eat right. American Dietetic Association

Original Research

Intake of Milk with Added Micronutrients Increases the Effectiveness of an Energy-Restricted Diet to Reduce Body Weight: A Randomized Controlled Clinical Trial in Mexican Women

JORGE L. ROSADO, PhD; OLGA P. GARCIA, PhD; DOLORES RONQUILLO; DEISY HERVERT-HERNÁNDEZ, MS; MARIA DEL C. CAAMAÑO, MA; GUADALUPE MARTÍNEZ, MHN; JESSICA GUTIÉRREZ; SANDRA GARCÍA, MS

ABSTRACT

Background Micronutrient deficiencies have been associated with an increase in fat deposition and body weight; thus, adding them to low-fat milk may facilitate weight loss when accompanied by an energy-restricted diet.

Objective The objective was to evaluate the effect of the intake of low-fat milk and low-fat milk with added micronutrients on anthropometrics, body composition, blood glucose levels, lipids profile, C-reactive protein, and blood pressure of women following an energy-restricted diet.

Design A 16-week randomized, controlled intervention study.

Participants/settings One hundred thirty-nine obese women (aged 34±6 years) from five rural communities in Querétaro, Mexico.

Intervention Women followed an energy-restricted diet (−500 kcal) and received in addition one of the following treatments: 250 mL of low-fat milk (LFM) three times/day, 250 mL of low-fat milk with micronutrients (LFM+M) three times/day, or a no milk control group (CON). Weight, height, and hip and waist circumferences were measured at baseline and every 4 weeks. Body composition measured by dual-energy x-ray absorptiometry, blood pressure, and blood analysis were done at baseline and at the end of the 16 weeks.

Main outcome measures Changes in weight and body composition.

Statistical analysis One-factor analysis of variance, adjusted by age, baseline values, and community random effects.

Results After the 16-week intervention, participants in the LFM+M group lost significantly more weight (−5.1 kg; 95% CI: −6.2 to −4.1) compared with LFM (−3.6 kg; 95% CI: −4.7 to −2.6) and CON (−3.2 kg; 95% CI: −4.3 to −2.2) group members (P=0.035). Body mass index change in the LFM+M group (−2.3; 95% CI: −2.7 to −1.8) was significantly greater than LFM group members (−1.5; 95% CI: −2.0 to −1.1) and CON group members (−1.4; 95% CI: −1.9 to −0.9) (P=0.022). Change in percent body fat among LFM+M group members (−2.7%; 95% CI: −3.2 to −2.1) was significantly higher than LFM group members (−1.8%; 95% CI: −2.3 to −1.3) and CON group members (−1.6%; 95% CI: −2.2 to −1.0) (P=0.019). Change in bone mineral content was significantly higher in LFM group members (29 mg; 95% CI: 15 to 44) and LFM+M group members (27 mg; 95% CI: 13 to 41) compared with CON group members (−2 mg; 95% CI: −17 to −14) (P=0.007). No differences were found between groups in glucose level, blood lipid profile, C-reactive protein level, or blood pressure.

Conclusions Intake of LFM+M increases the effectiveness of an energy-restricted diet to treat obesity, but had no effect on blood lipid levels, glucose levels, C-reactive protein, or blood pressure.

J Am Diet Assoc. 2011;111:1507-1516.

J. L. Rosado is a senior scientist, Human Nutrition Department, School of Natural Sciences, Universidad Autónoma de Querétaro, Querétaro, Mexico, and a member of the Scientific Committee, Center for Innovation and Technological Development in Chronic Disease (CINDETEC), Querétaro, Mexico. O. P. Garcia is a senior scientist, and D. Ronquillo, G. Martínez, and J. Gutiérrez are scientists, Human Nutrition Department, School of Natural Sciences, Universidad Autónoma de Querétaro, Querétaro, Mexico. D. Hervert- Hernández is a scientist, Nutrition Department I, School of Pharmacy, Universidad Complutense de Madrid, Madrid, Spain. M. del C. Caamaño is a scientist, Human Nutrition Department, School of Natural Sciences, Universidad Autónoma de Querétaro, Querétaro, Mexico, and a scientist with CINDETEC, Querétaro, Mexico. S. García is a scientist, CINDETEC, Querétaro, Mexico.

Address correspondence to: Jorge L. Rosado, PhD, Human Nutrition Department, School of Natural Sciences, Universidad Autónoma de Querétaro. Av de la Ciencia S/N Juriquilla, Querétaro, 76230, Mexico. E-mail: jlrosado@prodigy.net.mx

Manuscript accepted: May 9, 2011.

