

# Impact of Physical Activity and Dietary Programme on Metabolic Syndrome Risk Factors in Saudi Women

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**Abstract:** This study explores the impact of lifestyle factors on the development of metabolic syndrome (MS) in Saudi Arabian women. The efficacy of reducing energy intake, with or without increased PA, on risk factors associated with MS in overweight Saudi women was investigated in a pilot study. After a four-week programme, incorporating dietary modification alone (D) or in combination with regular vigorous aerobic exercise (D+E), improvements were seen in body composition and a range of metabolic risk factors. Both groups lost weight, but, paradoxically, those in D lost significantly more than those in D+E (5.3 vs. 3.3%,  $p=0.016$ ). Moreover, significant reductions were also found in blood pressure, plasma triacylglycerol, insulin, total and LDL cholesterol, with no significant differences between the two groups. Plasma glucose and HDL cholesterol remained unaltered. Overall, these changes led to a decline in prevalence of MS from 20% to 5% and 21% to 7% for the D and D+E groups, respectively. Thus, reducing energy intake appears, at least in the short term, more important than increasing PA in reducing body weight and associated metabolic risk factors. This study confirms that excessive dietary intake and physical inactivity both contribute to overweight/obesity and MS in Saudi Arabian women. With appropriate support, it is possible to both reduce energy intake and increase PA, although, in the short-term, the former appears to be most important. It remains to be established whether longer term improvements in PA would further improve metabolic health.

**Keywords:** Physical Activity, Dietary, Metabolic Syndrome, Saudi Women.

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## Abbreviations

BMI: Body Mass Index

BP: Blood Pressure

CVD: Cardiovascular Diseases

D: Diet

DASH diet: Dietary Approach to Stop Hypertension

DBP: Diastolic Blood Pressure

DE: Diet plus Exercise

DRVs: Dietary Reference Values

EAR: Estimated Average Requirement

EMR: Eastern Mediterranean Region

FBG: Fasting Blood Glucose

FFA: Free Fatty Acid

HDL: High Density Lipoprotein

HOMA-IR: Homeostatic Model of Insulin Resistance

IDF: International Diabetes Federation

IR: Insulin Resistance

KSA: Kingdom of Saudi Arabia

LDL: low Density Lipoprotein

MS: Metabolic Syndrome

PA: Physical Activity

RNI: Reference Nutrient Intake

SBP: Systolic Blood Pressure

TAG: Triacylglycerol

T2D: Type 2 Diabetes

TC: Total Cholesterol

UAE: United Arab Emirates

VAT: Visceral Adipose Tissue

WC: Waist Circumference

WHO: World Health Organization

W-SA: Women Living in Saudi Arabia

W-UK: Women Living in the UK

## 1. Introduction

The terms Metabolic Syndrome, Insulin Resistance Syndrome or Syndrome X have been used to define the clustering of factors that increase the risk of developing CVD and T2D (Sayon-Orea et al., 2014). The principal cause of MS is central obesity, being overweight with adipose tissue accumulation mainly around the waist. The results in the development of a range of risk factors for CVD/T2D including impaired fasting glucose, IR, elevated TAG level, high BP and decreased HDL cholesterol (IDF, 2006).

Saudi Arabia has experienced a marked increase in the prevalence of adult obesity over the last few decades, particularly in women. The consequences of obesity include an increased incidence of MS, CVD, T2D and other chronic diseases. According to the national epidemiological health survey, the prevalence of MS among the Saudi population has been reported to be approximately 40%, with a higher prevalence in females compared to males (42% vs. 37.2%) (Al-Nozha et al., 2005). Studies predict a sharp increase in the prevalence rates of the syndrome among Saudi females

during the next few years (Al-Qahtani et al., 2006). Obesity is the greatest, most easily observed and measurable risk factor for this syndrome. MS is found in about 5% of adults with normal body weight, 22% of those who are overweight and 60% of those who are obese.

However, as already indicated it is not only the amount of excess adipose tissue but also its distribution that may be important. Females have more body fat than males, but in contrast to the deleterious metabolic consequences of the central obesity typical of males, the pear-shaped body fat distribution of many females correlated with lower cardiometabolic risk (Karastergiou et al., 2012). Central obesity is a key feature of MS, reflecting the fact that the prevalence of the syndrome is driven by the strong relationship between WC and increased the adiposity (Després et al., 2008). Abdominal adiposity is associated with IR and creates an atherogenic inflammatory milieu. High levels of these biomarkers correlate with increased risk of T2D and CVD. A slight decline in body weight can significantly decrease abdominal adipose tissue, IR, LDL-C, TAG, BP and reduced overall cardiometabolic risk (Janet et al., 2006).

Weight reduction represents the major goal in preventing and treating MS. Interventions to modify dietary behaviour have been successful in both cases of people already diagnosed with metabolic disease, or in those at risk of developing such disease (Ammerman et al., 2002; Laws et al., 2004; Sinclair et al., 2008). Lifestyle interventions, including dietary changes, have been shown to reduce the incidence of diabetes by 58% compared to a control group of individuals at high risk (Kaur, 2014). It should be pointed out that no single diet is currently recommended for patients with MS. Therefore, it may be best for dietitians to focus on each patient's specific metabolic alterations when offering dietary advice. Babio et al. (2014) found that patients with MS who were advised to undertake the DASH diet were able to raise their non-HDL cholesterol and experienced a significant reduction in BP, lowered their blood sugar and TAG levels and even lost weight after six weeks.

## 2. Hypotheses

- Lifestyle modification (aerobic exercise and/or dietary advice with individual nutrition counselling) will significantly reduce early markers of MS and decrease body fat in Saudi women.
- The combination of diet and exercise would result in greater changes in anthropometric measurement and metabolic risk factors than diet alone.

## 3. Aim

To measure the impact of exercise training and/or diet in improving risk factors associated with MS in Saudi women (a pilot study).

While the benefits of reducing energy intake are widely accepted, the impact of increased physical activity on the features of MS remains more controversial. As body weight represents a balance between energy intake and expenditure, it might be expected that a combination of dietary restriction and increased PA would be of greater benefit than diet alone.

However, not all studies report that exercise plus diet are more successful in the treatment of MS than diet alone. In 2005 Kukkonen-Harjula et al reported that adding physical exercise to dietary counseling did not significantly alleviate MS more than diet alone. Thus, it can be seen that, while there is a generally held perception that the combination of dietary restriction and increased PA is more beneficial in treating or preventing MS than diet alone, the existing evidence is far from conclusive.

Physical exercise also varies in terms of its intensity, duration and this may influence its overall impact on MS. A study conducted in Saudi Arabia found that vigorous PA had a strong positive correlation with HDL-C and a negative correlation with BMI (Al-Ajlan and Mehdi, 2005).

Physical inactivity has previously been reported as extremely prevalent across all sex and age groups within the Saudi population (Al-Hazzaa, 2004b), with there being significantly more less active females (98.1%) than males (93.9%) (Al-Nozha et al., 2007). The relative impact of excess energy intake and decreased PA on metabolic risk in this population remains to be fully established. This is important as it might be anticipated that, in Saudi women, who face significant barriers to increasing PA, specific focus on dietary intervention may be more acceptable than increasing energy expenditure. To the best of our knowledge, in Saudi Arabia there have been no previous intervention studies specifically examining the association between PA, diet and MS in females. Therefore, the purpose of this pilot study is to examine the effect of an intensive dietary programme, including individual nutrition counseling, with or without increased PA, on MS-associated risk factors among Saudi women.

## 4. Objectives

- To determine the metabolic status (including BMI, WC, BP, fasting plasma glucose, insulin level, IR, TAG, TC, LDL and HDL) for two groups of overweight, adult, Saudi females, a diet-only group (D) and a diet plus exercise group (D+E).
- To improve MS-associated risk factors by modifying dietary habits and energy intake through provision of dietary advice, including follow-up (individualised nutritional counselling) using WhatsApp messages, focusing on dietary goals for reducing energy intake and adopting a 'healthy diet' involving lifestyle modifications and weight loss.

- To increase the PA of the diet plus exercise group through access to a fitness centre with a qualified fitness instructor, one hour six times a week.
- To measure usual intake of particular food groups (fruits, vegetables, grains and cereal products, dairy products, meats and alternatives, nuts and

seeds, beverages, snacks/sweets and crackers, fast food) and assess dietary intake (analysing carbohydrates, proteins, fats, selected vitamins and minerals, fibre and sugar intake) and assess level of PA pre- and post-intervention using a seven-day food/exercise diary.

programme. WhatsApp provides a convenient alternative to meeting with each participant face-to-face.

