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On behalf of the Japanese-Brazilian Diabetes Study Group*

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Abstract

We investigated the impact of lifestyle goal achievement on cardiovascular risk factors after a 2-year behavioral intervention program applied to 394 adults (113 with diabetes, mean age 60.2 ± 11.4 years, 56% women) and targeting four goals: ≥5% weight loss; ≥150 min/week physical activities; <10% saturated fat intake/day; ≥400 g fruit and vegetable intake/day. Baseline characteristics and changes in variables after intervention among the four categories of number of goals achieved (none, 1, 2, and ≥3) were compared by independent ANOVA or the Kruskal-Wallis test. Individuals without diabetes achieving a higher number of goals were more likely to be older (3 or 4 goals: 61.8 ± 12.6 years *vs* none: 53.3 ± 10.3 years, $P < 0.05$) and to have a lower mean BMI (3 or 4 goals: 21.7 ± 2.6 kg/m^2 *vs* none: 29.0 ± 4.8 kg/m^2, $P < 0.05$), diastolic blood pressure (3 or 4 goals: 77.3 ± 2.1 mmHg *vs* none: 85.4 ± 9.6 mmHg, $P < 0.05$), triglyceride (3 or 4 goals: 116.1 ± 95.1 mg/dL *vs* none: 144.8 ± 65.5 mg/dL, $P < 0.05$) and insulin levels (3 or 4 goals: 3.6 ± 2.4 µU/L *vs* none: 5.7 ± 4.0 µU/L, $P < 0.05$) than those achieving fewer goals. The absolute changes in cardiovascular risk factors tended to be more pronounced with increasing number of goals achieved in individuals without diabetes. The intervention had a beneficial impact on the cardiometabolic profile of individuals with normal or altered glucose metabolism. The number of goals achieved in this lifestyle intervention was associated with the magnitude of improvement of cardiovascular risk factors in individuals without diabetes. Participants with a better cardiometabolic profile seemed to be more likely to have a healthy lifestyle.

Key words: Behavioral intervention; Lifestyle; Goals; Glucose metabolism disturbance; Cardiovascular risk factor

Introduction

The effectiveness of behavioral intervention in preventing or at least postponing diabetes in individuals with impaired glucose tolerance has been demonstrated in randomized controlled trials (1-3). The behaviors targeted in these trials included reduction of saturated fat intake, increase in fiber intake, body weight control, and physical activity. Recently, the Finnish Diabetes Prevention Study (DPS) showed that these lifestyle modifications have beneficial effects on the components of metabolic syndrome (4). However, it is unknown if these interventions have a similar impact on unselected groups consisting of individuals with high risk for diabetes and also of individuals with normal glucose tolerance.

In a population-based study conducted in the UK, Simmons et al. (5) showed that the risk of diabetes was inversely associated with the number of behavioral goals for diabetes prevention that were achieved. The achievement of goals varies among populations and may be dependent on their

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level of development and particular habits. It is possible that the goals should be culturally tailored in order to maximize the response to behavioral interventions.

A population-based study on Japanese-Brazilians started in 1993 showed that this population has one of the highest prevalence rates of type 2 diabetes detected worldwide (6). The high frequencies of related diseases reinforced their high cardiovascular risk (7). The Japanese-Brazilian Diabetes Study (JBDS) Group found that fat intake was positively associated with metabolic syndrome in Japanese-Brazilians in cross-sectional and longitudinal studies (8,9). Based on these findings, in 2005 we conducted a community-based lifestyle intervention, using appropriate resources for our reality (a program that could be reproduced in our public health system), in order to improve the metabolic profile of this population. Weight loss, modifications of the consumption of saturated fat and vegetables and increase in physical activity were the goals of this study.

Since type 2 diabetes is becoming an alarming problem particularly in developing countries (10), intervention studies on these populations are of particular interest (11). The ability of goals based on dietary and physical activity parameters to improve the cardiometabolic profile, using resources feasible for the developing world, has been poorly investigated.

