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Design and challenges of a randomized controlled trial for reducing risk factors of metabolic syndrome in Mexican women through water intake

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Abstract

Objective—To describe the design, methods, and challenges encountered during a randomized clinical trial aimed to promote water intake for reducing risks of metabolic syndrome in Mexican women.

Materials and methods—In a randomized clinical trial in Cuernavaca, Mexico, overweight and obese (body mass index [BMI] ≥ 25 < 39) women, 18 – < 45 years old with an intake of sugar-sweetened beverages ≥ 250 kilocalories per day (kcal/day) were randomly allocated to the water and education provision group (n = 120) or the education provision only group (n = 120).

Results—We screened 1 756 women. The main difficulties encountered were identifying participants with the recruitment criteria, delivering water to participants, and the time demanded from the study participants.

Conclusions—The trial's main challenges were difficulties surrounding recruitment, delivery of the intervention, and the time demanded from the study participants. Modifications were effectively implemented without jeopardizing the original protocol.

Keywords

clinical trials; sugar; beverages; triglycerides; body mass index; diet; women; Mexico

In Mexico almost 72% of women were overweight or obese by 2006.[1] Furthermore, the prevalence of hypercholesterolemia and other blood lipid abnormalities in Mexico is similar to that found among Mexican Americans.[2]

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Evidence shows that sugar-sweetened beverage (SSB) intake is linked with increased energy intake, weight gain, and an array of cardiometabolic risks.[3–5] In Mexico SSB contributes 411 kilocalories per day (kcal/day) or 22.3% of the total energy intake among adults.[6]

More than 20 countries have banned SSBs in schools, tax them at the national level, and have issued guidelines for reducing their consumption.[7] Furthermore strong evidence from numerous studies shows the potential benefit of change in beverage consumption.[4,8–10] Nevertheless few random controlled trials have studied replacement of SSBs with water or other noncaloric options.[11] When properly implemented, randomized clinical trials are ideal for testing causality.[12,13]

The purpose of this paper is to describe the design methods of the trial and the most relevant difficulties encountered during recruitment and follow-up and strategies chosen to solve them. In addition we provide baseline data from the water intervention randomized controlled trial. The primary objective of the original water trial was to investigate whether replacement of SSBs with water could reduce plasma triglyceride concentration and other cardiometabolic factors over nine months in overweight and obese Mexican women.

Materials and methods

Subjects and eligibility

We recruited women 18 to < 45 years old with a body mass index (BMI) ≥ 25 to < 39 kg/m2 who reported SSB intake (including soft drinks; juices; sugar-sweetened traditional beverages, such as lemonade, hibiscus water, and rice water [*aguas frescas*]; sports drinks; sweetened tea or coffee; and alcoholic beverages) of at least 250 kcal/day.* Table I outlines inclusion and exclusion criteria.[14,15]

Recruitment, screening, and enrollment

Participants were recruited in Cuernavaca, Mexico, between April 2009 and November 2010, through an advertisement campaign. Applicants were screened via telephone to determine if they criteria.* Those who did then filled out three 24-hour recall questionnaires (two weekdays, one weekend) to identify their usual SSBs intake.

Eligible participants were randomly assigned to either the water and education provision (WEP) group (intervention) or the education provision only (EP) group (control). Written informed consent was obtained prior to research activity. The study was approved by the National Institute of Public Health (INSP) Review Board.

*Originally our cutoff for the SSB consumption criteria was > 300 kcal/day, however, finding women with this intake who met the other criteria was difficult and was lengthening the recruitment period. Thus we reduced the number of calories according to the intake of women interested in the study.

*Initially we had planned to include a cutoff for triglycerides of > 150 milligrams per deciliter (mg/dl), however, the triglyceride measure was highly variable and so was excluded.

Randomization

Blocked randomization (24 blocks with 10 randomized numbers each) was generated using Microsoft Excel. The randomization was done by the statistician of the group (MU) and the treatment allocation by the project manager (DGC)

Trial design

The intervention lasted nine months. Activities for the two groups are described on Table I. All activities and strategies to achieve the goal of each group were discussed with the participants in individual and group meetings. The WEP group meetings covered the rationale and strategies for replacing SSBs with increased water consumption. We took care to ensure equal attention to each group.