Permission and a letter of agreement were obtained from the researcher's official sponsor (King Faisal University) and approval from the clinic's owners; in addition, written informed consent was obtained from all subjects. Exclusion criteria included participation in exercise programmes in the previous 12 months, smoking, chronic diseases, pregnancy, bariatric surgeries and any medications contraindicated for study participation. Two participants from group D and one from group D+E withdrew at the baseline intervention and there were no reasons for withdrawal MS was defined based on the International Diabetes Federation's (IDF) new criteria with ethnic-specific values (Tables 4.1-4.2) (IDF, 2006).

## 5. Methodology

### 5.1. Study design

The study was carried out in Al-Ahsa Governorate, located in the Eastern province of Saudi Arabia, from September 2013 to June 2014. The study recruited 40 apparently healthy women, aged 18-54, who were at risk of developing MS (BMI over 27) to participate in the study; 20 subjects for the diet only group and 20 subjects for the diet plus exercise group. Details of recruitment of subjects are included in Section 2 below.

Baseline activity levels, water consumption and dietary intake were assessed using a seven-day diet and exercise diary for both groups. Dietary advice was provided, on an individual basis, by mobile phone using the WhatsApp

Table 4.1: The new International Diabetes Federation definition

According to the new IDF definition, for a person to be defined as having the metabolic syndrome they must have: Central obesity (defined as waist circumference* with ethnicity specific values) <u>Plus</u> any two of the following four factors:	
Raised triglycerides	≥ 150 mg/ dL (1.7 mmol/L) or specific treatment for this lipid abnormality
Reduced HDL cholesterol	< 40 mg/ dL (1.03 mmol/L) in males < 50 mg/ dL (1.29 mmol/L) in females, or specific treatment for this lipid abnormality
Raised blood pressure	Systolic BP ≥ 130 or diastolic BP ≥ 85 mm Hg or treatment of previously diagnosed hypertension
Raised fasting plasma glucose	(FPG) ≥ 100 mg/ dL (5.6 mmol/ L), or previously diagnosed type 2 diabetes. If above 5.6 mmol/L or 100 mg/ dL, OGTT is strongly recommended but is not necessary to define presence of the syndrome.
* If BMI is >30kg/m <sup>2</sup> , central obesity can be assumed and waist circumference does not need to be measured.	

Table 4.2: Ethnic-specific values for waist circumference

Country/ Ethnic Group	Waist circumference	
Europids* In the USA, the ATP III values (120 cm male; 88cm female) are likely to continue to be used for clinical purposes	Male	≥ 94 cm
	Female	≥ 80 cm
South Asians: Based on a Chinese, Malay and Asian- Indian population.	Male	≥ 90 cm
	Female	≥ 80 cm
Chinese	Male	≥ 90 cm
	Female	≥ 80 cm
Japanese**	Male	≥ 90 cm
	Female	≥ 80 cm
Ethnic South and Central Americans	Use South Asian recommendations until more specific data are available	
Sub- Saharan Africans	Use European data until more specific data are available	
Eastern Mediterranean and Middle East (Arab) populations	Use European data until more specific data are available	

\*In future epidemiological studies of populations of European origin, prevalence should be given using both European and North American cut-points to allow better comparisons. \*\*Originally different values were proposed for Japanese people but new data support the use of the values shown above.

## 5.2. Study sample

It is recognised that the ideal design for such an intervention study would be the selection of a representative sample of the target population and subsequent randomization to different treatment groups. Such groups could include a control (no intervention), diet only, exercise only and diet + exercise. The size of these groups would be decided on the basis of power analysis relating to the key outcome measures of the study. Data would be analysed on an 'intention to treat' basis to ensure that differences in dropout rate did not adversely impact on the outcome of the study. However, due to time constraints and the difficulty in recruiting Saudi females for such a study a number of significant compromises had to be made in the study design. The possible impact of these compromises on the outcome of the study is addressed below and further in the discussion of the results.

In this study, an attempt was made to increase the validity of samples by using selection criteria which ensured the groups studied were matched in terms of age and BMI. However, the model of having two distinct population groups means that not all bias could be eliminated.

## 5.3. Study length

For this pilot study, an intensive, four-week exercise and/or dietary intervention was selected. The study time frame was short but considered long enough to show changes in body weight and MS parameters as proven in previous studies (Clark and Burden, 2005; Johnson et al., 2009; Kauko, 2010).

## 5.4. Participants

A sample of 20 participants was selected from two clinics. The two clinics both had the same owner, the same system and same rules, and both had gyms with qualified expert fitness instructors, who designed the exercise sessions. Participants were required to perform an exercise session, six times per week, during which they undertook approximately 20 minutes' vigorous and 40 minutes' moderate exercise. Subjects were identified by the clinic medical directors and fitness instructors as potential participants. It was agreed with the clinics to display posters and to ask women, who come to register in the gym for the first time, to participate in the experiment. It has been recruited women who met the inclusion criteria and were eligible to participate in the project according to the pre-exercise screening questionnaire, which was adapted from the Active8 questionnaire (2009), and to give them the researcher's phone number to make contact, in order to determine suitable and serious subjects for the project.

## 5.5. Anthropometric data and biochemical measurements

All the anthropometric measurements both at baseline and at follow-up for both groups were taken by the same two nurses who have an extensive experience in the use of anthropometry. BMI determination remains the most reliable measure for the assessment of obesity, and should thus remain the cornerstone of anthropometric measurements in primary care. A study by Sebo et al. (2008) found that the inter-observer reliability for height, weight and derived BMI were excellent ( $R > 0.99$ ). Another study also has indicated that BMI tends to perform even better than more sophisticated measures like adipose tissue-free mass or fat-free mass estimated by dual-energy X-ray absorptiometry (Heymsfield et al., 2007). However, BMI does not directly measure fat, so it is not the most reliable or valid way of determining body fat levels or fat distribution. Athletic people whose BMI falls into the higher side of normal or lower end of overweight may actually have a healthy amount of body fat, but an abundance of muscle that causes them to weigh more (Cespedes, 2017).

### 5.5.1. Height

Height was measured using a stadiometer mounted on a wall with a fixed headpiece to measure the length from the floor, with the subject standing erect without shoes, arms to the sides, legs straight, shoulders relaxed and head in the Frankfort plane achieved when the orbital (lower edge of the eye socket) is in the same horizontal plane as the tragion (the notch superior to the tragus of the ear). Measurements were recorded to the nearest 0.5cm (International Standards for Anthropometric Assessment, 2001).

### 5.5.2. Weight

Participants were weighed to the nearest 0.1kg using a calibrated balance (Seca model 11770 Germany) in light indoor clothing and with bare feet or stockings.

### 5.5.3. Body Mass Index (BMI)

BMI was calculated using the formula  $\text{Weight (kg)}/\text{Height (m}^2\text{)}$  and classified according to WHO criteria into the following: underweight (BMI less than 18.5), healthy weight (BMI 18.5 – 24.9), overweight (BMI 25 – 29.9), obese (BMI 30 – 39.9), morbidly obese (BMI 40 or more).

### 5.5.4. Waist circumference

The WC as indicator of abdominal obesity was measured using a plastic measuring tape to the nearest 0.5cm. The WC was measured over light clothing, so that the tape measure could be held as closely against the body as possible. It was measured as the point midway between the

lower limit of the rib cage and the iliac crest.

### 5.5.5. Blood pressure

Seated systolic/diastolic BP was measured using a clinically-validated BP monitor (Omron HEM-907 model, Kyoto, Japan) on the left arm after at least five minutes of rest.

### 5.5.6. Blood analyses

Venous blood samples (two 20ml) were drawn from the participants' antecubital vein by two experienced nurses after a 12-hour fast and were then analysed in the clinics' laboratories by a laboratory technician. Blood serum was used to assay all the analyses. Fasting Blood Glucose (FBG, mmol/l), high-density lipoprotein cholesterol (HDL-C, mmol/l), low-density lipoprotein cholesterol (LDL-C, mmol/l), total cholesterol (TC, mmol/l) and triacylglycerol (TAG, mmol/l) were analysed using a Konelab 20 XTi Thermo Fisher Scientific (Vantaa, Finland) Analyser. Insulin ( $\mu\text{U/ml}$ ) was analysed using an Immulite 1000 Siemens Medical Solution Diagnostic (LA, USA) Analyser.

IR was computed from the Homeostasis Model Assessment-Insulin Resistance model (HOMA-IR) using the following formula:  $\text{fasting insulin } (\mu\text{U/ml}) \times \text{fasting glucose (mmol/l)} / 22.5$  (Matthews et al., 1985). The concentration of non-HDL-C was calculated using a simple equation:  $\text{non-HDL-C (mmol/l)} = \text{total cholesterol} - \text{HDL-C}$  (The International Atherosclerosis Society [IAS], 2013).

