, with mental disability and neurological or cognitive impairment will be excluded. Moreover, patients with severely impaired vision, hearing, or speech or who have known allergy to peanuts or any of the components of the MedDiet are to be excluded.

Sample size calculation

In order to calculate the right and sufficient sample size that will be the representative of the study population, the highest available estimated proportion of HbA1c for control and intervention were obtained from the previous carried out on Australian population (14). The formula for calculating sample size in hypothesis testing by comparing two proportion was used (15), whereby study sample size for each group is 61. In addition, calculation of sample size will be performed using G-Power software according to the highest statistical analysis, namely repeated measure at three time points (baseline, month 3 and month 6). Accordingly, a total of 126 participants (n= 63 per group) are required to achieve clinical meaningful contrast of HbA1c (the primary outcome measure of glycaemic control) at 0.5%, at statistical power of 80% and 5% significance level. There is no difference in sample size calculation based on the above two calculations. Attrition rate for similar study was ranged from 2.6% to 19% (16, 17). Allowing for a 10% dropout, a total of 140 participants will be needed in the recruitment.

Allocation concealment and randomization

During baseline data collection and informed consent meetings, participants will be blind to their group allocation. Eligible patients will be randomly allocated into control or intervention group. To reduce selection bias, randomization will be performed using computer-generated random numbers by the primary researcher who supervise the whole project, not residing in Oman, does not know the participants and is blind to the group allocation. Each allocated sequence will be written in a small card and placed in a sealed envelope. The envelope will be opened after the participant completes the baseline assessment. The onsite researcher will then inform the participant about the intervention allocation and follow-up process. Since study outcomes include changes in nutrition behaviors, it will be inappropriate to blind the participants throughout the entire study. Hence, an open-label design will be used.

Interventions

Wait-list control group

The participants who are allocated to the wait-list control group will continue to receive standard diabetes care from the Nutrition Clinic of National Diabetes and Endocrine Centre. The standard diabetes care includes two group-based educational sessions on a moderately low-fat calorie-controlled diet (≤30% fat of total calories) and sustainable healthy behaviors. The first session will be discussion about the meal plan and the following session will be checking on adherence of patients with the meal plan and problem solving on behaviors that hinder their dietary adherence. To minimize or avoid any possibility of contamination between the control and intervention participants, the control group will be invited to the nutritional clinic on different days or clinic slots. To standardize the dietary advice, the same nutritionist (onsite researcher) will perform the counseling to both the control and intervention participants. Participants who allocated in the control group will receive the same nutrition package as the intervention participants after the completion of the study.

Intervention group

The participants in this group will participate in the intervention for 6 months, which is a five-session program, comprising 30–45 minutes each session. It is well-recognised that changing an individual's dietary intake is difficult and complex, as it involves decision making and maintaining a change in behavior. Evidence is growing that use of psychological theory in behavior change is associated with larger intervention effects (18). In this study, the Health Belief Model (HBM) will be the underpinning theory to facilitate behavioral change that promote adherence toward MedDiet among the participants. The HBM is a widely used framework developed to understand health behaviour and increases the impact of nutrition education. There are six constructs of HBM, consists of perceived susceptibility, perceived severity, perceived benefits, perceived barrier, perceived self-efficacy and cues to actions. We intend that the adoption of HBM will assist participants to adopt a healthier diet pattern (MedDiet) by recognizing that they have health problems namely physical inactivity, poor diet quality (perceived susceptibility), accepting the reality and feeling threatened (perceived severity), being sensitive to its impact on health and being convinced that MedDiet is critical (perceived benefits). Along the intervention, possible barriers or problems encountered by participants (perceived barriers) will be identified and coping strategies to overcome barriers toward adoption of MedDiet (perceived self-efficacy)

will be implemented. Education booklets and leaflets (Physical and Digital copies) and weekly social media messages will further enhance the participations (cues of actions). Additionally, a counseling method will be adapted from cognitive behavioral therapy, whereby strategies including self-monitoring and goal setting will be employed. The researchers will apply the goal setting by giving each participant a goal chart during baseline.