To decrease potential treatment contamination between the groups, in addition to appointments scheduled on different days, all participants were directed not to share their instructions with other participants. Also the two specialists (one dietitian and one psychologist) leading all individual and group sessions were different for each group.

Intervention description and contacts

The goal for the WEP group was to increase water intake and reduce the intake of SSB (as defined above) by substituting water. To support the beverage modifications, participants attended monthly face-to-face meetings either individually or in a group. Group meetings (2 to 10 participants) were facilitated by trained dietitians and psychologists. Each group meeting had a different topic and consisted of activities that allowed women to get information, make their own reflections based on their experiences, and finally come up with their own commitments to behavior changes. In between group meetings women had an individual counseling session. Women could express the challenges of pursuing their commitments and through a guided reflexive process set their own goals and the strategies to accomplish them. In addition trained personnel called participants biweekly to maintain enthusiasm, ask about water supply status, and help address challenges faced during the week.

The topics and strategies to promote water consumption in both individual and group meetings were developed based on prior formative research guided by the Integrative Model of Behavioral Prediction.[16] The information collected allowed us to distinguish the influences of behavioral change needed to be adressed and define the strategies, themes, and content of the sessions. The design of the education-communication sessions was based on popular education,[17] nonformal education,[18] and counseling[19] principles. These approaches and strategies allow individuals' active participation in problem and solution identification and in consequence foster behavioral change. The design and broader description of the education component of the intervention will be the purpose of another paper. To ensure water availability, bottled water was delivered to WEP participants' homes during the intervention period and/or was available for pickup every two weeks. We provided two to three liters of water per person per day plus one additional liter per day to account for possible consumption by other family members.

EP group participants also attended group and individual meetings. The difference was that they set goals and strategies to achieve healthy eating behaviors not related to water intake but to *El Plato del Bien Comer*, the Mexican official guidelines and food pyramid equivalent.[20] The topics were sodium and healthy fat (unsaturated vs. saturated) content in the diet, healthy meal scheduling, and including vegetables in food preparations. The participants were not given information on reducing SSB intake or increasing water intake or information related to beverage consumption and health (Table I). They were contacted with the same frequency and stimulation to participate as were WEP group participants. For ethical reasons, after final measurements the EP group participated in an extra meeting regarding water and SSB intake.

Data collection

Anthropometry, diet, physical activity, blood pressure, and fasting blood were collected at baseline and at three, six, and nine months or as indicated in Table II. All assessments were conducted on weekdays between the hours of 7:00 AM and 11:00 AM at the INSP except water delivery information, which was obtained by telephone interview, and dietary information, which was obtained at participants' homes or other places of their preference. Participants were required to fast for 12 hours prior to the physiological and body composition measures. Participants received a $15 honorarium and a lunch at every visit.

Physiological measures

Fasting blood samples were collected in nonanticoagulated tubes and EDTA tubes according to protocol.[21] Serum was immediately frozen and stored at −80 degrees Celsius until determination of the comprehensive metabolic panel, including fasting triglycerides, glucose, total cholesterol, low-density lipoprotein, high-density lipoprotein, and osmolality. Whole EDTA-anticoagulated blood was obtained for measurement of glycosylated hemoglobin. Urine samples were collected at the venipuncture session and were stored as appropriate until determination of urine osmolality. All laboratory determinations were conducted at the end of the intervention.

Resting blood pressure was measured using a digital Baumanometer model HEM-781 INT Omron following standard procedures. After an initial five minutes of rest, the participant's blood pressure was measured on the right arm with the participant seated and her back supported. Three measurements were taken with at least two minutes between each.

We evaluated overall body composition using air displacement plethysmography (Bod Pod Life Measurement, Inc.). The Bod Pod was calibrated before each measurement using a 49.273-liter cylinder. For the test subjects wore minimal tight-fitting clothing (swimsuits) and swimming caps to compress the hair.[22,23] We used the volume of thoracic capacity to correct body volume (corrected body volume = total body volume - thoracic capacity). We calculated body density as body mass divided by corrected body volume.[24] We calculated fat mass (kilograms [kg]) using the Siri equation[24] and fat-free mass (kg) by subtracting fat mass from body weight.

