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A randomized clinical trial of home-based exercise combined with a slight caloric restriction on obesity prevention among women

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Abstract

Objective—The study investigated the effectiveness of home-based exercise combined with a slight caloric restriction on weight change during 12 months in non obese women.

Methods—A randomized clinical trial with a factorial design was conducted from 2003 to 2005. Two hundred three middle-aged women (Rio de Janeiro/Brazil), 25–45 years, were randomly assigned to one of two groups: control (CG) and home-based exercise (HB). The HB group received a booklet on aerobic exercise that could be practiced at home (3 times/week - 40 min/session), in low-moderate intensity, during 12 months. Both groups received dietary counseling aimed at a slight energy restriction of 100–300 calories per day.

Results—The HB experienced a greater weight loss in the first 6 months (–1.4 vs. –0.8 kg; $p=0.04$), but after 12 months there was no differences between groups (–1.1 vs. –1.0; $p=0.20$). Of the serum biochemical markers, HDL-cholesterol showed major change, with an increase at month 12 of 18.3 mg/dl in the HB compared to 9.5 in the CG ($p<0.01$).

Conclusion—Home-based exercise promoted greater weight reduction during the first six months after which no further benefits are observed. Continuous favorable changes in HDL-cholesterol after 1 year suggest that home-based exercise promote health benefits.

Introduction

Although small-changes approach has been suggested to be an effective way to curb the obesity epidemic, (Hill, 2009) others have questioned this approach (Swinburn, et al., 2009). Dietary

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Conflict of interest statement

The authors declare that there are no conflicts of interest.

restriction combined with physical activity (PA) may represent an effective strategy to promote weight loss and reduce fat mass (Jakicic and Otto, 2005; Mediano, et al., 2007). In a review article, Hansen et al. (2007) reinforced the role of PA on weight control, although many studies reported that the inclusion of PA in addition to a restriction in energy intake did not appear to facilitate weight loss (Christ, et al., 2004; Miller, et al., 1997). Despite these controversies, PA is considered to be a key part of the therapy for obesity, both for its effects on weight loss, and for the improvements it promotes in metabolic parameters such as insulin sensitivity and lipid profile (Bensimhon, et al., 2006; Votruba, et al., 2000).

Few studies have investigated the role of small amounts of exercise in preventing obesity (Kraus et al., 2001; Slentz et al., 2005). Since weight loss is difficult to maintain, weight gain prevention or prevention of obesity may be a useful strategy. In a 4-yr observational research in the Health Professionals Follow-up Study on predictors of weight change, Coakley et al. (1998) found that a decrease in 1.5 hours per week in physical activity predicted a gain of 0.6 kg, whereas an increase in activity over 1.5 hours per week predicted a weight loss of 0.9 kg. More recently, Williams et al. (2007) evaluated weight control practices and the resulting 2-yr weight changes among middle-aged women and found that only the combination of diet and exercise prevented mean weight gain. The mean weight gain of the cohort in that study was of 1.19 kg over the 2-yr period.

An important aspect of PA on prevention and treatment of obesity is the low adherence to formal programs, limiting the efficacy of these strategies (Rhodes et al., 2009). Many individual are unable to engage in a formal program due to difficulty with transportation, or not having adequate financial resources justifying the counseling of home-based exercise, but few studies compared this approach to traditional ones. Perri et al. (1997) compared the effectiveness of center- versus home-based exercise in a sample of sedentary, middle-aged obese women undergoing behavior weight loss treatment and found a better adherence to exercise in a home-based group after 12 months of follow-up. Krousel-Wood et al. (2008) found a BMI reduction in persons with diabetes, submitted to three months of home-based exercise intervention, with high adherence rates, about 80%. Therefore, home-based exercises could be an option that would improve PA adherence.

The purpose of this study was to investigate the effectiveness of home-based exercise combined with a slight caloric restriction on maintenance of small weight change in non obese women. Secondary outcomes were changes in waist circumference and biochemical markers. We hypothesized that addition of home-based exercise to a slight caloric restriction could facilitate weight loss.

Materials and methods

This randomized clinical study was primarily aimed at small weight loss comparing a low with a high glycemic index diet. Results did not indicate a difference between the low and high glycemic index diets on weight change. The full description and results of dietary intervention have been published elsewhere (Sichieri, et al., 2007). The trial had a factorial design, with half of the dietary intervention receiving also orientation for home-based exercise during 12 months, and the other half only dietary intervention. The study was conducted from October 2003 to March 2005.