Intervention delivery

All intervention participants in this study will undergo a six months MedDiet program comprising three individual dietary counseling and two group cooking classes. During the education session, participants will be consulted related to the MedDiet in according to an earlier controlled trial (19). An emphasis on the dietary modification according to principles of MedDiet which include an abundant of plant- based intake are highlighted to the participants. The details include:

a) Each participant will be provided with a healthy eating plate as an incentive, whereby they are required to first fill half of the plate with vegetables for lunch and dinner
b) Eat seafood twice a week. Participants are advised to consume shellfish, salmon, tuna, herring and other fish at least twice a week
c) Moderate intake of poultry at 2 servings per week
d) Cut down on the consumption of red meat at once every three weeks
e) 1-2 servings of dairy products per day
f) To use olive oil in cooking and in salad dressings
g) Switch from refined/process products to whole grains products
h) Increase raw unsalted nut intake (1-2 serving per day) and legumes (at least 2 serving per week)
i) Switch sweet desserts (e.g., Omani Halwa) or fried items (e.g., Lokma) with healthier snacks (e.g. fresh fruits)

A total of seven visits are needed with the details depicts on Figure 2. At the first visit, an individual dietary counseling section will be performed. Emphasis is made on the dietary modification as highlighted above. Participants will be provided with a small booklet (hard and soft copies) which contain useful tips on MedDiet such as the definition of the MedDiet and its benefits, MedDiet food groups and serving size needed to be consumed, how they can get started with MedDiet, common words in the MedDiet food glossary, common principles of MedDiet recipes, ways to cook foods, and recommended cooking methods. At third (week 2) and fifth (Month 3) visits, reinforcement of individual goals, follow-up on their adherence to nutrition advice and discussions on possible barriers or problems encountered with intervention will be addressed.

During cooking workshops or classes, participants will be educated on practical ways to prepare MedDiet, with simple meals to be cooked together with the

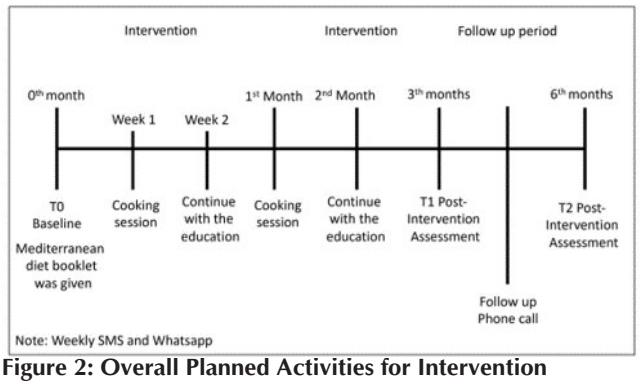

Figure 2: Overall Planned Activities for Intervention

participants. A social media platform (WhatsApp) will be created to disseminate information on a weekly basis. Possible obstacles and challenges faced by participants, along with appropriate coping strategies will be discussed. Periodically, discussions on healthy snack and food choices will be conducted. Participants will be reminded to adhere to the nutrition advice given. In addition to individual sessions, two telephone calls (each is estimated to last 10-15 minutes) will be made throughout the 6-month period. A structured topic guide will be used when telephone calls are made and would include reinforcement of individual goals, follow-up on their adherence to nutrition advice and application of MedDiet, and discussions on possible barriers or problems encountered. Therefore, the intervention program comprises of practical methods to rise perceived susceptibility, self-efficacy and advice for decreasing perceived barriers to MedDiet practice. Strategies will be employed to improve engagement and reduce attrition, including providing education booklets and leaflets as reminders of study participation at home. In addition, regular contact through phone or social media with participants throughout the trial is aimed to maximize engagement of participants in the trial and reduce attrition during follow-up stages. The acceptance of MedDiet will be ascertained through participants' compliance of the Mediterranean diet, satisfaction, feedback and input of the program. Adherence questionnaire on Mediterranean diet will be administered on a three monthly basis. Satisfaction level of participants on the educational materials used, support provided and overall educational program will also be obtained. For further improvement of the program, suggestions and feedbacks from the participants will be ascertained using appropriate instrument.