Carotid intima media thickness (IMT) was measured by B-mode SonoSite MicroMaxx ultrasound following standard methods by a physician trained for measurements and for reading ultrasound using the specific software. In brief, while participants were lying on a bed, a linear transductor was placed over the neck to observe and measure IMT.

Anthropometrics

All anthropometric measurements were taken by highly trained and standardized personnel. We assessed weight with a Tanita (model BWB-627-A, 100 g precision) digital scale with participants wearing tight-fitting swimsuits or spandex shorts and no shoes. We used a calibrated, wall-mounted stadiometer (Shorr Productions, Model 17802, 1 mm precision) to measure height. Participants were instructed to remove their shoes and to stand upright with their backs and heels against the wall.[21] We used a Gulick measuring tape to measure waist and hip circumference with participants clothed in a lightweight hospital gown. We obtained waist measurements at two points, the midpoint between the sternum and the umbilicus and the iliac crest, following procedures from Lohman.[25] We measured the hip at the largest point of the buttocks. We used the mean of two waist and hip measurements taken at each site.

Questionnaires

We measured energy expenditure with accelerometers (Actigraph GT3X) and the self-reported International Physical Activity Questionnaire (IPAQ) short form.[26] The subjects were asked to wear the Actigraph for five days of one week at waist level at the right anterior axillary in a nylon pouch attached to a belt. The IPAQ short version consists of nine items on time spent in four domains, including leisure time activities, domestic and gardening (yard) activities, work-related activities, and transport-related activities.

Highly trained interviewers administered three 24-hour dietary recalls (two on weekdays and one on a weekend day, all randomly selected). The recall included a complete audit of foods and beverages that the participant had consumed during the previous 24 hours, and specific probes for all beverages included measurement cups for a better estimation of liquid intake. For each type of food and beverage reported, we noted the amount consumed, portion sizes, preparation methods, and recipes. The elapsed time between the first and second interviews was no more than 14 days. We estimated daily energy intake using the food composition tables compiled by the INSP, the US Department of Agriculture, and the FNDD.[27,28] Intake was expressed as the average of the three questionnaires.

Treatment adherence measures

We registered the attendance at individual and group meetings and telephone calls. We kept a rigorous record of biweekly water deliveries to ensure that participants were receiving the appropriate amount of water. Finally, we measured the change in water and SSB consumption through prospective reports of all liquid consumption in one day in addition to the 24-hour recalls described above. Study participants filled out a seven-day fluid intake diary (fluid diary) during the same week that the 24-hour recalls took place. The fluid diary is a self-administered instrument designed specifically to register all fluid a space to register beverage consumption at different mealtimes, type of beverage, amount consumed (in both milliliter [ml] and portion sizes), and brand (for commercial beverages). To increase the accuracy of the reported portion size, interviewers went over the reported intake with the subjects every visit using standard measurement cups. Details of the diary methodology and results of comparisons of reported fluid intake with a prospective method (diary) with 24-hour recalls is described elsewhere.[*] Briefly, we found no significant difference in the estimated total median volume of fluid intake between dietary methods. In addition there were highly significant intake, showing a stronger correlation when reporting water and SSB intake.

Data safety

Study participants were assigned a unique identification number, and only the main investigator has access to the subject identification list. For all analysis and data management the identification number is used to ensure subjects' confidentiality.

Sample size justification

We designed the study to test the impact of replacing SSB with water in several outcomes, but mainly triglyceride levels (−31 ± 58 mg/dl) and weight loss (−1.8 ± 3.4 kg).[29] We estimated the need to recruit 120 women per group considering two-sided tests, with 90% power, and alpha 0.05, and we allowed for over 75% attrition.

Statistical analysis

The detailed description of the statistical approach for the main outcomes is described elsewhere.[‡] Briefly, we used intention-to-treat analysis for main outcomes, with the previous confirmation that randomization distributed equally potential confounders among groups. For the present analysis we contrast demographic and baseline data to evaluate comparability after randomization using two-sided *p*-values with a *t*-test for continuous variables and a chi 2 test for categorical variables.