0002-8223/$36.00
doi: 10.1016/j.jada.2011.07.011

Recent evidence shows that some micronutrient deficiencies may increase the risk of fat deposition and obesity (1). Overweight and obese individuals have lower blood concentrations of several micronutrients, such as iron and vitamins A, E, D, B-12, and folic acid, when compared to individuals with normal body mass index (BMI) (1-4). Micronutrients have different effects on obesity that have been previously reviewed (1). Specific micronutrient deficiencies may increase leptin concentrations, increase adipose tissue, and increase the risk of obesity and low-grade systemic inflammation (5-8). Vitamin E intake has been found to be a negative predictor of leptin concentrations in overweight children (8). One of the vitamin A metabolites, retinoic acid, may inhibit adipogenesis, enhance fat cells apoptosis, and regulate the production of adipokines such as leptin (7-9). Vitamin D inhibits the production of leptin and, thus, might be involved in the regulation of weight and body composition (7). Deficiencies of some micronutrients have also been associated with higher risk of hypertension and insulin resistance. Vitamin D, vitamin B-12, and folic acid deficiencies, for example, have been associated with high blood pressure (10,11). Retinoic acid has been shown to improve insulin sensitivity by reducing the concentration of the retinol-binding-protein 4 and activating the peroxisome proliferation-activated receptor delta (12,13). The addition of micronutrients to milk could enhance the potential benefit of milk intake on weight reduction and diseases related to obesity.

The effect of milk and dairy products intake on weight loss in overweight and obese persons is controversial. The evidence suggests that three daily servings of low-fat dairy products result in significant body fat loss in obese individuals (14-17), and the effect is greater when accompanied by an energy-restricted diet (15,17,18). However, a meta-analysis of 13 randomized controlled trials concluded that neither calcium supplements nor dairy products have additional beneficial effects on weight loss (19).

In addition to weight loss, other studies have demonstrated that the intake of low-fat dairy products help to reduce the risk of hypertension and type 2 diabetes (20-31). Dairy products intake has also been shown to decrease C-reactive protein (CRP) concentrations, a chronic inflammation biomarker, and thus, may play an important role in the prevention of heart disease (32). The objective of this study was to determine whether the inclusion of low-fat milk (LFM) or low-fat milk with added micronutrients (LFM+M) to an energy-restricted diet has additional benefits on weight loss, body composition, lipids profile, blood pressure, and fasting glucose and CRP levels in obese women living in rural communities in Mexico.

METHODS

Participants

Obese women (BMI ≥30), aged between 25 and 45 years, were recruited from five rural communities in Queretaro, Mexico. Participants were recruited and were included in the study from January to September 2008. Initially, 549 women were screened by measuring height and weight, from which 169 women were identified as obese and in compliance with all other inclusion criteria. All women received oral and written information regarding all aspects of the study and voluntarily accepted to participate and signed consent forms. Participants were excluded if they had one of the following: fasting glucose ≥126 mg/dL (7 mmol/L), triglycerides concentration ≥ 400 mg/dL (4.5 mmol/L), total cholesterol ≥239 mg/dL (6.2 mmol/L), blood pressure ≥140/90 mm Hg, renal insufficiency, eating disorders, or were pregnant or lactating. Women were also excluded if they were consuming more than three servings per day of milk or dairy products, if they had received any treatment for obesity, or had been treated with metformin, thiazolidinediones, or hormones within the 3 months before this study. Of the 169 individuals initially identified as potential participants, 139 were included and accepted to participate voluntarily in the study. The Internal Ethics Committee for Human Research of the Universidad Autonoma de Queretaro approved the study protocol.

Design of the Study

The study was a randomized, controlled, intervention trial. Participants were randomly assigned to receive one of three treatments: 250 mL of LFM consumed three times per day in addition to an energy-restricted diet (−500 kcal/day), 250 mL of LFM+M consumed three times per day in addition to an energy-restricted diet (−500 kcal/day), or to the control intervention (CON), an energy-restricted diet (−500 kcal/day) with no intake of milk. The random allocation sequence method was used to assign treatments consecutively to every enrolled patient. One researcher who had no direct contact with patients (M.C.C.) computed a randomization list that assigned a treatment code consecutively to enrolled participants. All treatments were administered for 16 weeks. Participants were asked not to modify their physical activity habits throughout the study and three physical activity questionnaires were administered at the beginning of the study, at 8 and 16 weeks to ensure compliance to this recommendation.

The LFM and LFM+M groups received milk in 1L Tetra Brik (Tetra Pak, Lausanne, Switzerland) containers that were coded so that participants, field workers, data managers, and investigators were blinded to these two treatments. Identification codes of both treatments were revealed to study personnel only after data analysis was completed. Addition of vitamin A and vitamin D to milk is mandatory in Mexico; thus, LFM and LFM+M included vitamin A (150 μg retinol equivalents/dose) and vitamin D (1.3 μg/dose). Additional micronutrients added to the LFM+M included iron (2.3 mg/dose); magnesium (40 mg/dose); vitamin E (2.4 mg α-tocopherol equivalents/dose); niacin (3.11 mg/dose); folic acid (63.9 μg/dose); and thiamin (0.3 mg/dose), vitamin B-6 (0.4 mg/dose), and vitamin B-12 (0.4 mg/dose), which have been shown to be associated with obesity and obesity-related diseases.

Women were transported to the metabolic unit at Universidad Autonoma de Queretaro to evaluate their body composition, to determine their blood pressure and to take a fasting blood sample at baseline and after 16 weeks of treatment. Weight, height, and hip and waist circumferences were measured every 4 weeks during the 16-week intervention at the health clinics of the communities.

Treatments

The energy-restricted diet was designed to reduce energy intake by 500 kcal/day of the calculated required energy