In brief, 644 women were screened and 230 were ineligible based on the following criteria: aged between 25 and 45 years with a body mass index (BMI) of 23–29.9 kg/m², not pregnant, not breastfeeding, had at least one child and did not anticipate a pregnancy in the next year. Women with physician-diagnosed thyroid disease or diabetes or who were menopausal were not eligible to participate. Recruitment was conducted in two primary health care centers of

the Rio de Janeiro State University, in Brazil. Randomization regarding a home-based exercise program and the progress of women during the study are shown in figure 1. All participants received information about the goals of the study, which aimed at a small weight loss during the follow-up. The study was approved by the Institutional Review Boards of Harvard School of Public Health and of Rio de Janeiro State University. A sample calculation made before the beginning of the study was based on a BMI difference of 1.2 kg/m^2 , with a standard deviation of 2.5 kg/m^2 , assuming 90% of power and a 5% significance level. The needed total sample size was 148 (Pocock, 1993). Allowing for non-compliance in both groups (Sato, 2000), the estimated sample size was 172, and with further accommodation for 20% of loss to follow-up, the total sample size was estimated to be 206.

Study design

Both groups received dietary counseling based on a slight energy restriction (100–300 kcal per day), with 26–28% of energy as fat (Sichieri, et al., 2007). Women were randomly assigned in a non blinded fashion to diet and to home-based exercise using sequentially numbered opaque sealed envelopes. The randomization list was computer-generated with blocking in advance and dieticians responsible for placing participants on study had no participation in the process of randomization. The intervention group received a booklet on physical exercise that could be practiced at home at least three times per week during 40 minutes per session (available at www.nebin.org). The exercise sessions were divided in three parts: 1) A warm-up routine consisting of gentle body movement and stretching exercises (5 minutes); 2) An aerobic cycle performed in a circuit with continuous movements involving large arm and leg muscles, as well as exercises using a ball, ropes, stair climbing, and standing up from a chair (balls and ropes were given to the participants) (30 minutes); and 3) a cool-down period, in which the same initial stretching exercises were performed (5 minutes). The participants were encouraged to engage in low to moderate exercise intensity with low impact, at least three times a week during 12 months. In the first week, women were advised to perform only a 20-minute session, increasing gradually (10 minutes/session/week) up to 40 minutes per session. Each session comprised activities with balls, ropes, stairs and chair. Additionally, all women were advised that they could reduce the exercising intensity if they felt any discomfort (e.g., if they were experiencing breathlessness or muscle aches). Compliance to the exercise program was assessed once a month during the nutritional counseling sessions. In the week prior to the counseling sessions, participants were asked to mark the days in which they exercised in a card printed with the days of the week, and then to bring the card with them to the appointment in order for us to ascertain whether they had performed the recommended exercises at three non-consecutive days.

Measurements

Weight was measured monthly, while circumferences, body composition, and fasting blood samples were collected at baseline and after 3, 6, and 12 months of follow-up. All measurements were performed in the morning, and blood was collected after the subjects had fasted for 10h. Height was measured to the nearest 0.5cm with a wall-mounted stadiometer, and body weight was measured by using the same calibrated digital scale for all participants. Circumference measures were taken at the largest girth of the hip and smallest girth of the waist. Body composition was assessed by means of a tetrapolar bioelectrical impedance analysis (BIA) using a RJL-101 and the software originally included in the analyzer. Electrodes were placed on the wrist and ankle, as specified by the manufacturer.

Plasma lipids and glucose were measured using GoldAnalisa kits with an intra-assay CV varying from 0.9% to 1.2%, and an inter-assay CV from 1.9% to 2.7%. The LDL and VLDL cholesterol concentrations were calculated according to the Friedewald equation (Friedewald, et al., 1972) based on the triacylglycerol measures. Serum insulin concentration was

determined by radioimmunoassay using an ImmuChem™ 125/RIA kit with an intra-assay CV varying from 4.2% to 8.2%, and an inter-assay CV from 6.4% to 8.8%. Relative insulin resistance [Homeostasis model assessment of insulin resistance (HOMA-IR)] was estimated according to the formula $[(\text{glucose in mmol/L} \times \text{insulin } \mu\text{U/ml})/22.5]$.