Results

Of the 1 756 women who responded to the study invitation, 1 488 were not considered potential participants, because they either did not meet the initial telephone screening BMI and age criteria (n = 1 217) or did not meet the diet criteria (n = 217). We collected dietary data on 539 women, and 54 did not complete the three 24-hour recalls, resulting in 485 women in the present analysis (Figure 1). Of these, 217 did not meet the SSB consumption criterion (≥250 kcal/day). The 268 women who did meet this criterion were randomly assigned to either the WEP or the EP group. Twenty-eight women were not interested in participating after assignment, thus the final sample size was 120 per group. For the purpose of this analysis we considered the women of both groups who did not fulfill the diet criteria (n= 217) and who were not interested in participating after assignment (n= 28) as not receiving the allocated intervention.

[*]Hernández-Cordero S, Olmedo N, Rodríguez S, Barquera S, Rivera-Dommarco J, Popkin B. Comparing a 7-days diary vs. 24 hr-recall for estimating fluid consumption in Mexican women. Nutrition Journal. Under review.
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Comparison of participants and nonparticipants

There were no differences among the women in age, parity, marital status, education, and occupation. As for BMI and dietary intake, as expected, participating women had slightly higher BMI and energy intake than women not included in the intervention (31.2 ± 3.7 vs. 30.5 ± 3.8, p = 0.050; and 2 032 ± 530 kcal/day vs. 1 670 ± 452 kcal/day, $p < 0.001$, respectively). The same trend was seen for SSB consumption, where participating women consumed more energy from SSBs in ml/d and in percentage of calories (Table III). Participating women were on average 33 years old, 26% were nulliparous, and 61% were married or living with someone at the time of the study. Baseline SSB intake was 406 ± 143 kcal/day, representing 21% of total energy intake (Table III). There were no statistical or biologically relevant differences in any baseline demographic or biological characteristics or in dietary intake between the groups (Table IV).

Challenges encountered and management

Recruitment—The recruitment was planned for 12 months. However, it took 19 months to screen 1 756 women and recruit participants. First, we found that our selection criteria of plasma triglyceride concentration at > 150 mg/dl and SSB consumption at > 300 kcal/day were too strict, making it difficult to find women fulfilling all selection criteria. Despite previous findings from the National Mexican Health and Nutrition Survey of 2006, which revealed that in Mexico the mean energy intake in adults from SSBs (including carbonated beverages, fruit and vegetable juices with and without added sugar, and milk and milk products with added sugar) was 411 kcal/day, representing 22.3% of the total per capita energy intake,[6] women interested in our study had a lower consumption of SSBs (data not showed in tables). The median intake for screened women was 265 kcal/day of SSBs, excluding calories from milk (176 and 383 kcal/day for percentiles 25 and 75, respectively). Our exclusion of milk calories from SSBs and our different beverage measurement methodologies were important factors for these differences.

Second, we found that 46.6% (n = 482) of screened women had triglyceride levels of > 150 mg/dl, a higher prevalence than that reported in the last national nutrition survey in Mexico, where close to 27.0% of adults had hypertriglyceridemia.[30] However, in our study only 30.0% of those with triglyceride levels of > 150 mg/dl (n = 102) reported SSB consumption of > 300 kcal/day. In addition our triglyceride screening method was based on a simple and quick capillary blood kit (Accutrend Plus, Roche), whereas the national measurement used a sophisticated approach with fasting blood (Triglyceride liquicolor, GPO-PAP method) that we will use in the evaluation of our results. Evidence shows that the concordance to classify subjects according to their triglyceride levels of Accutrend is low compared with the standard laboratory methods.[31] We thus lowered the SSB selection cutoff to > 250 kcal/day in October 2009. Literature suggests that adults consuming > 250 kcal/day of SSBs can realistically reduce consumption anywhere from 100 to 150 kcal/day. Chen *et al*.[32] report that adults participating in a behavioral intervention trial reduced their SSB intake from 310 ± 354 kcal/day at baseline to 140 ± 298 kcal/day after six months of intervention. A reduction of 100–150 kcal/day would result in a total reduction in calories of 700–1,050 kcal/week. Evidence shows that, with a constant total energy intake, adding the equivalent of 350 ml of SSBs per week or per day can result in a weight gain of 4.7 kg or 12.0 kg, respectively, in a year.[10] We eliminated triglyceride levels as a selection criterion in February 2010, and the recruitment rate dramatically improved. With these new criteria, our recruitment rate became constant.