### 5.6. Prevalence of metabolic syndrome

The criteria of IDF (Table 4.1-4.2) were used. The data were read through and, if conditions for MS were satisfied ( $\text{WC} \geq 80$  cm and  $\geq 2$  of the other criteria) at the pre- or post-intervention assessments, participants were marked with number 1 and, if the conditions were not satisfied, participants were marked with number 0.

### 5.7. Dietary and physical activity measurements (seven-day diet and exercise diary)

Baseline and post-intervention activity levels, water consumption and dietary intake were assessed using a seven-day diet and exercise diary for both groups.

#### 5.7.1. Dietary intake assessment

A 'Handy guide' for estimation of portion size was used to help the subjects estimate portion size for food consumed by comparison to a household element. The food diary data were analysed using the computerised nutritional analysis package (Dietplan6 P3 Windows & Mac Serial No: 6918) and analysis was completed.

The main purpose of the nutritional analysis of D and D+E was to observe and compare dietary intakes. In addition, the analysis allowed for comparison between the two groups with DRVs, RNI and EARs for specified ages and gender for macronutrients as well as for micronutrients to find out if it is less or above the recommendations as it

has a significant effect on health and weight gain.

#### 5.7.2. Physical activity assessment

Moderate intensity PA included activities such as normal-paced walking, brisk walking, recreational swimming, dancing, household activities, use of sports equipment and recreational sports such as volleyball, badminton and table tennis; vigorous-intensity PA and sports.

The participants' PA intensity was categorised into three groups: (1) low, defined as subjects who reported not participating regularly in programmed recreation, sport or heavy physical labour; (2) moderate, defined as subjects who reported participating regularly in moderate PA for a minimum of 150 minutes or in vigorous PA for a minimum of 60 minutes per week; and (3) high, defined as subjects who reported participating regularly in vigorous PA for  $\geq 60$  minutes or in moderate PA for  $\geq 150$  minutes per week.

### 5.8. Dietary and exercise advice provided

The researcher not only gave general advice to the subjects, but also individual counselling depending on their weight and condition in order to modify their eating habits and dispel some common dietary myths in the community. All subjects in both groups were provided with dietary advice, including follow-up using WhatsApp messages for a period of 30 days, focusing on goals for managing MS and weight loss involving lifestyle modifications, including changes in dietary habits and exercise training.

The researcher also provided the women with information about how to prepare and cook healthy, well-balanced meals at home and gave them some healthy recipes. Information was also given on reading nutrition fact labels and eating food that can stimulate the metabolism and strengthen the immune system.

Subjects were not instructed to count calories but requested to reduce their calorie intake gradually. It is possible to lose more weight on the same calorie deficit by avoiding certain foods or macronutrients. Thus, focus should be on types of food, portion size and cooking methods more than calories. The participants in the exercise plus diet group were given extra general advice on how to be less sedentary.

### 5.9. Statistical analyses

Comparisons between the two groups for the anthropometric and parameters related to MS at the baseline were performed with an independent t-test. Associations between risk variables related to MS (biological and anthropometric measurements) at the baseline were determined by using Pearson correlation analysis in the whole sample. To test the hypotheses stated, and differences between intervention groups were tested using repeated measures ANOVA. Tukey's HSD post hoc comparison test was used to locate significant differences.

## 6. Results

A total of 40 subjects aged 18-54 completed the study (n = 20 in each group – D and DE) and provided pre- and post-intervention for blood samples and body composition measurements. The women also completed a medical history questionnaire, diet and exercise diary.

### 6.1. Baseline physical characteristics of participants

The baseline physical characteristics of women showed that there were no significant differences between groups in age, height, weight and BMI (Table 4.3).

### 6.2. Socio-demographic characteristics

The demographic characteristics are presented in Table 4.4. No significant difference in age was seen between the participants in D and DE, 32.9± 6.8 and 35.1± 6.5 years old, respectively. The educational level for D was higher than DE; 65% of D subjects were university graduates versus 40% of W-SA. Similarly, the majority of participants in D were working (60%), whereas the women in the D+E group included 40% working and 55% non-working women/housewives. In relation to marital status, most of the sample was married, with a higher percentage in the D+E group, and a greater number of children as well.

### 6.3. The anthropometric and clinical characteristics of metabolic syndrome among study participants pre- and post-intervention

Table 4.5 presents the parameters related to MS and cardiovascular risk among study participants before the intervention. The independent t-test showed no significant differences at baseline between both groups for any of the MS parameters. It is noticeable that both groups of women at baseline displayed WC levels that would place them at risk of developing MS. However, all mean measures of metabolic health were within the normal range; only HDL-C was close to the range specified in the IDF criteria (mean 1.30 compared to cut-off of 1.29mmol/l).

Following the intervention (Table 4.6), women in both groups lost weight, but those in D lost significantly more

(mean 5.6%) compared to those in D+E (mean 3.7%, p=0.016 for an interaction between group and time). WC also significantly reduced after the programme in both groups, but with no significant difference between the groups (D: 6.4%; DE: 4.7%, p=0.235). Similarly, both D and D+E showed similar significant decreases in SBP (5.0 and 5.4mmHg, respectively, p=0.008) and DBP (4.4 and 3.7mmHg, respectively, p=0.012).

Moreover, significant changes following intervention were found both D and D+E groups in TAG (0.2 and 0.1mmol/l, respectively, p=0.006); plasma insulin (2.9 and 2.1µU/ml, respectively, p=0.015); TC (0.2 and 0.2mmol/l, respectively, p=0.002); and LDL (0.1 and 0.3mmol/l, respectively, p=0.023), whereas plasma glucose and HDL remained statistically unaltered. Furthermore, non-HDL cholesterol was significantly decreased in both groups (p=0.007), while the ratio between non-HDL and HDL cholesterol did not significantly change in either group. IR significantly improved in both groups, as indicated by HOMA analysis, which decreased by 0.7 and 0.6 in D and DE, respectively (p=0.008).

### 6.4. Physical activity level of the study participants

The prevalence of the various levels of PA among the study population is presented in Table 4.7. At baseline, the majority of females in both groups reported performing light PAs (D: 85% and DE: 75%). In total, 25% of D+E subjects reported performing moderate PA compared to the 10% of the D subjects and only 5% of the D subjects reported performing vigorous PA. However, at endpoint, the mean PA for both groups had increased in all the PA categories. The light PA percentage in D women decreased by 55%, whereas the moderate and vigorous PA percentages increased by 30% and 25%, respectively. As for the D+E women, PA level increased approximately twofold at endpoint. Regarding the intensity of PA, the intensity was low in both groups at baseline, but increased following the intervention from low to moderate in D and from low to vigorous in D+E (data not shown).

Table 4.3: Pre-intervention physical characteristics of participants

Variables	Diet	Diet+ Exercise	p-values*
Age (y)	32.9 ± 6.8	35.1 ± 6.5	0.292
Height (cm)	158.8 ± 5.4	157.8 ± 6.6	0.612
Weight (kg)	94.2 ± 16.2	89.4 ± 17.1	0.370
BMI (kg/m <sup>2</sup> )	37.2 ± 5.2	35.7 ± 5.1	0.365

Data are presented as mean ± SD \*t-test

Table 4.4: Socio-demographic characteristics of participants

Variables	Diet only group(%)	Diet plus exercise(%)
Educational level		
Intermediate school	15	20
Secondary school	20	30
Technical of college (diploma)	0	10
University graduate	65	40

Employment		
Unemployed or house wife	25	55
Student	15	5
Employed	60	40
Marital status		
Married	65	75
Single	35	25
Number of children (mean ± SD)	2 ± 2.1	2.4 ± 2.4
Data are presented as percentages or mean values ± standard deviation		

Table 4.5: Pre-intervention parameters related to metabolic syndrome and cardiovascular risk

Parameter	Diet	Diet + Exercise	p-values*	Optimal Values
WC (cm)	98.9 ± 11.9	99.9 ± 12.7	0.973	<80 <sup>1</sup>
Systolic BP (mmHg)	116.5 ± 13.2	119 ± 10.2	0.499	<130 <sup>1</sup>
Diastolic BP (mmHg)	79.4 ± 10.9	81.5 ± 8.8	0.506	<85 <sup>1</sup>
TAG (mmol/l)	0.9 ± 0.3	0.7 ± 0.2	0.213	< 1.7 <sup>1</sup>
Tot Chol (mmol/l)	3.4 ± 0.8	3.2 ± 0.6	0.395	<5.2 <sup>2</sup>
LDL-C (mmol/l)	1.8 ± 0.8	1.6 ± 0.7	0.640	<2.6 <sup>2</sup>
HDL-C (mmol/l)	1.3 ± 0.3	1.3 ± 0.3	0.691	>1.29 <sup>1</sup>
nonHDL chol (mmol/l)	2.2 ± 0.9	1.9 ± 0.7	0.379	<3.4 <sup>2</sup>
nonHDL/HDL (mmol/l)	1.8 ± 1.0	1.6 ± 0.8	0.424	-
Glucose (mmol/l)	4.9 ± 0.7	4.9 ± 0.6	0.787	<5.6 <sup>1</sup>
Insulin (µU/ml)	11.4 ± 6.6	10.4 ± 4.9	0.644	-
HOMAIR (Glucose(mmol/l)×Insulin (µU/ml))/22.5	2.5 ± 1.6	2.3 ± 1.1	0.692	<2.60
Data are presented as mean ± Sd *t-test, 1based on IDF cut-off point for diagnosing MS, <sup>2</sup> based on International Atherosclerosis Society guidelines for primary prevention of cardiovascular disease.				

