Lifestyle Intervention in Obese Arab Women

A Randomized Controlled Trial

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Background: Few randomized controlled trials on lifestyle interventions have been reported in non-Western populations; none have been reported in Arab populations.

Methods: From 2 Muslim Arab communities in Israel, obese, nondiabetic women aged 35 to 54 years with 1 or more components of the metabolic syndrome were randomized to either an intensive (n = 100) or a moderate (control) (n = 101) 12-month lifestyle intervention. Women in the intensive intervention had 11 individual and 11 group counseling sessions per year with a dietitian and 22 physical activity group sessions per year. Women in the moderate intervention had 3 individual and 2 group dietary counseling sessions per year and no guided physical activity. Cultural issues were addressed in the design and conduct of both interventions. The primary outcome measure was change in the metabolic syndrome and its components.

Results: At 12 months, the intensive intervention group had median declines of 3.0 mg/dL (to convert to millimoles per liter, multiply by 0.0113) in triglyceride levels compared with 0.4 mg/dL (to convert to millimoles per liter, multiply by 0.0555) in fasting plasma glucose and 4.5 mg/dL in the intensive intervention group and increased by 5.2% in the moderate intervention group (P = .01 and P = .02, respectively). The median waist circumference decreased by 5.4 cm in the intensive intervention group and by 3.1 cm in the moderate intervention group (P = .10). The prevalence of the metabolic syndrome decreased by 4.0% in the intensive intervention group and increased by 5.2% in the moderate intervention group (P = .12).

Conclusion: The 12-month culturally sensitive intensive lifestyle intervention was effective in improving some of the metabolic syndrome components in obese Arab women.

Trial Registration: clinicaltrials.gov Identifier: NCT00273572

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STUDY DESIGN AND PARTICIPANTS

This study was conducted as an open, parallel-group, randomized trial with an active control arm aiming to examine the effectiveness of frequent dietary counseling and guided physical activity sessions (intensive lifestyle intervention) compared with less frequent dietary counseling alone (moderate lifestyle intervention). The primary outcome measure was change in the metabolic syndrome and in its individual components. Secondary outcomes included attainment of the weight reduction and physical activity targets and quality of life (QoL) measures.

Eligible women were 35 to 54 years old and living in 2 Muslim Arab communities in the center of Israel, with a body mass index (BMI) less than 30 kg/m². Women with either prediagnosed diabetes or a BMI of 30 to 40 were invited for additional tests, which included obtaining waist circumference greater than 88 cm, blood pressure of at least 130/85 mm Hg, a fasting plasma glucose level of at least 110 mg/dL (to convert to millimoles per liter, multiply by 0.0555), triglycerides of at least 150 mg/dL (to convert to millimoles per liter, multiply by 0.0113), and high-density lipoprotein cholesterol (HDL-C) levels less than 50 mg/dL (to convert to millimoles per liter, multiply by 0.0259). Women with either pre-diagnosed diabetes or a plasma glucose level of at least 200 mg/dL 2 hours after a 75-g oral glucose load, current pregnancy, or a condition that might prevent physical activity were excluded.

INTERVENTIONS

Women assigned to the intensive lifestyle intervention participated in a monthly individual counseling session and a monthly group meeting with a dietitian. In addition, they participated in 2 monthly group sessions with a physical activity instructor. They were advised to maintain personal logs of daily physical activity and 24-hour records of dietary intake in the 3 days before scheduled personal sessions with the dietitian. Fifteen women were scheduled per dietary or physical activity group session. There were no meetings during the month of Ramadan. Women assigned to the moderate lifestyle intervention (control group) participated in 3 individual counseling sessions with a dietitian: at baseline and after 6 and 12 months. They also had 2 educational group sessions with a dietitian in the first month of the intervention.

Written educational materials in Arabic on healthy diet and physical exercise were provided for both groups. The duration of both lifestyle interventions was 12 months. The intervention targets were attainment of at least a 7% reduction of initial body weight and at least 150 minutes per week of leisure physical activity of moderate intensity.