Data analysis

Baseline characteristics of the two groups were compared by using either the Student's t-test or the chi-square test. We examined the temporal changes between groups for weight, circumferences, body composition, and blood lipids by performed repeated random regression (RRR) analysis using PROC MIXED in SAS (version 9.1; SAS Institute Inc, Cary, NC). The RRR is an intention-to-treat analysis because it includes all observations of each one of the subjects regardless of loss to follow-up or compliance. Analysis of weight and waist included BMI at baseline as a covariate, while for blood lipids, the baseline measures were included. Because of the nonlinear weight change observed, the model incorporated a quadratic term (time $\times$ time) variable. The term of interest was treatment $\times$ time interaction, which estimates the rate of changes in the outcomes. Residual plots of all models were examined and their distribution did not show major deviations from regression assumptions.

Changes between the groups for glucose, insulin and HOMA-IR, which were taken twice, were determined by Student's t-test. Statistical significance was set at $p < 0.05$ for all analyses.

Results

Baseline characteristics of the women randomly assigned to the two groups are shown in table 1. Most of the baseline characteristics showed no difference between the groups, but age showed a small difference and BMI and HDL cholesterol showed statistically significant difference ($p < 0.05$). Losses to follow-up during the 1-yr period were 45% for CG and 42% for the HB group (figure 1). No differences between completers and drop-outs were found for any baseline characteristics ($p > 0.20$). The number of women followed up at specific visits, as well as means changes from baseline for anthropometric variables, are shown in table 2. The HB group had a greater weight loss in the first 6 months (-1.4 vs. -0.8 kg; $p = 0.04$), but after 12 months of follow-up the weight change was not significantly different between groups (-1.1 vs. -1.0 ; $p = 0.20$). The same pattern was found for BMI in the first 6 months, without significant differences thereafter. The HB group showed a reduction in waist circumference at the third month (-1.4 compared with -0.6 cm; $p = 0.05$), and there were no significant differences between groups for waist-to-hip ratio and body composition at any time during the follow-up (table 2).

Of the serum biochemical markers analyzed (cholesterol, triglycerides, glucose, HOMA-IR), HDL-cholesterol showed major change during follow-up, with an increase of 18.3 mg/dl in the HB compared to 9.5 in the CG ($p < 0.01$). Except for a reduction in LDL-cholesterol at month 6 in the HB (-15.6 vs. -4.0 mg/dl; $p < 0.01$) in comparison to the CG, none of the other serum markers showed significant differences between groups (tables 3 and 4; $p > 0.20$). The main changes during the 12 months of follow-up are shown in figure 2.

The compliances to the exercise protocol among those in follow-up were: 78.2%, 79.5% and 86.1% for months 3, 6 and 12, respectively, and the HB exercise arm had almost the same percentage of loss to follow-up compared to the non-exercise group.

Weight change at 12 months according to the number of sessions accomplished per week had an average of 0.4 kg (± 1.8), 0.5 kg (± 2.0), and 1.9 (± 3.2) kg for women who exercised once, twice, and at least three times a week, respectively. The changes according to the number of

sessions accomplished per week were not statistically significant and most women completed at least three sessions per week.

Discussion

The major finding of the present study was that a small volume of home-based exercise in addition to a slight caloric restriction promoted a higher reduction in body weight during the first six months in comparison with a caloric restriction only. However, this change was not sustainable during one year of follow up. In addition, the exercise program did correlate with a substantial increase in serum HDL cholesterol levels, even at 12 months, indicating continued compliance and resulting in important health benefits. Also, weight loss was greater among those with higher compliance.

The role of exercise on body weight maintenance is considered important (Foster, 2006; Jequier, 2002), but there is no recommendation based on well designed randomized controlled trial. Redman et al. (2007) compared the effects of a 25% energy deficit by diet alone or diet plus exercise in 35 overweight subjects during 6 months. The authors found no additional effects of physical exercise on body weight, fat mass, and fat-free mass in comparison with diet alone, and concluded that exercise plays a role equivalent to caloric restriction in terms of energy balance.

On the other hand, in a randomized controlled trial, McTierman et al. (2007) studied the effects of 300 minutes (high volume) of moderately vigorous exercise without dietary intervention on prevention of weight gain during 12 months of follow up. Women lost 1.4+1.8 kg compared to an increase of 0.7+0.9 kg in controls and men lost 1.8 +1.9 kg compared to an increase of 0.1+0.1 in controls. It is important to highlight that our study had a small caloric restriction in both groups allowing examining the effects of a smaller amount of exercise that could be recommended in clinical practice.