The aim of the present study was to determine the effect of a behavioral intervention considering whether the number of goals achieved in a lifestyle intervention is indicative of metabolic improvement in the profile of a population at high cardiovascular risk.

Material and Methods

Material

First- (Japan-born) and second-generation (Brazil-born) Japanese-Brazilians, participants in the Study on Diabetes and Associated Diseases in the Japanese-Brazilian Population conducted in 2000 (6), in the city of Bauru (IDH-M 0.825; Source: IPEADATA: www.ipeadata.com.br), State of São Paulo, Brazil, were the target of a 2-year lifestyle intervention, which began in 2005. Invitation letters and telephone contacts, explaining the aims and potential benefits of the behavioral modification program, were sent. Of a total of 728 individuals who agreed to participate, 394 (113 with diabetes in 2005) were also evaluated in 2007 and were enrolled in this study.

The demographic and clinical characteristics of the participants in 2005 who were lost to follow-up by 2007 were similar to those of the individuals who completed the intervention period (data not shown).

The Ethics Committee of the Universidade Federal de São Paulo approved the study protocol and written informed consent was obtained from all participants.

Study protocol

For this community intervention to promote healthy eating behaviors and increase physical activity, all individuals who agreed to participate in the intervention were scheduled for laboratory procedures and visits with the multiprofessional team in the nutritional clinics of the Universidade do Sagrado Coração, in the city of Bauru (State of São Paulo, Brazil). At baseline and after two years of the intervention program, fasting blood samples (and also an oral 75-g glucose tolerance test) were obtained for the determination of biochemical and hormonal parameters. Individuals underwent a detailed medical examination and the International Physical Activity Questionnaire was applied. The subjects also reported three 24-h recalls at baseline and after 2 years of intervention. At the first visit, they were scheduled for further individual and group sessions with the multiprofessional team.

Intervention

The intervention strategy targeted changes in dietary intake and levels and patterns of physical activity (12,13), and was based on a previous trial conducted among overweight Brazilian adults (14). The major goals of the intervention program included ≥5% weight loss from baseline for individuals with overweight/central obesity, ≥150 min per week of physical activity, intake of ≥400 g/day fruit and vegetables and a diet with <10% total energy from saturated fat. The subjects were scheduled for individualized dietary counseling, 3 group sessions for nutritional and physical activity orientation and 2 community events of exercise, including walking, stretching and dancing, during the 2-year intervention program. On the occasion of the individualized visit, the participants had a face-to-face 1-h consultation with a nutritionist, when they received a diet prescription with a food exchange list and were encouraged to practice at least 30 min of physical activity every day. Group sessions included 10 participants and were coordinated by nutritionists and physical educators. The relatives of all participants were also invited to take part in the group sessions. During these sessions, professionals reinforced the importance of a healthy lifestyle and discussed the barriers to reaching the goals of the intervention program.

The dietary recommendation consisted of changes in total energy intake according to individual nutritional status. The proportions of macronutrients in relation to total energy intake were 50-60% carbohydrates, <30% total fat, <10% saturated fat, 10-15% proteins, <300 mg cholesterol, and 15 g vegetable fibers. Moreover, a low calorie diet was prescribed to overweight individuals or those with central obesity (with a restriction of 500 to 1000 calories daily from the estimated total energy expenditure), but not to normal weight individuals.

Clinical and laboratory procedures

Body weight and height were measured using calibrated electronic scales and a fixed rigid stadiometer, respectively, with the participants wearing light clothing and without shoes; body mass index (BMI) was calculated as weight (kg) divided by height squared (m^2). Waist circumference was measured with an inextensible tape, according to the WHO technique (15). Blood pressure was measured three times using an automatic device (Omron model HEM-712C, Omron Health Care, Inc., USA), after a 5-min rest in the sitting position. The mean of the second and third measurements was then calculated.