Table 4.6: Post-intervention parameters (and percent changes from baseline) related to metabolic syndrome and cardiovascular risk

Parameter	Diet		Diet + Exercise		Combined		p-values*	
	Mean ± SD	change (%)	Mean ± SD	change (%)	Mean ± SD	change (%)	Change within groups	Change between groups
Weight (kg)	88.9 ± 17.1	-5.6 ± 2.6	86.1 ± 17.3	-3.7 ± 2.3	87.5 ± 17.0	-4.7 ± 2.6	<0.001	0.016
BMI (kg/ m <sup>2</sup> )	35.1 ± 5.4	-2.1 ± 1.0	34.4 ± 5.3	-1.3 ± 0.9	34.7 ± 5.3	-1.7 ± 1.1	<0.001	0.024
WC (cm)	92.6 ± 11.9	-6.4 ± 4.9	95.2 ± 12.0	-4.7 ± 3.0	93.9 ± 11.9	-5.5 ± 4.2	<0.001	0.235
Systolic BP (mmHg)	111.5 ± 13.1	-5.0 ± 9.5	113.6 ± 9.8	-5.4 ± 3.2	112.5 ± 11.4	-5.2 ± 11.5	0.008	0.894
Diastolic BP (mmHg)	75.0 ± 10.1	-4.4 ± 9.9	77.8 ± 8.7	-3.7 ± 9.1	76.4 ± 9.4	-4.1 ± 9.5	0.012	0.834
TAG (mmol/l)	0.7 ± 0.3	-0.2 ± 0.2	0.6 ± 0.3	-0.1 ± 0.3	0.7 ± 0.3	-0.1 ± 0.2	0.006	0.413
Tot Chol (mmol/l)	3.2 ± 0.8	-0.2 ± 0.4	3.0 ± 0.5	-0.2 ± 0.3	3.1 ± 0.7	-0.2 ± 0.4	0.002	0.770
LDL-C (mmol/l)	1.7 ± 0.6	-0.1 ± 0.6	1.3 ± 0.6	-0.3 ± 0.4	1.5 ± 0.7	-0.2 ± 0.5	0.023	0.092
HDL-C (mmol/l)	1.2 ± 0.3	-0.1 ± 0.4	1.4 ± 0.4	+0.1 ± 0.2	1.3 ± 0.3	0.0 ± 0.4	0.507	0.288
nonHDL chol (mmol/l)	2.0 ± 0.7	-0.2 ± 0.6	1.6 ± 0.7	-0.4 ± 0.5	1.8 ± 0.7	-0.2 ± 0.5	0.007	0.323
nonHDL/HDL (mmol/l)	1.7 ± 0.7	-0.1 ± 1.0	1.3 ± 0.7	-0.3 ± 0.6	1.5 ± 0.7	-0.2 ± 0.9	0.130	0.581
Glucose (mmol/l)	4.6 ± 0.7	-0.3 ± 0.9	4.7 ± 0.4	-0.2 ± 0.5	4.6 ± 0.6	-0.3 ± 0.8	0.096	0.643
Insulin (µU/ml)	8.5 ± 4.5	-2.9 ± 5.4	8.3 ± 4.8	-2.1 ± 3.2	8.4 ± 4.5	-2.6 ± 5.4	0.015	0.696
HOMA-IR(mmol/l/µU/ml)	1.8 ± 1.1	-0.7 ± 1.5	1.7 ± 1.0	-0.6 ± 0.8	1.8 ± 1.0	-0.7 ± 1.3	0.008	0.739
Data are presented as mean ± SD *repeated measures analysis of variance Values in bold are significant								

Table 4.7: Physical activity level of the study participants pre- and post-intervention

Physical activity levels	Diet only group			Diet plus exercise group		
	Baseline %	After %	Changes%	Baseline %	After %	Changes %
Low	85	30	55	75	0	75
Moderate	10	40	30	25	0	25
High	5	30	25	0	100	100
Data are presented as percentages						

### 6.5. Nutritional intake for Saudi women pre- and post-intervention and comparison with Dietary Reference Values (DRVs)

Nutritional intake for the two groups of women was compared to the DRVs (excluding alcohol) as described by the UK panel on DRVs of the British Nutrition Foundation (2015). Energy consumption was compared to the EARs and micronutrient intake to the RNI. Additionally, energy percentage (E%) from carbohydrate, protein, fat and fatty acids from total calories consumed was assessed and compared to the DRVs recommended. The reference values used for this aspect of the analysis are specifically quoted for women between the ages of 18 and 54 years of age.

The independent t-test showed no significant differences at baseline between both groups for any of the dietary intake variables, except for vitamin E, monounsaturated and polyunsaturated fatty acids, which were higher in D. It is clear from Table 4.8 that women in both groups at baseline consumed considerably more energy than the EAR given in the UK reference standards. Mean intakes of carbohydrate, protein, fat, sugar, fatty acids and cholesterol at baseline all exceeded the DRV and RNI recommendations in both groups.

Paired t-test showed significant differences within each group from before to after for intake of the majority of nutrients. Women in both groups had significant reductions in total energy consumption (D: -41.1% and DE: -35%), and that from protein (D: -23.7% and DE: -22.4%), fat (D: -53.6% and DE: -45.4%) and carbohydrate (D: -35.8% and DE: -31.3%), which were close to the recommendations. Although the reductions in total caloric intake and macronutrients were greater in D subjects, there were no significant differences between both groups following the intervention. The mean daily intake of sugar (NMES) at baseline was high (D: 82.6g/d and DE: 91.2g/d) according to the maximum recommended intake of 60g/day (11%) by the DRVs. Following the intervention, the amounts of sugar consumed decreased significantly in both groups (D: 35.8g/d and DE: 38.5g/d), which met the recommendations (Table 4.9). The same trend was found for all fatty acids and cholesterol (Table 4.10).

On the other hand, the baseline dietary fibre (NSP) and water intakes were less than the recommended limit (Table 4.9) and these increased significantly after the intervention. Mean intake of fibre (NSP) was 14.3 g/day for D and 12.1 g/day for DE, below the DRV set for adults of at least 18g

per day, and this increased significantly close to the recommendations after the intervention (D: 17.8g/day and DE: 16.9g/day) (Table 4.9).

Mean consumption of water in each of the two groups was below the European Food Safety Authority (EFSA) (2010) recommendation (2.0 litres of water for women per day) and that also significantly increased following the trial (D: 53.3% and DE: 32.7%). As for vitamin and mineral intake, there were no significant differences between the two groups following the trial, except for folate, which was lower in DE. Additionally, there were no differences within each group regarding vitamin and mineral consumption, which were within the normal range except for Vitamin D which was below the recommended amounts for both groups (Tables 4.11 and 4.12).

The foods were also listed in groups to represent all major food groups consumed by the participants (Table 4.13). The independent t-test showed no significant differences between the two groups for any of the food groups both at baseline and at follow-up. However, paired t-test showed significant differences within each group from before to after for intake of the majority of food groups.

After the intervention, women in both groups had significant reductions in grains and cereals consumption (D: -32.5%,  $p < 0.001$  and DE: -18.6%,  $p < 0.001$ ), beverages (D: -42.9%,  $p = 0.021$  and DE: -50%,  $p < 0.001$ ), snacks/sweets (D: -32%,  $p = 0.002$  and DE: -41.7%,  $p < 0.001$ ) and fast food (D: -68.4%,  $p < 0.001$  and DE: -75%,  $p < 0.001$ ). On the other hand, the baseline vegetables consumption increased significantly after the intervention in both groups (D: 69.6%,  $p < 0.001$  and DE: 77.3%,  $p < 0.001$ ).