A meta-analysis by Curioni and Lourenço (2005) compared six randomized clinical trials (n = 265) with follow-up ranging from 10 to 52 weeks, and found a 20% greater weight loss in diet-plus-exercise groups, as well as a 20% greater sustained weight loss after 1 yr, when compared with the diet-only groups. Another recent meta-analysis (Shaw, et al., 2006) found a small yet significant decrease of 1kg in body weight in the diet-plus-exercise group when compared to the diet-only group. In addition, Bond Brill et al. (2002) studied the effects of walking in combination with a low-fat diet on weight loss and other health-related variables in 88 overweight women and, in accordance with our finding, a relatively small amount of exercise (30 min/d) during eight months of follow-up reversed the weight gain experienced in the control group.

The effects of different amounts of exercise training on body weight was evaluated by Slentz et al. (2004) in 120 overweight dyslipidemic subjects during eight months, with no changes in diet. They found that a modest amount of exercise (30 min/d) during the follow-up was positively associated with weight maintenance and improved the adherence to exercise programs. Poor adherence to a given exercise protocol may be one of the main reasons why randomized controlled trials often fail to find an association between physical activity and weight loss, especially in obese individuals. The prescribed amount of exercise may have paramount importance on exercise adherence, with more demanding exercise programs associated with poorer adherence (Fogelholm and Kukkonen-Harjula, 2000). The compliance to the exercise protocol in the present study was high at all times, and the HB exercise arm had almost the same percentage of loss to follow-up compared to the non-exercise group.

As reported in many other studies, maintenance of the weight loss after 6 months is difficult to sustain, and a substantial proportion of the patients will eventually revert to their original

body weight (Jeffery, et al., 2000; Wing and Hill, 2001). Although the results regarding the role of PA on prevention of weight regain are still considered controversial, its application has become a part of the strategies for weight maintenance following weight loss programs (Haskell, et al., 2007; Saris, et al., 2003; Wu, et al., 2009), and officially endorsed by the American College of Sports Medicine (Donnelly, et al., 2009). This institution states the need for a greater amount of physical activity, reaching 250 to 300 min per week of moderate-intensity PA, in order to help prevent weight regain. Our study suggest that a small volume of PA, about 120 min per week, may be a good start for increasing in PA and it also suggest that after 6 months this volume should be increased to maintain long-term weight losses.

We did not find any major differences between the groups for measures of central obesity, except at the third month, when the HB group showed a greater reduction in waist circumference. Mourier et al. (1997) studied 24 overweight and obese subjects and showed that, although the exercise group showed major reduction of abdominal fat as evaluated by magnetic resonance, no differences were found for waist circumference and waist-to-hip ratio in comparison with non-exercisers. Thus, more accurate methods to determine small changes in abdominal fat would be necessary. In addition, no differences between the groups were found for fat-mass percentage during the follow-up and bio-impedance is not also a golden measure of fatness (Dehghan and Merchant, 2008; Pateyjohns et al., 2006).

Numerous studies have documented that PA has favorable effects on metabolic parameters such as lipid profile and insulin sensitivity (Kraus, et al., 2002; Tuomilehto, et al., 2001; Warburton, et al., 2006). For the metabolic parameters analyzed in our study, the most striking difference between the groups was for HDL-cholesterol, with a two-fold elevation for the HB in comparison with controls after 1 year of follow-up. These results have been extensively described (Donnelly, et al., 2000; Durstine, et al., 2001; Leon and Sanchez, 2001) among obese and hypercholesterolemic subjects, and our findings confirmed this association for middle-aged non-obese and non-hypercholesterolemic women, an important finding since high HDL cholesterol is one of the few protective factors for cardiovascular disease (Alwaili, 2010; Singh et al., 2007).

Although many studies have shown beneficial effects of PA on insulin sensitivity, (Holloszy, 2005; Matthaei, et al., 2000; Tuomilehto, et al., 2001) others which evaluated the combined effects of PA and diet in comparison with diet-only showed no differences in the results (Larson-Meyer, et al., 2006; Weinstock, et al., 1998). Our results suggest no significant additional effects of PA on insulin sensitivity evaluated by HOMA-IR. However, most women evaluated in the present study were not insulin resistant at baseline, according to the Brazilian criteria for insulin resistance (Geloneze, et al., 2006), which may explain the lack of a difference between the groups.