PRINCIPALS OF THE DIETARY INTERVENTION

A 1500-kcal/d target was set for participants who consumed 2500 kcal/d or more at baseline and a 1200-kcal/d target for women who reported consuming less than 2500 kcal/d. Approximately 40% of the daily energy intake was to be provided by carbohydrates, 30% by protein, and 30% by fat, mostly in the form of polyunsaturated and monounsaturated fats. Women were advised to increase their consumption of fruits and vegetables, low-fat dairy products, and whole grains; to substitute red meat with fish and poultry; and to avoid refined carbohydrates and sweetened beverages. The personal dietary counseling was based on the dietary assessment performed at baseline and was updated according to repeated assessments performed after 6 and 12 months in both groups. In women assigned to the intensive intervention, the 24-hour dietary intake logs provided additional information used in the personal monthly dietary counseling sessions.

Dietary assessment was performed using a semiquantified food frequency questionnaire. An electronic version of a modified questionnaire, consisting of 90 food items and including traditional Arab foods, was developed for the present study. The curriculum for the group sessions with the dietitian included teaching the skills of food label reading, meal planning, sensible food purchasing, and coping strategies.

PHYSICAL ACTIVITY

Participants assigned to the intensive intervention participated in group sessions with a physical activity instructor. The sessions included muscle strengthening, aerobic exercise, and provision of instructions for home exercise. One of the objectives of these sessions was to teach types of physical exercise that can be performed indoors.

CULTURAL SENSITIVITY

Focus groups were conducted with local women. The themes discussed, such as social norms and women’s role in Arab society and in the family, were addressed in the intervention design. Meetings with community and religious leaders were arranged before starting to gain their support. All the program activities were conducted indoors, and the program personnel, that is, coordinators, dietitians, and physical activity instructors, was composed exclusively of local Arab women. Written educational materials and group meeting curricula were culturally relevant, addressing themes such as coping with diet during Ramadan, how to maintain an active lifestyle without violating social codes, and how to compromise between personal needs and familial and social expectations. The dietary counseling included advice on modification of local dishes according to dietary requests. To reduce family barriers, maximal flexibility in session scheduling was provided.

PROCEDURES

Potentially eligible women were identified from patient registries of Clalit Health Services, the largest health maintenance organization in Israel. Their primary care practitioners were informed about the study, and their collaboration was requested. Potential participants were invited for body weight and height measurements. Women with a BMI of 30 to 40 were invited for additional tests, which included obtaining waist circumference and blood pressure measurements and collecting a 12-hour fasting blood sample for plasma glucose, triglycerides, HDL-C, insulin, and high-sensitive C-reactive protein (hs-CRP) assessment. Another blood sample was taken for glucose levels 2 hours after a 75-g oral glucose load. These measurements were repeated after 6 and 12 months of the intervention in enrolled women, except for postload oral glucose measurements, which were taken after 12 months of intervention only.

Participants were enrolled between January 26, 2006, and July 10, 2007, with study completion on July 21, 2008. The study protocol was approved by the institutional review board of the Sheba Medical Center, Tel-Hashomer. Participants provided 2 written informed consent forms: before screening and before randomization. Eligible women were randomly assigned to the 2 study groups after completing a baseline evaluation and providing written informed consent. Randomization was stratified by community and 10-year age group using a central computerized randomization program.
Study nurses and laboratory technicians who performed the follow-up measurements and assays were blinded to group assignment. Otherwise, there was no blinding to group assignment after randomization of participants, study coordinators, dietitians, and investigators.