### 6.6. The prevalence of metabolic syndrome among the participants

Based on IDF criteria (Table 4.1-4.2), the overall baseline prevalence of the MS was 20% for D and 21% for D+E (Table 4.14) and there was no significance in the prevalence between the groups as tested by chi-squared test. Among the five MS components, abdominal obesity (WC) was the commonest abnormality among both groups (100% and 95% for D and DE, respectively) followed by low HDL-cholesterol (60% and 57% for D and DE, respectively) and high BP (30% in both groups).

At endpoint, the overall prevalence of the MS declined substantially to 5% for D and 7% for DE, but this change



just failed to reach significance for the combined groups ( $p=0.074$ ) and no significant difference was seen in prevalence of MS, or any of the components, when the distribution was compared between D and D+E post-intervention. Abdominal obesity (as measured by WC) decreased in both groups (80% and 85% for D and DE,

respectively,  $p=0.024$  for combined groups) and high BP decreased to 10% in D+E and 5% in D ( $p=0.016$  for combined groups). The prevalence of low HDL-cholesterol appeared to drop more for the D+E group (28%) than the D group (55%), but this difference between groups was not significant ( $p=0.127$ ).

Table 4.8: Daily intake of energy and macronutrients among study participants

Nutrients	Diet only group			Diet plus exercise group			Reference value
	Baseline	After	change%	Baseline	After	change%	
Energy (kcal/d)	3436 ± 739	2023 ± 822	-41.1 *	3173 ± 829	2060 ± 736	-35 *	1940 kcal/d
Protein (g/d)	108.9 ± 25.2 (12.7%)	83.1 ± 25.9 (16.4%)	-23.7 *	112.1 ± 30.4 (14.1%)	87 ± 23.5 (16.9%)	-22.4 *	(15%)
Fat (g/d)	145.9 ± 38.1 (38.2%)	67.7 ± 28.6 (30.1%)	-53.6 *	125.3 ± 36.6 (35.5%)	68.4 ± 28.5 (29.9%)	-45.4 *	(35%)
CHO (g/d)	449.4 ± 99.2 (52.3%)	288.7 ± 130.5 (57.1%)	-35.8 *	424.8 ± 117 (53.6%)	291.7 ± 114.3 (56.6%)	-31.3 *	(50%)

(Data are presented as mean ± SD Values in parentheses indicate % of total energy intake) (P-values were determined by independent and paired t-test) (\*Significantly different within each group from before to after)

Table 4.9: Daily intake of sugar, fibre and water among study participants

Nutrients	Diet only group			Diet plus exercise group			Reference value
	Baseline	After	Change%	Baseline	After	Change%	
Sugar (NMES) (g/d)	82.6 ± 35.2 (9.6%)	35.8 ± 25.3 (7.1%)	-56.7 *	91.2 ± 43.1 (11.5%)	38.5 ± 31.5 (7.5%)	-57.8 *	(10%)
Fibre (NSP)(g/d)	14.3 ± 4.1	17.8 ± 6.9	+24.5 *	12.1 ± 6.1	16.9 ± 10.6	+39.7 *	18 g/d
Water (ml/d)	1269.6 ± 353.4	1946.4 ± 254.6	+53.3 *	1360.8 ± 358.7	1805.4 ± 256.9	+32.7 *	2000 ml/d

(Data are presented as mean ± SD Values in parentheses indicate % of total energy intake) (P-values were determined by independent and paired t-test) (\*Significantly different within each group from before to after)

Table 4.10: Daily intake of fatty acids and cholesterol among study participants

Nutrients	Diet only group			Diet plus exercise group			Reference value
	Baseline	After	Change%	Baseline	After	Change%	
Saturated fatty acids (g/d)	46.4 ± 10.5 (12.2%)	21.8 ± 9.5 (9.7%)	-53 *	43.1 ± 13.4 (12.2%)	23.4 ± 9.5 (10.2%)	-45.7 *	(11%)
Monounsaturated fatty acids (g/d)	49.6 ± 13.9 (13%) ‡	24.4 ± 11.5 (10.9%)	-50.8 *	40.9 ± 11.7 (11.6%)	22 ± 7.5 (9.6%)	-46.2 *	(13%)
Polyunsaturated fatty acids (g/d)	28.8 ± 9.5 (7.5%) ‡	12.4 ± 6.4 (5.5%)	-56.9 *	22 ± 8 (6.2%)	10.5 ± 5 (4.6%)	-52.3 *	(6.5%)
Trans fatty acids (g/d)	3.1 ± 0.9 (0.8%)	1.3 ± 0.6 (0.6%)	-58.1 *	2.9 ± 1.3 (0.8%)	1.6 ± 0.7 (0.7%)	-44.8 *	(2%)
Cholesterol	341 ± 116.4	273.4 ± 103	-19.8 *	349.1 ± 117.8	281.3 ± 84.2	-19.4 *	245

(mg/d)							
(Data are presented as mean ± SD Values in parentheses indicate % of total energy intake) (P-values were determined by independent and paired t-test) (*Significantly different within each group from before to after)( ‡Significantly different from the other group)							

Table 4.11: Daily intake of selected vitamins among study participants

Nutrients	Diet only group			Diet plus exercise group			Reference value
	Baseline	After	Change%	Baseline	After	Change%	
Retinol (µg/d)	736.1 ± 910.5	622.3 ± 1322.8	-15.5	1255.1 ± 1516	920.5 ± 1305.7	-26.7	600
Vitamin D (µg/d)	2.1 ± 0.7	1.4 ± 0.6	-33.3 *	1.9 ± 1	1.6 ± 0.8	-15.8	10
Vitamin E (mg/d)	15.3 ± 6.7 ‡	6.5 ± 3.2	-57.5 *	10.6 ± 5	6.3 ± 2.3	-40.6 *	6
Thiamine (mg/d)	2.1 ± 0.6	2 ± 0.7	-4.8	1.8 ± 0.5	1.9 ± 0.6	+5.6	0.8
Vitamin B <sub>12</sub> (µg/d)	5.8 ± 4.5	5.3 ± 6	-8.6	8.6 ± 6.8	6.7 ± 4.7	-22.1	1.5
Folate (µg/d)	280.3 ± 113.2	350.4 ± 131.8	+25	235.7 ± 79	271.3 ± 99.4 ‡	+15.1	200
Vitamin C (mg/d)	134.2 ± 167.8	144.7 ± 87.5	+7.8	88.2 ± 50.4	127.8 ± 64	+44.9 *	40

Data are presented as mean ± SD P-values were determined by independent and paired t-test \*Significantly different within each group from before to after ‡Significantly different from the other group

Table 4.12: Daily intake of selected minerals among study participants

Nutrients	Diet only group			Diet plus exercise group			Reference value
	Baseline	After	Change%	Baseline	After	Change%	
Calcium (mg/d)	1329.5 ± 285.5	997.1 ± 300.3	-25 *	1231.6 ± 412.4	948.1 ± 348.9	-23 *	700
Magnesium (mg/d)	415.1 ± 133.9	333.2 ± 125.6	-19.7	366.2 ± 120.1	281.7 ± 91.6	-23.1 *	270
Iron (mg/d)	17.3 ± 5.1	16.7 ± 4.5	-3.5	18.3 ± 7.4	15.6 ± 8.5	-14.8 *	14.8
Zinc (mg/d)	14.2 ± 4.6	10.8 ± 3.8	-23.9 *	14.6 ± 4.5	11.1 ± 3.2	-24 *	7.0

Data are presented as mean ± SD P-values were determined by independent and paired t-test \*Significantly different within each group from before to after

Table 4.13: Average daily consumption of servings in each food group among study participants

Food groups	Diet only group			Diet plus exercise group		
	Baseline	After	% change	Baseline	After	% change
Fruits	2.1± 1.0	2.0± 0.7	- 4.8	2.2± 0.9	2.1±0.6	-4.5
Vegetables	2.3±0.8	3.9±1.2	+69.6 *	2.2±1.0	3.9±1.2	+77.3 *
Grains and cereal products	12.6±1.9	8.5±2.7	-32.5 *	11.8±2.3	9.6±3.0	-18.6 *
Dairy products	2.1±0.9	1.7±0.4	-19.0	2.3±0.7	1.8±0.6	-21.7
Meats and alternatives	3.0±1.2	2.4±0.8	-20	3.2±1.2	2.7±1.1	-15.6
Nuts and seeds	0.4±0.4	0.3±0.4	-25	0.4±0.4	0.3±0.4	-25
Beverages	1.4±0.7	0.8±0.8	-42.9 *	1.6±0.5	0.8±0.6	-50 *
Snacks/ sweets	2.5±0.8	1.7±0.7	-32 *	2.4±1.0	1.4±0.6	-41.7 *
Fast food	1.9±1.1	0.6±0.8	-68.4 *	2.0±1.1	0.5±0.7	-75 *