Fasting blood samples were taken and a 75-g oral glucose tolerance test was performed. The American Diabetes Association criteria were used to diagnose diabetes, impaired fasting glucose and impaired glucose tolerance (16). Samples were immediately centrifuged and analyzed in the local laboratory. Plasma glucose was measured by the gluco-oxidase method and lipoproteins were determined enzymatically with an automatic analyzer. The remaining samples were stored at -80°C prior to hormone and inflammatory marker assays. Insulin was determined by an immunometric assay using a quantitative chemiluminescent kit (Euro DPC Ltd., UK), with analytical sensitivity of 2.0 μIU/mL. The intra-assay coefficient of variation ranged from 5.3 to 6.4% and the inter-assay coefficient of variation from 5.9 to 8.0%. The high sensitivity C-reactive protein was assessed by an immunometric assay using a quantitative chemiluminescent kit (DPC, Diagnostic Products Corporation, USA) with an analytical sensitivity of 0.01 mg/dL and a functional sensitivity of less than 0.02 mg/dL; the intra-assay coefficient of variation ranged from 4.2 to 6.4% and the inter-assay coefficient of variation from 4.8 to 10.0%.

The homeostasis model assessment of insulin resistance (HOMA-IR) was calculated (17). The cardiovascular risk score was based on equations derived from the US Framingham cohort study (18).

Achievement of goals

For the purpose of the present study, we used goals similar to those considered in the Finnish Diabetes Prevention Study (DPS) (1) and U.S. Diabetes Prevention Program (DPP) (2), and those recommended by the World Health Organization (WHO; 19) for the prevention of type 2 diabetes mellitus. Individuals were classified according to the achievement of the following goals: ≥5% weight loss from baseline for individuals with overweight/central obesity or maintenance for those with normal weight; ≥150 min per week (30 min, most days of the week) of physical activities; dietary intake with saturated fat corresponding to <10% of total energy; daily intake of ≥400 g of fruits and vegetables, which are considered relevant fiber sources by the WHO (18).

Since the number of individuals who achieved four goals was very small (4 without and 3 with diabetes), and their characteristics were similar to those who achieved three goals, we formed a group consisting of those who achieved three or four goals. Four categories of individuals were created according to the number of goals achieved at the end of the intervention program: none, 1, 2, and 3 or 4 goals.

Statistical analysis

Since exploratory analysis showed that the presence of diabetes influenced outcome variables, for further analyses the subjects were stratified into groups with and without diabetes at baseline. Baseline characteristics are reported as means and standard deviations and were compared by the Student *t*-test.

Analyses were performed according to the number of goals achieved. The percentage of individuals in each category of number of goals achieved (0, 1, 2, and 3 or 4) was determined. The baseline characteristics of the four categories (none, 1, 2, and ≥3 goals achieved) were compared by independent ANOVA or by the Kruskal-Wallis test, complemented with the Tukey test (honestly significant differences). Two-year changes in these variables were calculated independent of goal achievement and for each category of goals achieved.

Sensitivity analyses were conducted regarding the use and/or change of medicines that could interfere with the variables of interest.

Statistical analyses were performed using SPSS 12.0 software (SPSS Inc., UK), with the level of significance set at 5%.

Results

Of the 387 individuals (mean age 60.2 ± 11.4 years) who completed the follow-up, 113 had a diagnosis of diabetes at baseline. Approximately 56% were women and 84% were of second generation.

Diabetic individuals had a worse cardiometabolic profile, including higher mean (± SD) BMI (25.8 ± 3.5 *vs* 24.2 ± 4.0 kg/m^2, P < 0.001), systolic blood pressure (142.4 ± 20.7 *vs* 136.4 ± 22.0 mmHg, P < 0.05), fasting plasma glucose (139.7 ± 48.7 *vs* 99.7 ± 11.1 mg/dL, P < 0.001), HOMA-IR (2.6 ± 4.2 *vs* 1.2 ± 1.0, P < 0.001), triglyceride (202.7 ± 160.6 *vs* 142.9 ± 85.6 mg/dL, P < 0.001), and lower HDL cholesterol values (51.7 ± 11.3 *vs* 54.8 ± 13.0 mg/dL, P < 0.01) than those without diabetes at baseline (data not shown in the table).