Data Management

Data cleaning will be performed before analysis to enhance data quality. Activities include the detection, removal and correction of imperfect or flawed data because of missing and inconsistency. Generally, inconsistent data can result from the error which can occur during data entry. Cross-checking will be performed by using paper trace in which the raw dataset will be printed out and screened and corrected manually after completing the data entry. Additionally,

effort will be made to minimize missing data during the data collection by which the case report form will be checked to confirm that all information required has been collected before ending the interview sitting.

Planned data analysis

All data will be analyzed via Statistical Package for the Social Sciences (SPSS) program version 24.0. For each continuous variable, the mean, standard deviation and range will determine via descriptive statistical analysis. Percentages and frequencies were used to describe categorical variables. Exploratory data analysis conducted to determine the normality of the variables. Nutrient consumption will be examined for normality via the Kolmogorov-Smirnov test and those intakes that will skewed will transform. To determine significant differences in dietary intake data and anthropometric between control and intervention groups, independent t-tests will be performed.

The general linear model repeated measure will be used to test whether there are changes in dietary assessments, anthropometric measurements, physical activity, fasting blood glucose, blood pressure, blood lipid profile, and sleeping quality existed within each group over the baseline, 3 months (Post intervention 1) and 6 months (Post intervention 2) after the intervention. The 2 x 3 mixed-design ANOVA will be used to determine the changes in outcome variables over the full study period between the two groups controlling for potential confounding variables. An intention to treat analysis will be used for this study. Statistical significance is set at $p< 0.05$.

Ethical consideration

Ethical approvals were granted by the Medical Research Ethics Committee of Universiti Putra Malaysia (JKEUPM-2019-456) and Ministry of Health Sultanate of Oman (SRC#22|2019). Participants will be enrolled from the Outpatients Nutrition Clinic with formal written informed agreement to be obtained by onsite researcher from each participant prior to study enrolment. The study is registered with UMIN Clinical Registry Trial UMIN000041152.

Outcome measures

The primary outcomes in this study are changes in glycaemic control (HbA1c) and metabolic profiles (Lipid profile and blood pressure), anthropometric parameters (Waist circumference, weight and body mass index), with secondary results involve changes in Mediterranean Diet Score, dietary consumption (calories, carbohydrates, protein, fat, minerals as well as vitamins), physical activity, psychosocial factors (perceived barriers to health eating and self-efficacy) and sleep quality.

Measurements

In both groups, each participant will be assessed before beginning of the intervention (baseline), after the study intervention (after 3 and 6 months). Entering the data into the database will be via using as unique study codes for all participants. A set of pre-tested structured questionnaire will be performed to obtain details on sociodemographic, lifestyle features and clinical data of the participants. Assessment of dietary data and physical measurement including anthropometric measurements, blood pressure, and biochemical parameters will be performed accordingly. The original questionnaire was prepared in English and was translated into Arabic by a university academician with health science background and who is proficient in both languages. The translated and back-translated questionnaires were consistent.

Socio-demographic and lifestyle characteristics

Information about gender, age, work status, educational level, marital status and family monthly income of the participants will be ascertained. Lifestyle characteristics such as smoking behavior and pattern of alcohol consumption will also be collected. Physical activity of participants will be assessed using the 7-item, short form International Physical Activity Questionnaire (IPAQ-SF) (20). IPAQ-SF allows researchers to assess engagement (frequency and duration) of participants in walking, moderate-intensity activities and vigorous-intensity activities. This allows quantification of physical activity score of participants in the form of metabolic equivalent (MET) and categorization of level of physical activity of participants into low, moderate or high (IPAQ Research Committee, 2005). Sleep quality of participants will be ascertained using Epworth Sleepiness Scale, which is commonly used as subjective assess of an individual's sleepiness. Participants will be required to rate their fall asleep or doze off in the eight situations, according to their normal way of life in current times.