(Data are presented as mean ± SD) (P-values were determined by independent and paired t-test)  
(\*Significantly different within each group from before to after)

Table 4.14: Prevalence of individual risk factors for metabolic syndrome pre- and post-intervention

Variables	Diet only group		Diet plus exercise group		Combined groups		p-values* for combined groups pre vs. after
	Baseline %	After %	Baseline %	After %	Baseline %	After %	
Age (year)	32.9± 6.8		35.1± 6.5				
Abdominal obesity	100	80	95	85	98	83	0.024
High fasting blood glucose	5	5	7	0	6	3	0.555
High blood pressure	30	10	30	5	30	8	0.016
High triglycerides	0	0	0	0	0	0	-
Low HDL-cholesterol	60	55	57	28	59	42	0.225
Metabolic syndrome	20	5	21	7	21	6	0.074

The diagnosis of metabolic syndrome is made if subjects have central obesity plus any two or more other indicators are present.  
\*chi-squared test Values in bold are significant

## 7. Discussion

The baseline physical characteristics of women showed that there were no significant differences between groups in age, height, weight and BMI (Table 4.3). Similarly, the independent t-test showed no significant differences at baseline between both groups for any of the parameters

related to MS and cardiovascular risk (Table 4.5). This means that, in terms of metabolic health, the study is not affected by the non-random sampling.

The demographic information showed that educational level and percentage of employees were higher in D, while the percentage of married couples and number of children were higher in DE. It is possible that this influenced why the participants in D reduced their body weight and BMI more than D+E participants. In relation to the results,

several past studies have demonstrated that low educational attainment is directly associated with incidence of MS (Go et al., 2014; MacPherson et al., 2016). A recent study, conducted in Saudi Arabia, also found a significant association between marital status and a higher prevalence of MS in males. In the same study, and based on occupation, non-employed subjects presented a lower prevalence of MS than those in professional classes. For women, those with no professional activities were more susceptible to develop MS, while those with a higher level of education appeared to have a protection against the syndrome (Al-Daghri et al., 2014).

Associations between risk variables related to MS (biological and anthropometric measurements) at the baseline were determined by using Pearson correlation analysis in the whole sample. The analysis shows that BMI

and WC were strongly associated with most of the MS and cardiovascular risk factors, mainly with TAG, glucose, insulin and HOMA-IR. Our findings support and extend those of Akl et al. (2016), which showed a strong MS association with BMI > 25kg/m<sup>2</sup>. A study conducted in the UAE strongly indicated that problems with being overweight and obesity are associated with metabolic health conditions. Pearson correlations showed that, in men, BMI was significantly and positively correlated with WC, LDL-C and BP, whereas, in women, all parameters of MS were positively correlated with BMI, except for HDL-C, which was negatively correlated ( $P < 0.01$ ) (Al-Sarraj et al., 2010).

Another striking finding from this study was the strong relationship between weight, insulin, and HOMA-IR in addition to the strong correlation between DBP and plasma TC. Such results were similar to those observed in other studies (FAO 1994; Akl et al., 2016; Aristizabal et al., 2016). Consistent with our findings, evidence indicates that chronic elevation of plasma cholesterol is associated with higher DBP, probably as a result of atherosclerotic vascular changes (FAO, 1994).

This study compared two four-week lifestyle change programmes, incorporating either separate dietary modification or combined with regular vigorous aerobic exercise intervention. Both interventions produced significant and clinically relevant reductions in body composition and improvements in MS abnormalities, which is in agreement with Hypothesis 1. Anthropometric outcome measures showed significant changes in body weight and BMI. Participants in the D+E group lost an average 3.7% of their starting weight, whereas those in the D group had a more marked decrease in body weight with an average weight loss of 5.6%. Studies have demonstrated comparable degrees of weight reduction to those we found with our intervention, though research varies widely with respect to the type of PA, diet restriction, duration, size and measurement of MS (Roberts et al., 2002; American Diabetes Association, 2008; Kaur, 2014). Our findings for weight loss are similar to those published by McTigue et al. 2003, which found that counselling on diet or physical exercise and behavioural interventions resulted in a weight loss of 3-5 kg over three months.

As already discussed, the impact of increased PA on MS is unclear. However, it is generally accepted that long-term PA of sufficient intensity, duration and frequency has a favourable influence on weight reduction and body fat distribution. Evidence supports the hypothesis that the effectiveness of PA to induce weight loss is directly related to the initial degree of obesity and the total amount of energy expenditure (Pitsavos et al., 2006). However, a previous study showed that short-term (four weeks) aerobic exercise decreased circulating free fatty acids without weight loss in previously sedentary obese men and premenopausal women. In that study, a significant

decrease in hepatic and visceral lipids was also observed, indicating that short-term aerobic exercise can mitigate cardiovascular risk and this is not contingent upon weight loss (Johnson et al., 2009). In a similar vein, recent results showed that, despite the absence of weight loss, aerobic training induced beneficial effects on functional, anthropometric and biochemical parameters in women with MS (Farinha et al., 2015). Moreover, Dunn (2009) studied the effects of exercise and dietary intervention on MS markers in inactive premenopausal women and it was found that, despite reductions in insulin, inflammation, WC, respiratory exchange ratio during exercise, BP and an increase in aerobic power, women gained body mass and fat mass following the intervention (Dunn, 2009). However, reductions (23%-44%) in all-cause mortality with increases in fitness, regardless of weight loss, have been shown (Gaesser, 1999).

Our study produced two unexpected results. Firstly, despite exhibiting BMI and waist circumferences which would have predicted increased risk of MS, the prevalences of MS in the D and D+E groups at baseline were only 20% and 21% respectively. This suggests that despite the accumulation of adipose tissue (apparently within the visceral area as predicted by WC) many of these women were maintaining a level of insulin sensitivity which prevents the metabolic complications. This may be because of their relatively young age ( $32.9 \pm 6.8$  and  $35.1 \pm 6.5$  y in D and D+E groups respectively).

The second unexpected result was that our findings show that diet alone apparently had a greater influence on women's body weight and BMI than did diet with exercise. Thus, these results do not support Hypothesis 2. The explanation for this finding is unclear, but may specifically relate to differences between the cohorts that have not adequately been identified. As discussed, by necessity, the design of the study was not randomized. Due to the cultural barriers, not all females would be prepared to undertake the exercise intervention and we were reliant on comparing a diet-only intervention with diet intervention in a group who had specifically identified their willingness to undergo exercise.

In any case, our outcomes are consistent with Melville's study (2012) in which it was reported that a diet intervention alone provided greater improvement in BMI than the combination of diet and exercise for obese adults with an average BMI of 37. They found that for the diet only group, body weight was decreased by about 10% and, in the diet plus exercise group, body weight loss was 9%, but there was no decrease in body weight in the exercise or control groups (Melville, 2012). In a similar vein, a systematic review found that the diet only group showed a greater BMI reduction than the diet plus resistance training group (pooled difference,  $-0.40$ ; 95% CI,  $-0.71$  to  $-0.08$ ;  $I^2 = 0\%$ ) over 4 months (Ho et al., 2013). Bertz et al. (2012) reported that the dietary behaviour modification treatment

was sufficient to provide significant and clinically meaningful weight loss in lactating women. The combined treatment (D+E) did not yield further significant weight or body composition changes beyond those of dietary treatment alone. Weight changes after the intervention and one-year follow-up were  $-8.3$  and  $-10.2$  kg, respectively, in the D group;  $-6.9$  and  $-7.3$  kg, respectively, in the D+E group. The main effects of D treatment, but not of exercise treatment, on body weight were significant at both times ( $p < 0.001$ ). Meta-analyses suggest that the observed increase in BMI in D+E compared to D may be due to gain in lean body mass, which is beneficial for long-term weight loss. (Ho et al., 2013).

In this study, a significant reduction in abdominal obesity was observed after the programme in both groups by means of WC (D: 6.4%; DE: 4.7%). Visceral body fat, as measured by WC, is used in conjunction with BMI to assess the risk of T2D and CVD (American Diabetes Association, 2008). In fact, the reduction in abdominal fat may be the main determinant for insulin sensitivity improvement (Hamman et al., 2006; Rana et al., 2007). This corresponds with the findings in our intervention that insulin sensitivity was significantly improved in both groups, as indicated by HOMA analysis.