The most common type of energy consumed per goal achieved was saturated fat; 74.5% of the subjects (74.2% without and 75.2% with diabetes) consumed less than 10% saturated fat of total energy intake per day. Almost 42% (46.8% without and 29.7% with diabetes) of the individuals reached a ≥5% weight loss compared to baseline. Thirty-nine percent (36.5% without and 48.7% with diabetes) achieved the goal of fruit and vegetable intake (>400 g per day) and only 7.4% (5.2% without and 14.4% with diabetes) reported that they practiced at least 150 min of physical activity per week.

The percent of individuals in each category according to the number of goals was very similar for those without (none = 7.5%, 1 goal = 37.0%, 2 goals = 39.9%, and 3 or 4 goals achieved = 15.7%) and with diabetes (none = 6.2%, 1 goal = 35.4%, 2 goals = 45.1%, and 3 or 4 goals achieved = 13.3%).

The anthropometric and metabolic characteristics at baseline according to the number of goals achieved are shown in Table 1. The individuals without diabetes who achieved a higher number of goals were more likely to be older and to have lower weight, BMI, waist circumference, diastolic blood pressure, triglyceride, and insulin levels than those achieving fewer or no goals. Other variables in the subset without diabetes were not significantly different in terms of the number of goals achieved. In the subset with diabetes, the mean values of weight, BMI, waist circumference, diastolic blood pressure, triglyceride, and insulin did not differ according to the number of goals.

Absolute changes in the variables after two years of intervention in both subsets of individuals (with and without diabetes), independent of goal achievement and as a function of the number of goals achieved, are shown in Figure 1. There were significant reductions in most of the cardiovascular risk factors after the intervention independent of goals, except for systolic blood pressure in subjects with diabetes and fasting glucose and triglyceride levels in subjects with and without diabetes. The figure shows that the differences tended to be more pronounced as the number of goals achieved increased in the group without diabetes. Regarding the subset of individuals with diabetes, no tendency to an association between goal achievement and changes in variables was observed.

Sensitivity analyses were conducted regarding the use and/or change of medicines that could interfere with the variables of interest, but most results did not change, except for the individuals taking hypoglycemic agents, who were excluded from the ANOVA.

Discussion

Behavioral intervention trials focusing on a healthy diet and physical activity goals conducted in developed countries were successful in preventing diabetes in individuals with impaired glucose tolerance. Achievement of the behavioral goals is thought to have a beneficial impact on the cardiometabolic profile. Whether the number of goals achieved in a lifestyle intervention is indicative of such benefits regarding cardiovascular risk factors has not been previously investigated.

In the present study, most of the participants (78%), with or without diabetes, achieved only 1 or 2 goals. The percentage of reaching 3 or 4 goals was 15%; the low rates of achievement of all goals are in agreement with other intervention studies (1,5). The proportion of participants reaching the goal of weight reduction and fiber consumption was similar to data reported for the intervention group in the DPS and DPP. However, the number of individuals with and without diabetes achieving the goal of physical activity in the present study was much lower than that reported for the DPS, DPP and European Prospective Investigation into Cancer (EPIC) participants (1,2,5). This may be attributed in part to the fact that we only provided counseling about physical activity during the group sessions, which is a less intensive approach than that employed in other intervention trials (1-3). Our approach to physical activity was based on available resources from our public health system, which are unable to modify this type of behavior. On the other hand, the goal of saturated fat intake of less than 10% per day was achieved by almost 75% of the individuals, which is considerably higher than found in the other intervention trials (1,2). Previous findings by our group in the same population showed that, after adjusting for a number of variables, red meat consumption was associated with the incidence of metabolic syndrome (9). Based on these findings, our team emphasized the deleterious role of a high fat diet for the health of the participants and the benefits of the traditional Japanese diet. It is possible that such counseling for a population of Japanese ancestry may have facilitated compliance with the goal of saturated fat reduction.