Three blood pressure measurements were taken according to the standard protocol using a sphygmomanometer (MiNiatur 300 B, Welch Allyn GmbH & Co KG, Jungingen, Germany). The mean value of the second and third measurements was used for analysis. Body weight and height were measured while participants were barefoot and lightly dressed. Waist circumference was measured in the midspace between the lowest costal margin and the iliac crest. Assessment of leisure physical activity, using a validated questionnaire, was performed at baseline and after 6 and 12 months of intervention. Quality of life was measured at baseline and after 12 months of intervention using the Arabic version of the 36-Item Short Form Health Survey.16

Blood samples were transferred to the laboratory at 4°C within 2 to 4 hours of collection. Blood samples for plasma glucose measurement were collected in iodoacetate-containing test tubes and were assayed using the hexokinase method.17 Serum insulin levels were measured using solid-phase radioimmunoassay (Coat-A-Count Insulin; Diagnostic Products Corp, Los Angeles, California). The homeostatic model assessment for insulin resistance (HOMA-IR), a surrogate measure for insulin sensitivity, was calculated as the product of fasting plasma insulin and fasting plasma glucose divided by 22.5.18 Serum levels of HS-CRP were assessed using a commercial immunoturbidimetry kit (Olympus AU2700 Analyzer; Olympus Diagnostic Systems Group, Melville, New York). Plasma levels of triglycerides and HDL-C were measured using commercial enzymatic kits (Boehringer, Mannheim, Germany). The HDL-C was assayed after precipitation of the apolipoprotein B–containing lipoproteins with phosphotungstic acid. Lipid level determination was performed following the US Lipid Research Clinics protocol in a batch analyzer (Vitalab; Vital Scientific, Spankeren, the Netherlands).

STATISTICAL ANALYSIS

Sample size calculations were made for the following components of the metabolic syndrome: fasting glucose, insulin, and triglyceride levels; systolic and diastolic blood pressure; and waist circumference. Information on the components’ variances and expected changes after 1 year of intervention was obtained from the Finnish Diabetes Prevention Study results.20 Calculations were performed using a statistical power analysis software package (Power and Precision; Biostat, Englewood, New Jersey) for an unmatched 2-tailed t test with equal-sized groups, for 5% statistical significance, at least 80% statistical power, and assuming a dropout rate of 20%. A sample size of 100 women per group provided the requisite statistical power for the following mean differences between the intensive and moderate lifestyle interventions: −3.1 cm in waist circumference, −3.4 mg/dL in fasting plasma glucose, −24.7 mg/dL in fasting plasma triglycerides, 2.7 mg/dL in HDL-C, −6.5 mm Hg in systolic blood pressure, and −4 mm Hg in diastolic blood pressure.

The components of the metabolic syndrome were tested as continuous and binary variables. The metabolic syndrome was defined as having 3 or more of the syndrome components according to the National Cholesterol Education Program–defined cutoff points.21 All the analyses were performed according to the intention-to-treat principle.

Missing information on the primary study outcome was imputed using the multiple imputations approach.22 For each missing value, we performed 5 imputations using the SAS MI procedure with the Markov Chain Monte–Carlo method. Imputations were performed separately for dropouts (ie, women who did not receive or discontinued the assigned intervention) and nondropouts. The results were further combined using the SAS procedure MIANALYZE for obtaining the variance of the statistic of interest and the relevant P value.22

Comparisons between the 2 study groups were made using an unpaired t test for normally distributed variables (ie, age, weight, BMI, HDL-C, and blood pressure); the Wilcoxon test for continuous variables with a nonnormal distribution (ie, years of education; hip and waist circumference; plasma glucose, insulin, HOMA-IR, HS-CRP, and triglyceride levels; and QoL scores); and the χ² test for discrete variables. Because the baseline insulin and HOMA-IR values differed between the 2 study groups, comparisons of the changes after intervention were further adjusted for baseline insulin or HOMA-IR values using multiple linear regression for variables with a normal distribution and rank regression models for variables with a nonnormal distribution. Where adjusted analyses did not change the results, unadjusted findings were reported.

Comparison of the change in the metabolic syndrome status after 12 months of intervention was made using logistic regression analysis controlling for baseline metabolic syndrome status and study group. All the analyses were 2-tailed and were considered significant at α < .05. Statistical analysis was performed using a software program (SAS version 9.1; SAS Institute Inc, Cary, North Carolina).