In addition the A H1N1 flu epidemic began during early recruitment, and the recommendation was to stay at home most of the time. The highest magnitude of the epidemic was in April October 2009.[33] Furthermore women had difficultykeeping their appointments at the study clinic due to problems with public transportation (buses), which we solved by providing the cost of a taxi.

Water provision—Water was delivered every two weeks to participants' homes or elsewhere according to individual preferences following pre-established routes and schedules (Monday to Friday, mornings only). In some cases women were not at home when water was delivered, thus delivery was delayed for up to a couple of weeks. We tried to solve this problem by providing extra bottles of water (enough for one extra week) and revisiting the location on a different day of the same week. However, given that most participants worked outside their homes, we needed to program the deliveries according to their availability. Thus by the beginning of 2011 we worked with one driver delivering exclusively to the study participants to schedule the deliveries according to each participant's availability.

Group meetings—The main challenge encountered was low attendance at meetings. The main reasons were 1) women reported that sessions were too long, 2) women lacked interest in some group sessions, and 3) some sessions required that women achieve some goals perceived as difficult (i.e. creating healthy scheduling of meals). Staff members identified those obstacles in time and made the following small but significant session attendance: 1) reduced the time assigned to anthropometric measurements at the beginning of the session; 2) slightly modified activities to arouse women's interest; and 3) emphasized that some goals may take a little bit more time and effort.

Discussion

The aim of this paper is to describe the methodology of a water intervention randomized controlled trial. To our knowledge this is the first randomized trial assessing the replacement of SSBs with water and its effect on health in the Mexican population. The Choose Healthy Options Consciously Everyday (CHOICE) trial was conducted in the United States during the same period.[34] CHOICE was a three-arm intervention that examined the effect on weight and risk of metabolic syndrome of replacing SSB intake with either water or nonnutritive-sweetened beverages. In addition, CHOICE provided only a six-month intervention compared to our nine-month intervention, in which we expected to see greater effects over a longer period.

Other researchers have examined reduction of SSB intake in adolescents[5,35] or have examined the effects of drinking water on weight loss as part of a secondary data analysis.[29,36]

In the present study women receiving the intervention had similar characteristics except in dietary intake and BMI as those not receiving the intervention. This was expected, given the selection criteria and recruitment strategy. The intervention groups did not differ at baseline in either the demographic or the main outcome variables, demonstrating an effective randomization of treatments.

This study was originally aimed at women 18 to 45 years old with BMI ≥ 25, SSB consumption > 300 kcal/day, and hypertriglyceridemia (triglycerides > 150 mg/dl). We did not anticipate difficulty recruiting participants based on the combination of selection criteria. Almost 60% of screened women had SSB consumptions below our original criteria. It is possible that our screening methodology for energy intake (24-hour recall) underestimated energy intake from SSBs; however, a validation study we conducted suggests that the screener survey worked well.[*] We did not take into account calories from milk, which might have lowered the energy intake from beverages. Eliminating triglyceride levels as selection criteria and lowering the required SSB consumption allowed us to successfully recruit enough women without affecting our outcomes. This kind of adjustment is not uncommon in clinical trials, where modification of procedures (i.e., inclusion/exclusion criteria) during the conduct of the trial occur without undermining the validity and integrity of the trial.[37] These modifications only expanded criteria slightly to ensure that we obtained the full sample needed and did not affect randomization of the treatment.[38] The only potential impact is to make it more difficult to obtain a significant effect on triglycerides and other cardiometabolic outcomes.[39] However, as we mentioned above, women with SSB intake at ≥ 250 kcal/day can reduce their intake by 100–150 kcal/day to achieve weight loss and a decrease in triglyceride levels.