When examining the characteristics of the participants at baseline, it is interesting to note that the individuals reaching a larger number of goals had a better original cardiometabolic profile, in agreement with a study conducted on the general population (5). This finding may suggest that they are more aware of a healthy way of life, which could be contributing to their more favorable anthropometric variables and metabolic biomarkers. It was previously shown that individuals with more change-predisposing attributes generally require less intensive outside support to respond to interventions (20). The intervention program used in the present study involved a smaller multiprofessional team and was less intensive than that employed in the DPS or DPP.

We found a beneficial impact of the intervention on most of the cardiovascular risk factors, independent of goal achievement. Previous studies have described an inverse correlation between the number of goals achieved and the incidence of diabetes among individuals with impaired glucose tolerance (1) and also in the general population (5). Along the same line, we found that the differences in the mean values of the cardiovascular risk factors tended to improve as the number the goals increased among the participants with normal or impaired glucose tolerance (Figure 1). It is important to note that, among individuals with diabetes, the number of goals met did not seem to influence the changes in variables of interest.

The lack of a control group is the major limitation of the present study. However, given the high prevalence of type 2 diabetes, hypertension, and dyslipidemia among Japanese-Brazilians, for ethical reasons a lifestyle counseling program should not be withheld from these indi-

Table 1. Baseline characteristics of Japanese-Brazilians with or without diabetes according to the number of goals achieved at the end of the 2-year intervention.

	None (N = 28)	1 goal (N = 144)	2 goals (N = 163)	3 or 4 goals (N = 59)	P
Age (years)					
Without diabetes	53.3 (10.3)	58.3 (12.0)	61.6 (11.1)[a]	61.8 (12.6)[a]	0.007
With diabetes	61.1 (10.0)	59.8 (11.1)	64.3 (8.9)	62.4 (10.6)	
Weight (kg)					
Without diabetes	73.9 (16.4)	59.8 (10.1)[a]	59.3 (11.8)[a]	54.4 (7.9)[a,b]	<0.001