RESULTS

Body weight and height were measured in 410 women, and 230 of them participated in further screening tests (Figure). Of 206 eligible women, 201 were randomly assigned to either an intensive lifestyle intervention (n=101) or a moderate lifestyle intervention (n=101). Table 1 provides the participants’ baseline characteristics. Their mean age was 44 years and mean BMI was 34, and 25% of them had 3 or more components of the metabolic syndrome. The 2 study groups were similar at baseline except in insulin levels. Women assigned to the intensive intervention had significantly higher basal and postload insulin levels and were more insulin resistant compared with women assigned to the moderate intervention.

Three women (3%) in the intensive lifestyle intervention group did not receive the assigned intervention, and 14 (14%) discontinued the intervention. The corresponding numbers in the moderate intervention group were 3 (3%) and 6 (6%) (Figure). Women assigned to the intensive lifestyle intervention attended a median of 9 physical activity sessions per year, 10 dietary group sessions per year, and 11 individual dietary counseling sessions per year. Women assigned to the moderate intervention attended a median of 1 dietary group session per year and 3 individual dietary counseling sessions per year.

Assessment of the individual metabolic syndrome components was completed for 94.0% to 96.0% of the participants after 6 months of intervention and for 92.5% to 98.5% of the participants after 12 months. Quality of life was evaluated at baseline and after 12 months of intervention in 97.5% to 99.0% of the participants.

At 6 months, women in both study groups reported reductions in their mean daily energy intakes: by 25% in the intensive intervention group and by 18% in the moderate intervention group (P < .05). The percentage of daily energy derived from carbohydrates decreased by
2.7% in women assigned to the intensive intervention and increased by 3.3% in women assigned to the moderate intervention ($P < .001$). The percentage of daily energy derived from fat increased by 1.2% in women assigned to the intensive intervention and decreased by 3.1% in women assigned to the moderate intervention ($P < .001$). However, the percentage of daily energy derived from saturated fat decreased by 1.4% in women assigned to the intensive intervention and increased by 2.4% in women assigned to the moderate intervention ($P = .003$). Similar trends were observed at the 12-month evaluation (data not shown).

Both interventions were associated with weight reduction and increased leisure physical activity. However, a greater proportion of women assigned to the intensive intervention attained the weight reduction and physical activity targets (Table 2). The intensive intervention was associated with reductions in fasting plasma glucose and triglyceride levels, whereas an opposite trend was seen in women assigned to the moderate intervention ($P < .001$). A similar trend was observed for postload plasma glucose levels. Waist circumference decreased in both study groups, with a maximal effect observed at 12 months.

The HOMA-IR index declined in both groups, indicating improved insulin sensitivity, with a maximal effect observed at 6 months. Women assigned to the intensive intervention had greater decreases in HOMA-IR than did women assigned to the moderate intervention. However, they also had significantly higher baseline values. After controlling for the baseline HOMA-IR level, the differences between the 2 study groups in HOMA-IR declines were not statistically significant. There were no significant differences between the 2 groups in changes in blood pressure, HDL-C, and HS-CRP levels (Table 2).

After 12 months, the prevalence of the metabolic syndrome decreased by 4.0% in women assigned to the intensive intervention and increased by 5.2% in women assigned to the moderate intervention ($P = .12$). The baseline QoL scores were similar in both study groups. After 12 months, women assigned to the intensive lifestyle intervention had significantly better scores in most of the QoL domains compared with women assigned to the moderate intervention (Table 3).

On average, the total manpower dedicated per participant assigned to the 12-month intensive intervention included 8 hours of a dietitian, 2 hours of a physical activity instructor, and 6 hours of an administrator. All program activities were performed in local public buildings. Neither lifestyle intervention was associated with adverse events.

**COMMENT**

We found that in obese Arab women, a culturally sensitive intensive lifestyle intervention, combining dietary advice and guided physical activity, was feasible and more effective than was a moderate lifestyle intervention in improving the metabolic syndrome and 3 of its components (waist circumference, fasting plasma glucose levels, and triglyceride levels). The intensive intervention was also associated with better QoL and was significantly more effective than was the moderate intervention in attaining the weight loss and physical activity targets.