Ideally a clinical trial should have a blinded design. However, in food intervention studies this is not possible.[40] The unblinded design might result in an overestimation of the effect of the intervention if there is an overreport of any outcome measure or change in the promoted behavior. Subjective outcomes are often found to be biased,[41] in contrast with physiological outcomes, where this bias does not exist. To reduce the potential bias in collection of dietary information, all participants were treated identically in interviews. Another potential bias may be performance bias resulting from a systematic difference in the follow-up of the groups.[42] To reduce this bias all participants were treated according to a strict protocol. Finally, there is a greater chance of attrition bias. In our study the EP group had a lower retention rate. The potential effect of a low retention rate is selection bias, which we will minimize using intention-to-treat analysis in our main analysis.[42]

This trial was assessing changes over nine months, and women received water. More long-term trials and those in more realistic situations are needed to see if changes can be sustained. We encountered a few logistical issues, namely, in recruitment, beverage delivery, and participants' time commitment to the study. We solved these issues by assessing a large number of potential participants and devising effective strategies to provide water and to decrease the time participants invested. This trial allows us to determine

[*]Hernández-Cordero S, Olmedo N, Rodríguez S, Barquera S, Rivera-Dommarco J, Popkin B. Comparing a 7-days diary vs. 24 hr-recall for estimating fluid consumption in Mexican women. Nutritional Journal. Under review.

whether replacing SSB consumption with water promotes a decrease in triglyceride levels and other cardiometabolic indicators over nine months in overweight women.

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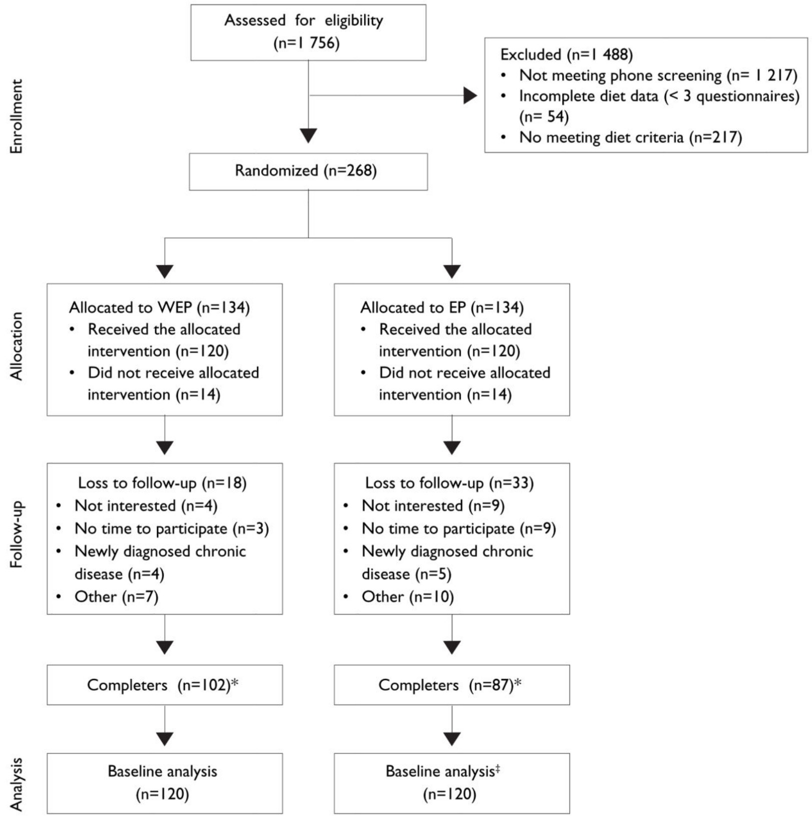

Figure 1. Flow of participants through the trial

*Based on attendance at last appointment

‡All subjects, except one of the EP group, had waist circumference measurement, thus comparison between groups for that measurement was done in 119 subjects in the EP group

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Table I

Final inclusion and exclusion criteria and major features of the intervention groups. Cuernavaca, Morelos, Mexico, April 2009–November 2010