With diabetes	66.0 (17.3)	68.1 (12.6)	64.0 (12.1)	60.0 (11.3)	
BMI (kg/m^2)					
Without diabetes	29.0 (4.8)	24.6 (3.4)[a]	23.8 (4.0)[a]	21.7 (2.6)[a,b,c]	<0.001
With diabetes	27.3 (3.6)	26.6 (3.7)	25.4 (3.3)	24.2 (3.0)	
Waist circumference (cm)					
Without diabetes	95.1 (11.0)	87.7 (8.9)[a]	85.6 (11.3)[a]	81.2 (8.3)[a]	<0.001
With diabetes	96.0 (9.6)	92.7 (9.8)	91.4 (9.3)	87.5 (9.6)	
Systolic BP (mmHg)					
Without diabetes	136.0 (15.4)	138.3 (23.4)	136.4 (22.4)	133.5 (19.4)	
With diabetes	154.4 (22.8)	139.7 (21.5)	143.9 (21.7)	140.0 (15.1)	
Diastolic BP (mmHg)					
Without diabetes	85.4 (9.6)	82.9 (12.2)	79.5 (11.8)	77.3 (2.1)[b]	0.01
With diabetes	89.0 (12.2)	83.8 (12.8)	80.5 (9.2)	78.9 (10.7)	
Fasting glucose (mg/dL)*					
Without diabetes	101.8 (12.2)	100.1 (11.7)	99.5 (10.4)	97.8 (11.0)	
With diabetes	102.1 (16.8)	130.3 (36.3)	118.5 (20.2)	146.7 (38.7)	
2-h glucose (mg/dL)*					
Without diabetes	137.9 (30.4)	133.0 (28.9)	130.6 (34.3)	128.7 (35.1)	
With diabetes	226.9 (3.0)	229.1 (48.4)	231.0 (58.0)	221.0 (43.0)	
Total cholesterol (mg/dL)					
Without diabetes	213.3 (34.2)	220.5 (45.9)	218.5 (60.0)	211.6 (40.1)	
With diabetes	231.8 (88.3)	219.4 (55.0)	206.5 (42.8)	207.1 (48.3)	
HDL cholesterol (mg/dL)					
Without diabetes	52.6 (9.3)	53.6 (13.1)	55.6 (13.1)	56.8 (13.9)	
With diabetes	43.6 (6.8)	51.2 (11.2)	53.1 (10.9)	49.6 (13.7)	
LDL cholesterol (mg/dL)					
Without diabetes	127.4 (35.8)	136.4 (37.6)	128.8 (35.7)	135.2 (37.8)	
With diabetes	122.8 (50.6)	123.3 (48.2)	123.3 (38.1)	116.2 (40.1)	
Triglyceride (mg/dL)*					
Without diabetes	144.8 (65.5)	150.4 (87.3)	145.2 (84.7)	116.1 (95.1)[b,c]	0.01
With diabetes	277.9 (153.6)	242.9 (203.9)	163.1 (97.9)	218.7 (154.4)	
Insulin (µU/L)*					
Without diabetes	5.7 (4.0)	5.2 (4.1)	4.4 (3.1)	3.6 (2.4)[b]	0.03
With diabetes	3.0‡	6.7 (5.4)	6.1 (4.6)	6.4 (4.6)	
HOMA-IR*					
Without diabetes	1.44 (1.06)	1.28 (1.01)	1.08 (0.80)	0.87 (0.60)[a,b]	0.02
With diabetes	0.66‡	2.23 (2.01)	1.85 (2.1)	1.52 (0.57)	
C-reactive protein (mg/dL)*					
Without diabetes	0.19 (0.34)	0.27 (0.53)	0.20 (0.31)	0.16 (0.34)	
With diabetes	0.31 (0.41)	0.16 (0.22)	0.16 (0.28)	0.13 (0.16)	
Framingham risk score					
Without diabetes	5.5 (5.5)	6.3 (5.7)	6.6 (4.1)	5.5 (4.0)	
With diabetes	13.6 (3.4)	9.9 (4.0)	10.5 (3.4)	10.27 (3.1)	