Psychosocial domains

Perceived barriers to healthy eating of participants will be assessed using a 11-items questionnaire (21). Ascertainment of personal and environmental barriers (barriers about access to information, motivation, enjoyment, skills, access, and cost), social and environmental barriers (barriers related to the partner, child and friends' support, time due to job demand, and time due to family commitments) are rated and performed on a 3-point Likert scale as (1) not a barrier, (2) a somewhat important barrier or (3) a very important barrier. Total possible scare will be ranged between 11 to 33 with higher score corresponds to greater perceived barriers to healthy eating.

In addition, self-efficacy for diabetes of the participants will be assessed using the Self-efficacy for Diabetes instrument (22), which consisted of 8-item in which participants will ranked their degree of confidence in managing daily diabetes self-management or self-care behaviors, including medication adherence, blood sugar monitoring, physical activity and diet. The participants

will rate their degree of confidence from 1 to 10 with higher score indicates higher self- efficacy.

Biochemical and Clinical parameters

Biochemical data including fasting blood glucose, HbA1c, lipid parameters, blood pressure and renal function tests of the participants will be retrieved as secondary data from hospital records, which are scheduled on three monthly basis as part of the routine clinical care. Clinical history of the participants including duration of T2DM, prescribed diabetic medications and its compliance, presence of other comorbid diseases such as thyroid diseases, Genitourinary diseases, Gastrointestinal tract diseases, hypertension, dyslipidaemia, bone diseases or behavioural and psychological diseases will be ascertained.

Assessment of Body Composition

Assessment of body composition will be performed by qualified researcher. Body weight of participants will be taken via medical body composition analyzer (seca 515, Hamburg Germany) and recorded to the nearest 0.1 kg after participants in light clothes remove their shoes and empty their pockets. Weight will be measured twice and the average being recorded. Height of the participants will be taken by using stadiometer to the nearest 0.1 cm. Before measurements are carrying out, participants are required to stand upright with feet together in the center of the base plate. As proxy measure of body weight status, Body Mass Index (BMI) of the participants will be computed as weight square divided by height. Besides weight and height, body composition namely fat free mass and fat mass of the participants will also be determined using the medical body composition analyzer (seca 515, Hamburg Germany). A 4-compartment model using deuterium oxide dilution (D2O), Dual Energy X-Ray Absorptionmetry (DEXA) and Air displacement plethysmography (ADP) will be used as reference for fat free mass. On the other hand, waist circumference of the participants will be assessed and recorded to the nearest 0.1 cm with the use of fiberglass measurement tape according to standard protocols (23). The measurement should be made at the end of a normal expiration while the participants stand with arms at the sides, feet close to each other, and weight evenly distributed across the feet. Waist circumference measurement is taken at a point midway between the lowest rib and the superior border of the iliac crest in the mid-axillary line. Presence of abdominal obesity is confirmed when the waist circumference reading is more than 90 cm and 80 cm for male and female, respectively (World Health Organization, 2000).

Dietary Assessment

Dietary assessment of participants will be performed using a pre-tested validated 117-items food frequency questionnaire (FFQ) (24) which allow the ascertainment of dietary pattern and nutrient intakes, respectively. The FFQ contains breads/ cereals, vegetables, fruits, olive oil, nuts, legumes, milk and dairy products, fermented beverages, fish, eggs, red meat, white meat, sweets and traditional Omani dishes. The participants will be interviewed to recall the portion size and frequency of consumption of food and beverage over the previous month. Besides FFQ, participants are required to complete a 24-hour dietary recall for quantification of nutrients intake. The dietary recall will be analysed using the Cronometer software Inc., (https://cronometer.com) Nutrient File within the nutritional analysis software program ESHA Food Processor (version 11.1). Adherence to Mediterranean diet among the intervention participants will be assessed by applying a reliable and validated self-administered questionnaire (25) that address adherence of participants on particular dietary aspect for example the number of daily serving of fruits and vegetables, the consumption of olive oil as a main source of dietary fat, the number oof seafood-based meals consumed per week, the consumption of red meat as well as the quantity of sweetened or carbonated beverages intake and so on.