	Inclusion	Exclusion
Criteria	Women aged 18 – < 45 years	Reported weight loss > 5% of current body weight in the previous 6 months
	BMI ≥ 25 to < 39	Reported participation in a diet to reduce weight at the time of recruitment
	≥ 250 kcal/day from SSBs*	Confirmed pregnancy at the time of the recruitment, reported pregnancy during the previous 6 months, lactating at the time of the recruitment, or reported plans to become pregnant in the following 12 months
	Women planning to live in the study area over the next year	Reported treatment for any medical condition that could impact metabolic function (e.g., diabetes, cancer) at the time of recruitment
	Willingness to participate in the required evaluations	History of myocardial infarction or heart surgery, such as bypass or angioplasty
		Reported use of medication that could affect metabolism or energy intake or change body weight (e.g., hypothyroidism medications)
		Reported regime to increase muscle mass or taking anabolics at the time of recruitment
		Excessive consumption of alcoholic beverages, defined as 21 or more drinks‡ per week
Goal	WEP Increase water intake and reduce intake of sweetened caloric beverages to achieve a substitution of water for sweetened caloric beverages Give general recommendations on healthy eating behaviors (reducing sodium intake, healthy fat content in the diet [type of fat]), healthy meal scheduling, and including vegetables in preparations	EP No change in the intake of caloric beverages or diet attributable to the intervention Give general recommendations on healthy eating behaviors (reducing sodium intake, healthy fat content in the diet [type of fat]), healthy meal scheduling, and including vegetables in preparations
Intervention	WEP Biweekly deliveries of water at home with an extra provision added for family sharing Participate in individual counseling meetings and group meetings targeted to rationale and strategies for replacing caloric beverages with water to promote weight loss and general healthy eating behaviors	EP No water delivery Participate in individualized counseling meetings and group meetings targeted to rationale and strategies for healthy eating behaviors
Contact schedule	WEP 5 individual bimonthly meetings (including baseline measurements) 4 group bimonthly meetings Biweekly phone calls	EP 5 individual bimonthly meetings (including baseline measurements) 4 group bimonthly meetings Biweekly phone calls

* SSBs include soft drinks; juices; sugar-sweetened traditional beverages, such as lemonade, hibiscus water, and rice water (*aguas frescas*); sports drinks; sweetened tea or coffee; and alcoholic beverages

‡ One drink defined as 12.0 ounces of regular beer or wine cooler, 8.0 ounces of malt liquor, 5.0 ounces of wine, 1.5 ounces of 80-proof distilled spirits or liquor (gin, rum, vodka, whiskey)[14,15]

Table II

Data collection and timing during follow-up of participating women. Cuernavaca, Morelos, Mexico, April 2009–November 2010

Measures	Baseline	Months of follow-up		
		3	6	9
Physiological measures				
Blood tests: triglycerides, fasting glucose, total cholesterol, HDL, LDL, HbA1c,* and serum osmolality*	X	X	X	X
Urine test: urine osmolality*	X			X
Body fat: air displacement plethysmography	X			X
Blood pressure‡	X	X	X	X
Carotid IMT	X			X
Physical activity (accelerometer)	X	X	X	X
Anthropometrics				
Height	X			
Weight	X	X	X	X
Waist and hip circumferences	X	X	X	X
Questionnaires				
Demographics, weight, and smoking history	X			
Physical activity recall (IPAQ)	X	X	X	X
24-hour dietary recall and beverage intake diary (2 weekdays and 1 weekend day)	X	X	X	X
Beverage intake diary (1-week record)	X	X	X	X
Attendance at individual and group meetings, drugs intake and adverse events‡	X	X	X	X
Water delivery§	X	X	X	X

*Measured at baseline and 9 months only

‡Measured every month

§Measured every two weeks either at individual or group sessions or via telephone call

Table III

Comparison of selected characteristics of women receiving and not receiving the intervention (n= 485). Cuernavaca, Morelos, Mexico, April 2009–November 2010

	Receiving the allocated intervention (n = 240)		Not receiving the allocated intervention (n = 245)*		p-value‡
Age, years [Mean (SD)]	33.3	(6.7)	33.5	(7.1)	0.700
BMI, kg/m^2 [Mean (SD)]	31.2	(3.7)	30.5	(3.8)	0.050
Nulliparous, N (%)	63	(26.2)	67	(27.3)	0.400
Marital status, N (%)					
Married/living with someone	147	(61.2)	150	(61.2)	0.500
Not married	93	(38.8)	95	(38.8)	
Education, N (%)					
Incomplete middle school or less	10	(4.2)	9	(3.7)	0.090
Complete middle and high school	108	(45.0)	86	(35.1)	
Technician	35	(14.6)	52	(21.2)	
Professional or more	87	(36.2)	98	(40.0)	
Occupation, N (%)					
Professional, administrator, executive	32	(13.3)	49	(20.0)	0.200
Clerical work, administrative support, sales, technician	98	(40.9)	81	(33.1)	
Crafts, trade, factory work, service, labor	20	(8.3)	23	(9.4)	
Unemployed, retired, student, other	90	(37.5)	92	(37.6)	
Dietary intake					
Total energy intake kcal/day [Mean (SD)]	2 031.6	(529.6)	1 670.4	(452.1)	< 0.001
Beverages with sugar§					
Kcal/day [Mean (SD)]	406.2	(142.9)	200.6	(121.3)	< 0.001
Ml/day [Mean (SD)]	1 107.4	(404.9)	597.8	(348.5)	< 0.001
Percentage of calories from beverages with sugar [Mean (SD)]	20.7	(7.3)	12.2	(7.3)	< 0.001