Data are reported as means ± SD. Bauru, SP, Brazil, 2005-2007. BMI = body mass index; BP = blood pressure. *Log-transformed variables (for non-normal distribution). ‡Only one individual in this category. P < 0.05 (Tukey test): [a]versus category of none; [b]versus category of 1 goal; [c]versus category of 2 goals. Number of individuals in each category: without diabetes (none = 21; 1 = 104; 2 = 112; 3 or 4 goals achieved = 44); with diabetes (none = 7; 1 = 40; 2 = 51; 3 or 4 goals achieved = 15).

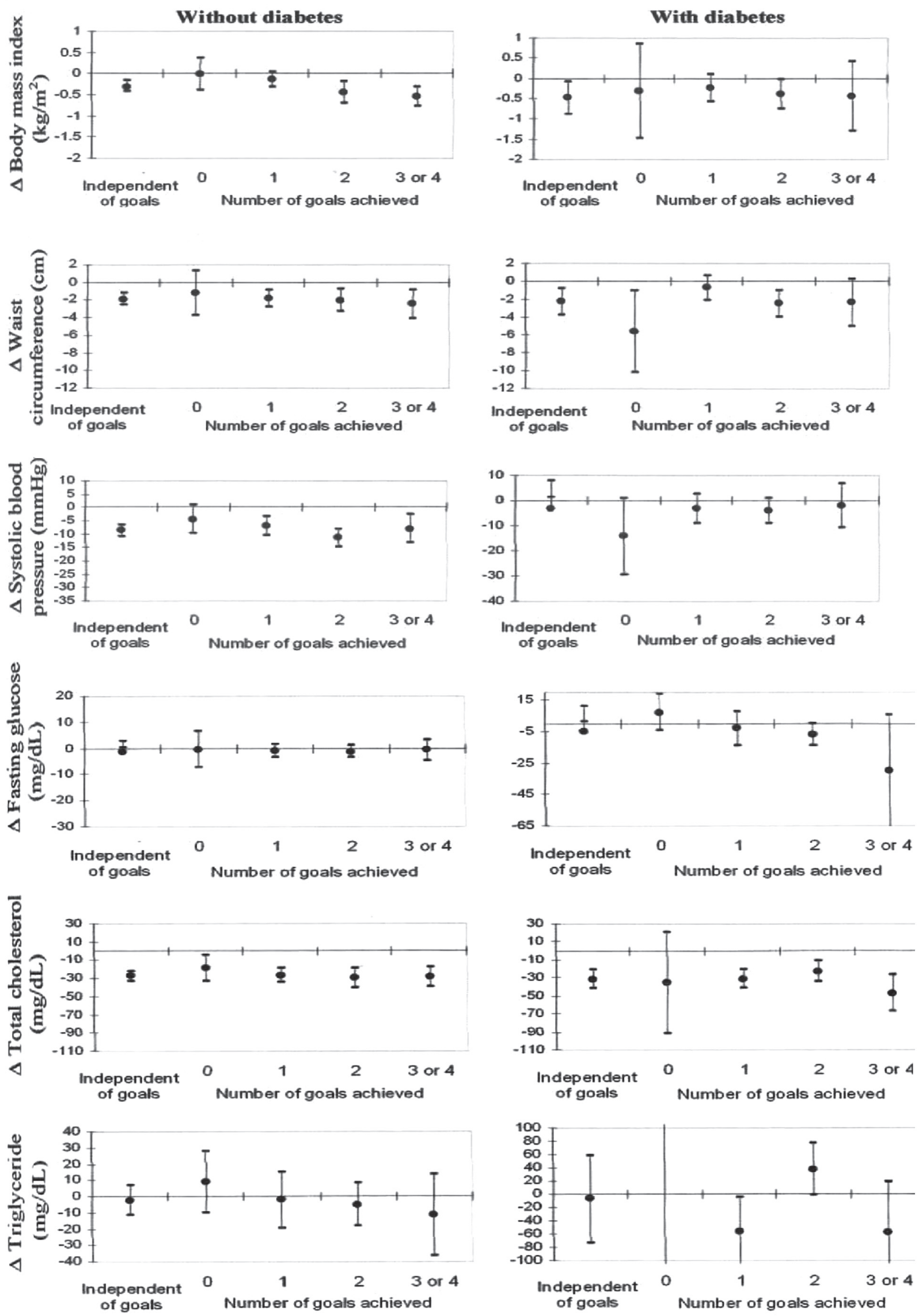

Figure 1. Absolute differences in variables of Japanese-Brazilians with or without diabetes at baseline, after a 2-year intervention (2005-2007) independent of achievement of goals and according to the number of goals achieved. Data are reported as means ± SD. Number of individuals in each category: without diabetes (none = 21; 1 = 104; 2 = 112; 3 or 4 goals achieved = 44); with diabetes (none = 7; 1 = 40; 2 = 51; 3 or 4 goals achieved = 15).

viduals. Another limitation of the present study is related to the assessment of dietary intake. Although three 24-h diet recalls were collected from the participants in winter and spring of both years, regarding week and weekend days, diet recall data do not represent variation of the diet throughout a full year.

We found a beneficial impact of the intervention on the cardiometabolic profile of individuals with normal or altered glucose metabolism. Some isolated goals were associated with benefits on cardiovascular risk factors, and the number of goals achieved in this lifestyle intervention was indicative of improvement in the cardiometabolic profile of individuals without diabetes at baseline. The results obtained in a minority population at high cardiovascular risk cannot be extrapolated to other population samples. Also, it is unknown whether a program of this type would result in a reduction of cardiovascular risk in the long term. However, using the limited resources available and considering the economic reality of a developing country, slight changes in cardiometabolic variables after 2 years of follow-up may indicate the beginning of a changing process for the individuals involved.

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