Regarding BP, both diet modification and moderate aerobic exercise training have an effect on reducing BP. Our results showed significantly reduced mean values for SBP (4.3% in D and 4.5% in DE) and DBP (5.5% in D and 4.5% in DE). This almost agrees with studies which found that a short-term (under three weeks) strict diet and PA intervention reduced both SBP and DBP by 10% in participants and enhanced the metabolic profile (Roberts et al., 2002; Luo et al., 2013).

Based on our findings, plasma insulin decreased significantly following the intervention in both groups (25.4% and 20.2% for D and DE, respectively), which was similar to the reduction (25%) demonstrated by Dunn (2009) with a 12-week intervention using the same sprint protocol. The current study showed no apparent additional improvement in HOMA-IR in the D+E group compared to D alone. This is in contrast to a study by Nelson et al. (2013) who found that moderate to vigorous daily activity during one year was effective in reducing IR and, thus, improved metabolic profile. Sixty minutes of daily exercise improved IR by 25%. Another study by Misra et al. (2008) showed parallel results, but with combined diet and exercise over a period of three months. One important factor might be the length of intervention which was associated with the differences in the outcomes of metabolic health.

It is noteworthy that of the cardiometabolic risk factors associated with MS at the baseline, only HDL-C was close to the range specified in the IDF criteria (mean 1.30 compared to cut-off of 1.29mmol/l). Our results agree with

those published by Al Qahtani et al. (2015) who found that low HDL-C level was the most common lipid disorder among Saudis, with 82.9%. Among the lipid disorders, only low levels of HDL-C contributed to significant mortality risk ( $p$ -value  $< 0.01$ ) (Al Qahtani et al., 2015). However, in this study, a slight (0.1mmol/l), but not significant, increase in HDL was only observed among the D+E group after four weeks of the intervention; this percentage may increase over a longer training period. Our finding is in agreement with previous studies which found that moderate exercise in Saudi young men having low levels of HDL-C resulted in significant effect on their TAGs levels, but no considerable change in their HDL-C levels (Al-Hazzaa et al., 1994; Al-Ajlan and Mehdi, 2005).

The combination of a diet programme involving low-calorie, unrefined and high fibre carbohydrates and intense moderate PA showed an improvement in TAG (Luo et al., 2013; Sonestedt et al., 2016). The reduction in insulin also played a role in decreasing TAG levels. A three-month study using a low carbohydrate diet also found a 20%–25% decrease in TAG in obese individuals (Foster et al., 2003). Similarly, in our four-week study, TAG decreased significantly in D and D+E (22.1% and 14.3%, respectively). The improvement in TAG experienced by both groups could be due to adherence to the programme. Additionally, our data indicate a significant improvement in TC and LDL in both groups. This finding accords with a study which reported a 0.6–0.8 mmol/l reduction in TC in overweight women following 12 weeks of low-calorie intake and physical training (Nieman et al., 2002; Luo et al., 2013).

Regarding the practice of exercise, the baseline and post-intervention activity levels were assessed using a seven-day exercise diary. The different PA levels were then categorised into light, moderate and vigorous PA depending on the frequency, intensity of exercise and duration, taking into account the exercise sessions for DE. The prevalence of the various levels of PA among the study population is presented in Table 4.7. At baseline, the majority of females in both groups practised low to no PA at all (D: 85% and DE: 75%). In total, 25% of D+E subjects reported performing moderate PA compared to the D subjects (10%) and only 5% of the D subjects reported performing vigorous PA.

However, one of the most striking findings of our study was that, at post-intervention, the mean PA for both groups had increased in all the PA categories. The light PA percentage in D women decreased by 55%, whereas the moderate and vigorous PA percentages increased by 30% and 25%, respectively. As for the D+E women, PA level increased approximately twofold. Such results were similar to those observed in other studies (Jassas, 2012; Al-Eisa et al., 2016).

Regarding the intensity of PA, in the present study, it was low in both groups at baseline, but increased following

the intervention from low to moderate in D and from low to vigorous in D+E (data not shown). The effects of exercise on metabolism are highly influenced by the intensity and duration of the exercise, but the level of PA needed for a beneficial impact on coronary risk remains controversial.

Studies have shown that dietary advice plays an important role in modifying dietary behaviour and individuals' health. Meta analyses have shown that randomised controlled trials comparing weight loss programmes based on dietary counselling with usual care interventions produced a mean net weight loss of approximately 5kg after one year, of which about half was maintained after three years (Dansinger et al., 2007; Franz et al., 2007). It has been reported that participants receiving advice from dietitians experienced a greater reduction in blood cholesterol than those receiving advice only from doctors (-0.25mmol/L [95% CI, -0.37, -0.12mmol/L]) (Thompson et al., 2003). The evidence suggests that more specific dietary advice to modify intake of fat sources, particularly dietary saturated fatty acids, and increase the consumption of fruit and vegetables, is probably necessary for combating chronic disease risk (Ammerman et al., 2002).

Furthermore, study has proven that patients with MS who were advised to undertake the DASH diet were able to raise their good cholesterol and experienced a significant reduction in BP, lowered their blood sugar and TAG levels and even lost weight after six weeks (Azadbakht et al., 2005). It has also been proved that participants who followed the Mediterranean diet pattern showed a reduction in blood sugar levels and abdominal obesity, in addition to 28.2% of participants with MS on the diet who no longer met the criteria at the end of the study (Babio et al., 2014; Salas-Salvado et al., 2016).

With regard to dietary nutrient intake status, in this study, subjects in both groups at baseline reported a trend towards high consumption of total energy intake, total fat, total protein, saturated fatty acids, cholesterol and sugar, a pattern consistent with a Western diet, as reported by Alissa et al. (2005). A Western diet is high in saturated fatty acids and simple sugars and is associated with several metabolic abnormalities including IR and inflammation, the initiating factors in the development of MS (Bullo et al., 2007). It is clear from Table 4.8 that women in both groups at baseline consumed considerably more energy than the EAR given in the UK reference standards. Mean intakes of carbohydrate, protein, fat, sugar, fatty acids and cholesterol at baseline exceeded the DRV recommendations in both groups. The high intake of carbohydrate and sugar was specifically associated with consumption of starchy foods and sugary drinks. The most frequently consumed foods, as observed in the food diaries, were grains and cereal products. Eating snacks and fast foods were also a common habit among women. The independent t-test showed no significant differences at baseline between both groups for any of the dietary intake variables, except for

vitamin E, monounsaturated and polyunsaturated fatty acids, which were higher in D. The high intake of calories in this study explains the prevalence of overweight and obesity among participants, as illustrated by BMI. One study demonstrated that higher intakes of energy (>7500kj per day) showed a significant increasing trend in obesity in females aged 40-64 (Chamieh, 2013).

Despite the lack of studies showing calorie consumption rates among Saudis, particularly obese women, our results are similar to some recent national studies. Our data revealed that the mean daily intake of energy at baseline (3436 kcal/day and 3172.6 kcal/day for D and DE, respectively) coincides with a recent Saudi report which found that the average per capita calorie intake is 3176 per day, which is 14% higher than the world average (Saudi Arabia report, 2014). Another recent study showed that the dietary energy supply for Saudi adults was 3078kcal/capita/day (Adam et al., 2014).

Furthermore, total fat intake per capita per day among the Saudi population was 145g, containing 72% animal fat and contributing 42% to the total energy intake (Madani, 1996). This percentage of fat is similar to our results (145.9g and 125.3g for D and DE, respectively). Indeed, the nutritional imbalance due to high energy, fat, high sugar intake and high energy % of saturated fatty acids and dietary cholesterol among a substantial proportion of Saudi women in this study is likely to increase their risk of MS and CVD in later life. However, our findings revealed that participants in both treatment groups decreased their total caloric intake and macronutrients significantly following the four-week intervention. Women in both groups showed significant reductions in their proportion of calorie intake (D: 41.1% and DE: 35%), protein (D: 23.7% and DE: 22.4%), fat (D: 53.6% and DE: 45.4%) and carbohydrate (D: 35.8% and DE: 31.3%), which were close to the recommendations.

Numerous studies have confirmed that dietary modification is considered the cornerstone of the management of MS and T2D. Consistent with our study, Aldesi (2014) found that a 500kcal deficit/day, in the absence of exercise, during a three-month dietary intervention among adult Saudi females, resulted in improved anthropometric, glucose levels and lipid profile in both the overweight and T2D groups. Available evidence has also shown that calorie restriction, i.e., a low-calorie diet intervention, has a considerable impact on improving metabolic risk factors, even if the duration is only 7-10 days (Matsuo et al., 2015).