Limitations of the present studies include: 1) We have not used a golden standard measure of PA but self reported diary shows good correlation with other methods such as accelerometers and double labeled water (Besson, et al., 2010; Meriwether, et al., 2006). In addition, we did not assess PA in control group during the intervention, but a lack of major changes for metabolic parameters in this group, mainly for HDL cholesterol, may confirm no changes in PA status; 2) adiposity was measured by BIA, which is a measurement with many limitations (Dehghan and Merchant, 2008); 3) subjects were only females and not obese, therefore we may not extrapolate the results to obese and males individuals. These measurements error appears to be non differential and would change findings towards the null hypothesis.

In conclusion, a home-based exercise program was feasible and promoted greater weight reduction in the first 6 months, after which no further weight reduction was observed. Favorable changes in HDL-cholesterol after 1 year suggest that home-based exercise is a good strategy

to initiate and increase physical activity and promote health benefits. Whether modifying training modalities after 6 months would increase these clinical benefits could be an important topic for future research.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
Progress of participants through the trial (Rio de Janeiro/Brazil, 2003–2005).
LGI - Low glycemic index; HGI - High glycemic index

Figure 2.
Estimated changes in weight, waist circumference and HDL-cholesterol based on repeated measurement analysis (Rio de Janeiro/Brazil, 2003–2005).
HB group – home-based exercise group

Table 1

Baseline characteristics of participants (Rio de Janeiro/Brazil, 2003–2005).

Variable	Control (n=101)	Intervention (n=102)	<i>p</i> -value ^a
Age (years)	38.1 (5.5)	36.6 (5.4)	0.06
Body weight (kg)	67.6 (7.5)	68.6 (6.6)	0.31
Height (m)	1.61 (0.06)	1.60 (0.06)	0.62
Waist circumference (cm)	81.1 (5.5)	81.6 (5.2)	0.50
Hip circumference (cm)	104.2 (6.0)	104.1 (5.4)	0.87
Body mass index (kg/m ²)	26.2 (1.95)	26.8 (1.8)	0.03
Waist-to-hip ratio	0.78 (0.05)	0.79 (0.06)	0.44
Total cholesterol (mg/dl)	191.7 (35.3)	191.3 (36.6)	0.93
HDL cholesterol (mg/dl)	45.4 (17.5)	40.9 (13.1)	0.04
LDL cholesterol (mg/dl)	128.7 (34.1)	132.2 (35.8)	0.47
VLDL cholesterol (mg/dl)	17.7 (7.4)	18.1 (10.5)	0.72
Triacylglycerol (mg/dl)	88.3 (37.1)	89.7 (52.0)	0.83
Glucose (mg/dl)	84.6 (11.7)	87.5 (17.2)	0.17
Insulin (μU/ml)	11.3 (3.8)	12.1 (4.8)	0.24
HOMA -IR	2.37 (0.92)	2.59 (1.11)	0.15
Race (%)			
White	57.4	46.9	0.23
Mulato	28.7	31.2	
Black	13.9	21.9	
Schooling (%)			
< 8 years	28.0	22.3	0.64
8 – 12 years	46.0	47.9	
≥ 12 years	26.0	29.8	

^aStudent's and chi-square test.

Data are expressed as means (standard deviation) and prevalence of frequency.

HOMA-IR: Homeostasis model assessment of insulin resistance

Crude means (standard deviation) and changes from baseline (Δ) for anthropometric characteristics and fat mass (%) during the follow-up by physical activity groups (Rio de Janeiro/Brazil, 2003–2005).