	Receiving the allocated intervention (n = 240)		Not receiving the allocated intervention (n = 245)*		p-value‡
Water consumption, ml [Mean (SD)]	780.2	(611.7)	972.3	(611.8)	< 0.001

*Includes women not fulfilling the SSB consumption criteria (> 250 kcal/day from SSBs; n= 271) and those who fulfilled the SSB consumption criteria and were allocated to one of the intervention groups but declined to participate in the study (n= 28)

‡Differences between groups

§Includes beverages with sugar (processed juices, soft drinks, *atole* [beverage with sugar, without milk], fruit beverages with sugar, coffee or tea with sugar); fruit juices (natural fruit and vegetable juices without sugar added); and milk and milk products with added sugar (sweetened milk, yogurt and fermented beverages, *atole* with milk and sugar, milk with chocolate, milkshakes, coffee or tea with milk and sugar added)

Table IV

Baseline demographics and main outcomes by intervention group (n= 240). Cuernavaca, Morelos, Mexico, April 2009–November 2010

	WEP (n = 120)		EP (n = 120)		p-value for differences between groups[1]
Age, years [Mean (SD)]	33.5	(6.7)	33.1	(6.8)	0.6
Nulliparous, N (%)	36	(30.0)	27	(22.5)	0.2
Marital status, N (%)					
Married/living with someone	69	(57.8)	78	(65.0)	0.3
Not married	51	(42.5)	42	(35.0)	
Education, N (%)					
Incomplete middle school or less	4	(3.3)	6	(5.1)	0.2
Complete middle and high school	47	(39.2)	61	(50.8)	
Technician	19	(15.8)	16	(13.3)	
Professional or more	50	(41.7)	37	(30.8)	
Occupation, N (%)					
Professional, administrator, executive	17	(14.2)	15	(12.4)	0.2
Clerical work, administrative support, sales, technician	42	(35.0)	56	(46.7)	
Crafts, trade, factory work, service, labor	9	(7.5)	11	(9.2)	
Unemployed, retired, student, other	52	(43.3)	38	(31.7)	
Weight, kg [Mean (SD)]	76.9	(9.5)	76.0	(11.4)	0.5
BMI, kg/m^2 [Mean (SD)]	31.1	(3.7)	31.2	(3.8)	0.9
Body fat, % [Mean (SD)]	42.5	(5.1)	42.2	(5.2)	0.7
Waist circumference, cm^2 [Mean (SD)]	98.3	(9.2)	98.5	(9.9)	0.8
Hip circumference, cm [Mean (SD)]	111.2	(8.0)	111.1	(8.2)	0.9
Systolic blood pressure, mmHg [Mean (SD)]	100.0	(10.2)	102.0	(9.8)	0.1

	WEP (n = 120)		EP (n = 120)		p-value for differences between groups[1]
Diastolic blood pressure, mmHg [Mean (SD)]	68.3	(8.7)	70.0	(8.0)	0.1
Energy intake, kcal/day Mean SD	2 013	(525.0)	2 020	(536.0)	0.6
Beverages with sugar [Mean (SD)]					
ml/day	1 127	(399.0)	1 088	(412.0)	0.4
kcal/day	406	(155.0)	407	(155.0)	0.9
% of calories	20.9	(7.3)	20.4	(7.2)	0.5
Water consumption, ml [Mean (SD)]	737	(559.0)	823	(660.0)	0.3

*Differences between groups

‡For the EP group, n= 119 for waist circumference only