The median reductions in fasting plasma glucose and triglyceride levels observed in this study were within the range of reductions associated with lifestyle interventions in obese people and in people at risk for diabetes. The intensive lifestyle intervention was associated with significant increases in QoL scores. Improvement in well-being and QoL may encourage people to maintain a healthy lifestyle.
We found no other published results of randomized clinical trials on lifestyle intervention in Arab populations. Attitudes and barriers toward lifestyle modification differ across cultures.10,22,23 The high prevalence of lifestyle-related states in Arabs, that is, obesity, the metabolic syndrome, diabetes, and cardiovascular disease,4,5 emphasize the need for effective intervention. Cultural sensitivity was a central factor in this study. Participants encountered familial and social barriers that interfered with the demands of dietary modification, physical activity, and participation in program activities. The high attendance rate in the individual and group dietary sessions and the modest dropout rate indicate that the intensive intervention was successful in coping with some of these barriers. However, attendance at the physical activity sessions was significantly lower. This could have been due to turnover of physical activity instructors during the study (3 within 1 year), low motivation for physical exercise, or both.

The proportion of women who completed follow-up assessment in this study was high. Complete follow-up information is particularly important in evaluating the effectiveness of lifestyle interventions because people who miss follow-up assessments tend to gain more weight than do those who attend follow-up visits.

The screening strategy used in this study was simple and more efficient than was that reported in similar trials. Altogether, almost half of the women who went through the screening process were enrolled. Several factors contributed to efficient recruitment: recruitment was based on the metabolic syndrome component(s) rather than being focused exclusively on glucose tolerance status; the prevalence of eligible people in the target population was high; electronic patient records were available and allowed the exclusion of most noneligible people without the need for further testing; and a high consent rate. Efficient algorithms for identification and recruitment of high-risk individuals are a prerequisite for cost-effective primary prevention of type 2 diabetes mellitus.26 Furthermore, the higher the proportion of people enrolled from among people who are considered eligible, the greater the external validity of the study results.

The control arm in the present study consisted of a moderate lifestyle intervention. The intensity of this intervention was similar to the lifestyle advice offered to...
Table 2. Changes in Body Weight, Leisure Physical Activity, and Characteristics of the Metabolic Syndrome After 6 and 12 Months of Lifestyle Intervention

<table>
<thead>
<tr>
<th>Variable</th>
<th>6 mo of Lifestyle Intervention</th>
<th>12 mo of Lifestyle Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intensive (n=100)</td>
<td>Moderate (n=101)</td>
</tr>
<tr>
<td>Difference from baseline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Waist circumference, cm</td>
<td>−4 (−19.4 to 9.6)</td>
<td>−2.1 (−20.8 to 10.2)</td>
</tr>
<tr>
<td>Triglycerides, mg/dL</td>
<td>−6.5 (−196 to 74)</td>
<td>3 (−156 to 118)</td>
</tr>
<tr>
<td>HDL-C, mean (SD), mg/dL</td>
<td>0.62 (7.3)</td>
<td>0.66 (7.0)</td>
</tr>
<tr>
<td>FPG, median (range), mg/dL</td>
<td>−2 (−22 to 49)</td>
<td>0 (−16 to 30)</td>
</tr>
<tr>
<td>SBP, mean (SD), mm Hg</td>
<td>0.4 (12.1)</td>
<td>1.4 (12.5)</td>
</tr>
<tr>
<td>DBP, mean (SD), mm Hg</td>
<td>4.6 (8.8)</td>
<td>4.3 (8.5)</td>
</tr>
<tr>
<td>Weight, mean (SD), kg</td>
<td>−3.4 (4.7)</td>
<td>−0.4 (4.2)</td>
</tr>
<tr>
<td>Weight, mean (SD), %</td>
<td>−3.9 (5.3)</td>
<td>−0.5 (4.8)</td>
</tr>
<tr>
<td>HOMA-IR, median (range)</td>
<td>−0.7 (−5.3 to 15.0)</td>
<td>−0.1 (−4.4 to 4.6)</td>
</tr>
<tr>
<td>HS-CRP, median (range), mg/L</td>
<td>−0.4 (−26.8 to 23.6)</td>
<td>−0.3 (−26.1 to 47.5)</td>
</tr>
<tr>
<td>2-h Postload oral glucose PG, median (range), mmol/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attainment of intervention targets, No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical activity ≥150 min/wk</td>
<td>30 (30.0)</td>
<td>7 (6.9)</td>
</tr>
<tr>
<td>Weight reduction ≥7%</td>
<td>24 (24.0)</td>
<td>6 (5.9)</td>
</tr>
</tbody>
</table>