Follow-up data collection

Follow-up data collections are performed at 3 months and 6 months, according to the specific timeline. All participants will be invited to obtain or complete follow-up data collection, regardless of their compliance to the recommendation. Assessments are performed for all parameters, with the exception on demographic data which will only be assessed once at baseline. In addition, a structure program evaluation will be performed at the end of the study period. Participants' satisfaction with the educational materials, support, and overall educational program will be obtained. Feedback regarding understanding and benefits of the program and suggestions for further improvement of the program will be ascertained. Further details of these measures are indicated on Table I.

Pre-testing

Pre-testing will be conducted among 14 T2DM patients (10% of the calculated sample size), who will not be included in the actual study. Clarity of instructions and understanding of questions of the questionnaires and feasibility in answering the questionnaires will be ascertained. Problems that are encountered by participants in answering the questionnaires will be identified and amendments will be performed as deemed fit to improve the instruments.

Dissemination

The outcomes from current study will be disseminated through research findings seminar to the participants enrolled in the study, presentations at related conferences for healthcare professionals and researchers, additionally in peer-reviewed publications.

Table 1: Assessment of parameters at different time points

Timepoint	Study Period			
	Enrollment	Baseline	3 months	6 months
Enrolment				
Eligibility screen	X			
Informed consent	X			
Allocation reveals to participants	X			
Interventions				
Mediterranean Diet Intervention				
Standard Nutrition care				
Assessments				
Demographic		X		
Biochemical		X	X	X
Anthropometric		X	X	X
Physical activity		X	X	X
24-hour diet recall		X	X	X
Past-month food frequency		X	X	X
Mediterranean Diet score		X	X	X
Perceived barrier to healthy eating and self-efficacy		X	X	X
Sleep quality		X	X	X
Program Evaluation				X

DISCUSSION

As in other countries, Oman is experiencing drastic multi-dimensional transition. The shift from rural to urban dominance and sedentary lifestyles lead to dramatic increases in incidences of obesity, T2DM and CVD (26). Type 2 Diabetes Mellitus is a lifestyle-dependent disorder which need a multidisciplinary and multidirectional management (27), with dietary management as the cornerstone of management. Nevertheless, it is widely recognized that lifestyle changes is the most problematic and difficult section of the treatment (28), which had reflected on the high prevalence of non-compliance on dietary management (29) attributed to patient factors. Inevitably, lifestyle interventions specifically adherence to MedDiet have produced favorable health outcomes (30). Nevertheless, evidence was mostly among non-diabetics, with inconclusive outcomes on the effect of the MedDiet reducing the cardiovascular risk among diabetics. In addition, the health benefits of the MedDiet in the Oman population have not been explored. The collection of dietary and other parameters over 6 months in this protocol will inform whether MedDiet can be applied for Omani and whether there will be parallel health benefits results as seen in other countries. Therefore, this current study has theoretical, practical and research significance.

The expected outcomes of the study include an improvement in the glycaemic control (HbA1c) and metabolic profiles (Lipid profile and blood pressure) among the intervention participants after 6 months intervention of Mediterranean Diet. On the other hand, it is expected intervention participants will improve their anthropometric parameters (waist circumference, weight and body mass index), dietary intake, psychosocial factors (perceived barriers to health eating and self-efficacy) and sleep quality.

Limitations

Several possible limitations in the current study should be addressed. Participants' recruitment may be challenging as lifestyle intervention is scarce in Oman, so strategies are needed to attract the participation, including mounting of recruitment advertisement or poster at the clinic, and through word of mouth. Attrition rate can be high because of the long duration of follow-up (6 months).

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