Table 2

	3 months (Control=56 Intervention=60)			6 months (Control=48 Intervention=56)			12 months (Control=55 Intervention=59)		
	Mean(sd)	Δ^a	p^a	Mean(sd)	Δ^a	p^a	Mean(sd)	Δ^a	p^a
Body Weight (kg)									
Control	67.2 (8.7)	-0.5		66.6 (7.5)	-0.8		65.7 (7.1)	-1.0	
Intervention	67.3 (5.9)	-0.9	0.08	67.6 (7.6)	-1.4	0.04	68.0 (6.6)	-1.1	0.20
Body Mass Index (kg/m²)									
Control	26.0 (2.1)	-0.2		25.9 (2.0)	-0.3		25.6 (2.0)	-0.4	
Intervention	26.3 (2.1)	-0.4	0.06	26.2 (2.0)	-0.6	0.03	26.1 (2.1)	-0.4	0.21
Waist Circumference (cm)									
Control	81.1 (6.2)	-0.6		80.0 (5.4)	-1.0		78.7 (5.2)	-1.3	
Intervention	80.7 (5.2)	-1.4	0.05	82.2 (5.4)	-1.1	0.94	80.7 (5.8)	-1.2	0.55
Waist – to – hip ratio									
Control	0.79 (0.05)	0.001		0.78 (0.05)	0.002		0.77(0.04)	0.0004	
Intervention	0.79 (0.05)	-0.005	0.09	0.80 (0.06)	-0.002	0.55	0.78(0.06)	-0.005	0.70
Fat mass (%)									
Control	31.3 (4.6)	-0.4		29.9 (5.33)	-1.9		29.9 (5.00)	-2.9	
Intervention	31.4 (5.1)	-0.5	0.71	31.8 (4.83)	-0.8	0.09	31.5 (5.74)	-1.7	0.17

^aModel based on repeated measures include time, treatment and time $\times$ treatment interaction adjusted for BMI at baseline;

Table 3

Crude means (standard deviation) and changes from baseline (Δ) for lipid profile during 3, 6 and 12 months of follow-up by physical activity groups (Rio de Janeiro/Brazil, 2003–2005).

	3 months (Control=62 Intervention=68)			6 months (Control=55 Intervention=63)			12 months (Control=43 Intervention=36)		
	Mean(sd)	Δ^a	p^a	Mean(sd)	Δ^a	p^a	Mean(sd)	Δ^a	p^a
Total Cholesterol (mg/dl)									
Control	193.7 (43.2)	1.2		193.8 (34.7)	-2.0		188.2 (38.6)	-5.4	
Intervention	195.2 (34.1)	1.3	0.90	177.9 (36.3)	-4.8	0.24	199.5 (34.5)	0.3	0.11
HDL-cholesterol (mg/dl)									
Control	45.7 (12.5)	-1.8		49.1 (10.2)	3.4		54.7 (14.0)	9.5	
Intervention	46.1 (9.3)	6.5	0.001	53.5 (13.9)	12.5	0.0006	55.3 (15.4)	18.3	0.01
LDL-cholesterol (mg/dl)									
Control	130.9 (42.2)	3.3		128.6 (34.4)	-4.0		113.4 (36.2)	-15.9	
Intervention	130.6 (33.5)	-4.2	0.08	110.6 (35.2)	-15.6	0.005	123.8 (34.7)	-18.5	0.79
VLDL-cholesterol (mg/dl)									
Control	17.0 (8.6)	-0.2		16.2 (7.1)	-1.1		20.1 (15.9)	1.4	
Intervention	18.5 (10.5)	-1.0	0.65	16.0 (8.0)	-0.4	0.59	20.6 (10.4)	1.4	0.99
Triacylglycerol (mg/dl)									
Control	84.8 (43.0)	-1.4		78.5 (33.0)	-7.6		100.7 (79.3)	6.1	
Intervention	87.3 (50.8)	-9.1	0.17	78.1 (39.3)	-4.3	0.45	99.9 (53.3)	5.5	0.99

^aModel include time, treatment and time×treatment interaction adjusted for baseline values;

Serum fasting glucose, insulin and homeostasis model assessment of insulin resistance (HOMA-IR) by physical activity groups (Rio de Janeiro/Brazil, 2003–2005).

Table 4

	Baseline		3 months		Change from baseline		<i>p</i> ^a
	Control (n=99)	Intervention (n=101)	Control (n=68)	Intervention (n=67)	Control (n=67)	Intervention (n=66)	
Glucose (mg/dl)	84.6 (11.7)	87.5 (17.2)	83.8 (9.7)	84.4 (14.7)	-0.6 (14.7)	-5.5 (17.7)	0.09
Insulin (μU/ml)	11.3 (3.8)	12.1 (4.8)	11.6 (3.5)	12.2 (4.5)	-0.1 (4.6)	0.4 (3.5)	0.54
HOMA-IR	2.37 (0.92)	2.59 (1.11)	2.40 (0.89)	2.53(1.08)	-0.04(1.21)	-0.05(0.88)	0.93

^aStudent's t test;

Data are expressed as means (standard deviation).