Abbreviations: DBP, diastolic blood pressure; FPG, fasting plasma glucose; HDL-C, high-density lipoprotein cholesterol; PG, plasma glucose; HOMA-IR, homeostatic model assessment for insulin resistance (calculated as the product of fasting plasma insulin [in milli-International Units per liter] and FPG in millimoles per liter divided by 22.5); HS-CRP, high-sensitive C-reactive protein; SBP, systolic blood pressure.

15 Differences in body weight, physical activity levels, and characteristics of the metabolic syndrome were evaluated using the paired t test for the difference in weight, the Wilcoxon test for the difference in waist circumference, and the Kruskal-Wallis test for the difference in triglycerides. The unpaired t test was used for the difference in HDL-C, SBP, and DBP; the χ² statistic for the proportion of participants attaining the intervention targets; and the rank regression model for the difference in HOMA-IR levels controlling for the baseline HOMA-IR level.

*Higher score indicates a better state.

Table 3. Quality of Life, Assessed Using the 36-Item Short Form Health Survey, at Baseline and After 12 Months

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline</th>
<th>At 12 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intensive (n=99)</td>
<td>Moderate (n=100)</td>
</tr>
<tr>
<td>Reported health transition</td>
<td>3 (1-5)</td>
<td>3 (1-5)</td>
</tr>
<tr>
<td>Physical functioning</td>
<td>85 (5-100)</td>
<td>85 (0-100)</td>
</tr>
<tr>
<td>Role physical</td>
<td>75 (0-100)</td>
<td>75 (0-100)</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>62 (0-100)</td>
<td>62 (0-100)</td>
</tr>
<tr>
<td>General health</td>
<td>71.5 (5-100)</td>
<td>66.5 (5-100)</td>
</tr>
<tr>
<td>Vitality</td>
<td>55 (5-100)</td>
<td>50 (5-100)</td>
</tr>
<tr>
<td>Social functioning</td>
<td>87.5 (12.5-100)</td>
<td>75 (0-100)</td>
</tr>
<tr>
<td>Role emotional</td>
<td>100 (0-100)</td>
<td>66.67 (0-100)</td>
</tr>
<tr>
<td>Mental health</td>
<td>72 (8-100)</td>
<td>68 (4-100)</td>
</tr>
</tbody>
</table>

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Author Contributions: Dr Kalter-Leibovici had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Kalter-Leibovici, Younis-Zeidan, Atamna, Lubin, Alpert, Daoud, and Freedman. Acquisition of data: Kalter-Leibovici and Younis-Zeidan. Analysis and interpretation of data: Kalter-Leibovici, Lubin, Chetrit, Novikov, and Freedman. Drafting of the manuscript: Kalter-Leibovici. Critical revision of the manuscript: Younis-Zeidan, Atamna, Lubin, Alpert, Chetrit, Novikov, Daoud, and Freedman. Statistical analysis: Kalter-Leibovici, Chetrit, Novikov, and Freedman. Obtained funding: Kalter-Leibovici and Atamna. Administrative, technical, and material support: Kalter-Leibovici, Younis-Zeidan, Atamna, and Alpert. Study supervision: Kalter-Leibovici, Younis-Zeidan, Lubin, and Alpert.

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Additional Contributions: We extend profound gratitude to all the women who participated in this study.

REFERENCE