While most would agree that modifying diet and lifestyle is necessary for the prevention of MS, T2D and CVD, especially for individuals consuming a diet high in fat or high in processed foods, there is disagreement as to what macronutrient composition would provide the greatest benefit. A study reported a 0.6–0.8mmol/L decrease in TC in overweight women following 12 weeks of energy

restriction and exercise training (Nieman et al., 2002; Luo et al., 2013), while a three-month study utilising a low-carbohydrate diet found a 20%–25% decrease in TAG levels in obese adults (Foster et al., 2003). Results from several studies also indicate that low fat diets were more effective for weight loss than either low protein or low carbohydrate diets (Skidmore, 2007). On the other hand, some cohort studies have shown inconsistent results regarding the association of fat intake with excess weight gain or obesity (Summerbell et al., 2009; Chamieh, 2013). It may be easier for some subjects to reduce carbohydrate than fat; therefore, perhaps better individualised tailoring of different diets based on preferences and experiences in the nutrition counselling could increase compliance with dietary interventions.

Based on our findings, the mean daily intake of sugar (NMES) at baseline was high (D: 82.6g/d and DE: 91.2g/d) according to the maximum recommended intake of 60g/day (11%) based on the DRVs. In this regard, nutritional advice during this intervention focused on dietary habits to promote health and well-being rather than recommending what to eat or completely avoid. Subjects were requested to reduce intake of sugar and food containing added sugar. Following the intervention, the amounts of sugar consumed decreased significantly in both groups (D: 35.8g/d and DE: 38.5g/d), meeting the recommendations (Table. 4.9). These results support previous findings showing that consumption of sugar and sugar products was as high as 67% among Saudi female students, which explains the significant relationship between BMI and consumption of sweets in their sample (Majeed, 2015). Previous evidence showed controversial links between added sugar intake, diet quality and increasing the prevalence of MS components (Van Horn et al., 2010).

Our data revealed that the baseline dietary intake of saturated, unsaturated fatty acids and cholesterol exceeded the recommended limit, as shown in Table 4.10. In fact, obesity and saturated fatty acids-rich-diets have long been associated with markedly increased IR and inflammation; both of which give rise to metabolic diseases, including T2D (Mathers et al., 2005; Al-Attas et al., 2014; Aldesi, 2014). In dietary treatment for MS, it is recommended that individuals decrease their intake of saturated fatty acids to less than 7% of total energy (Grundy et al., 2005). In this study, the intake of saturated and trans fatty acids decreased significantly following the intervention to meet the recommendation of DRVs, with no significant differences between the groups, which shows the women's response to the dietary tips given to them.

It is noteworthy that the dietary advice that was given to women in this study limited the intake of saturated fatty acids (found in animal fats and tropical oils) and trans fat (hydrogenated or hardened) along with vegetable fat found in margarine and many types of cookies, crackers and other snack foods. Both those types of fat have been shown to

raise LDL-C and TAG. On the other hand, liquid or soft polyunsaturated fatty acids (vegetable oil, soft margarine), monounsaturated fatty acids and Omega-3 fatty acids are associated with lower LDL-C, TAG and increased HDL-C levels (Bednarzyk, 2009).

With regard to fibre, trends in the dietary pattern for the Saudi population illustrate a decreased intake of fruit, vegetables and wholegrain (Midhet et al., 2010). Indeed, the main cereals consumed in Arab countries are rice and wheat and the rice consumed is polished and contains only 0.5% crude fibre. Wheat is mostly consumed as Arabic bread made from flour with an extraction rate of 70%-75% (Musaiger, 1998). A study showed that 78% of Saudi female students were not consuming fruit and vegetables on a daily basis (Al-Otaibi, 2013) and the mean intake of fibre was found to be low (14.6g/d) (Bano et al., 2014). These findings are in agreement with our study; the baseline mean intakes of dietary fibre (NSP) were 14.3g/day for D and 12.1g/day for DE, below the DRV set for adults of at least 18g per day. However, at endpoint, the amount of fibre consumed had increased significantly close to the recommendations (D: 17.8g/day and DE: 16.9g/day) (Table 4.9).

According to our results, there were no significant differences between the two groups in terms of vitamin and mineral intake following the trial, except for folate, which was lower in DE. Additionally, there were no differences within each group regarding vitamin and mineral consumption, which are close to or above the recommendations (Tables 4.11 and 4.12).

With respect to vitamin D intake, the new guidelines on vitamin D recommended by the Scientific Advisory Committee on Nutrition (SACN) that adults and children over the age of four years should increase the RNI for vitamin D to 10 µg, particularly during autumn and winter (British Nutrition Foundation, 2017). The mean daily intake of vitamin D for our sample was similar pre- and post-intervention and was lower than RNI standards of 10µg/d and RDA standards of 5µg/d. This is in line with previous findings which revealed that vitamin D deficiency is common in healthy Saudi females (34.8%) (Alsuwadia et al., 2013). Accumulating research suggests that circulating concentrations of vitamin D might be inversely related to the prevalence of diabetes, to the concentration of glucose and to IR. Additionally, vitamin D deficiency might be a risk factor for MS (Ford et al., 2005).

## 8. Strengths and limitations

To the best of our knowledge, this is the first intervention in the KSA to examine the association between PA, diet and MS. Also, this is the first study in general using the WhatsApp programme for dietary counselling which was a culturally appropriate method for Saudi society. Along with careful monitoring of the diet, the programme provided all subjects with dietary advice, including follow-

up (individualised nutritional counselling) using WhatsApp messages for 30 days. This enabled the researcher to maintain constant communication with the sample, a daily monitoring of the diet and to send nutritional information in interesting forms, such as images and videos. Moreover, its chief strength lies in the rigorously supervised exercise sessions at the gym for all D+E subjects, which reduced problems with adherence and helped ensure a standardised programme for all participants. In addition, the design of the exercise programme focused on moderate to vigorous exercise training, because this is what is recommended in most public health guidelines for adults. Also, it used a seven-day food diary, which is the most accurate and valid method for assessing diet. It is noteworthy that we experienced excellent adherence to the intervention and low drop-out rates.

Moreover, due to the unavailability of the devices in Saudi Arabia at the time of the research application the body composition was not measured in the current study and changes in lean body mass in the exercise group may have offset some changes in fat mass. Therefore, future studies should address these limitations by using method for estimating body composition, and in particular body fat such as Bod pod, Dual energy and Bio-electrical impedance.

## 9. Conclusion

Results of this pilot study support the feasibility of implementing an intensive dietary intervention which has favourable effects in altering MS risk factors in obese Saudi women. However, combining this with a rigorous exercise regimen did not produce any further improvement. At baseline, both groups of women displayed excessive intakes of dietary energy and low PA, which were associated with high BMI and WC levels that would place them at risk of developing MS. However, of the cardiometabolic risk factors associated with MS, only HDL-C was close to the range specified in the IDF criteria (mean 1.30 compared to cut-off of 1.29mmol/l) in the group as a whole and only about 20% of the study groups fulfilled the criteria to be diagnosed with MS. Following the intervention, reduced energy intake and weight reduction considerably improved their metabolic profiles independently of whether this was accompanied by increased exercise. It has been found that WC, BP, TC, insulin, IR and plasma TAG were all significantly reduced independently of PA inclusion. The study suggests that, during short-term intervention, dietary energy restriction should be the primary goal in improving cardiometabolic health.

Also, the results demonstrated the positive impact of some of the lifestyle interventions in improving the MS biomarkers among Saudi women. Tests of efficacy and effectiveness over time are needed to determine the utility of this intervention as a programme to promote diet and PA among women and support long-term health outcomes.

Based on this preliminary data, future studies could be designed to enhance power and generalizability. If the obstacles identified in providing Saudi females with access to increased PA could be overcome, then a study in which a more representative cohort of the population could be randomized to the treatment groups would overcome concerns around the introduction of bias. Increasing the length of the study may identify benefits of increased PA that were not seen in the present study. While such changes might be expected to lead to greater drop-out rates this could be addressed by adopting 'intention to treat' statistical analysis.

Overall, the present study indicates that in the short-term, dietary intervention leading to significant changes in energy and macronutrient intakes, can lead to significant improvements in the metabolic health of adult, overweight Saudi females. While we have failed to demonstrate that the inclusion of increased PA has a further positive impact on health over this period, it remains to be established whether any such additional benefits would be seen over a more prolonged period.

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