# Benefits on quality of life concomitant to metabolic improvement in intervention program for prevention of diabetes mellitus

Adriana Cezaretto · Antonela Siqueira-Catania · Camila Risso de Barros · Emanuel Péricles Salvador · Sandra Roberta G. Ferreira

Accepted: 9 April 2011/Published online: 3 May 2011 © Springer Science+Business Media B.V. 2011

#### **Abstract**

Objective To evaluate whether an interdisciplinary intervention program on lifestyle results in better quality of life (QoL) and lower frequencies of depression and binge eating disorder (BED) in individuals at risk for type 2 diabetes mellitus.

Methods A total of 177 individuals (32.2% men, age  $55.4 \pm 12.5$  years) at risk for diabetes were allocated to a 9-month traditional (TI) or intensive interdisciplinary intervention (II) on dietary habits and physical activity including psychoeducative groups. They were submitted to questionnaires and clinical and laboratory examinations. Predictors of non-adherence were analyzed by logistic regression.

Results Only individuals submitted to II had blood pressure and plasma glucose levels reduced. Frequencies of depression reduced in both interventions but of BED only in II (28.0–4.0%, P < 0.001). Increments in the scores of SF-36 domains (physical functioning:  $11.1 \pm 14.0$  vs.  $5.3 \pm 13.0$ , role-emotional:  $20.4 \pm 40.2$  vs.  $6.2 \pm 43.8$ , P = 0.05) were greater in the II than in TI, respectively. Changes in SF-36 correlated with decreases in anthropometry, blood pressure and glucose levels, depression and

Introduction

Worldwide, a 122% rise in the number of adults with diabetes mellitus (DM) is projected for 2025 [1]. In developing countries, it is projected to grow by 170% from

BED scores. Male gender was independently associated

Conclusions In addition to metabolic benefits, an inter-

disciplinary approach may induce desirable extrametabolic

effects, favoring the control of psychiatric disorders and

**Keywords** Intervention · Prevention · Diabetes mellitus ·

Quality of life · Binge eating · Depression · Adherence

improving the QoL of individuals at risk for diabetes.

with non-adherence to the II.

developing countries, it is projected to grow by 170% from 84 to 228 million people. This global increase has been attributed to population aging and growth, as well as to obesity, unhealthy diets and a sedentary lifestyle. Considering the impact of DM on morbidity and mortality, prevention strategies have been proposed aimed to increase longevity and improve quality of life (QoL).

Prospective randomized controlled studies have shown that behavioral interventions targeting diet and physical activity can delay or prevent the progression to DM [2, 3]. The Finnish Diabetes Prevention Study [2] included individuals at high risk for type 2 DM allocated to a control (annual medical visits and written information about diet and exercise given) or intervention group (medical visits, individual sessions with nutritionist and physical orientation). The study conducted in United States [3] had 3 arms, lifestyle changes based on diet and physical activity, pharmacological (metformin) intervention and placebo. Goals were to achieve at least 150 min per week of moderate physical activity and to reduce weight by 7% from

A. Cezaretto  $\cdot$  A. Siqueira-Catania  $\cdot$  C. R. de Barros  $\cdot$  E. P. Salvador

Nutrition Department, School of Public Health, University of São Paulo, São Paulo, SP, Brazil e-mail: cezaretto@usp.br

S. R. G. Ferreira (⋈) Nutrition Department, School of Public Health, University of São Paulo, Av. Dr. Arnaldo, 715, São Paulo, SP 01246-904, Brazil e-mail: sandrafv@usp.br

baseline. Participants were assigned a personal coach who met with them 16 times over the first 24 weeks to complete a core curriculum and then met at least bimonthly for the remainder of the trial. Periodic group sessions and campaigns were used to maintain weight and activity goals. Participants in both placebo and metformin arms received standard lifestyle recommendations in the form of written information and annual individual session that emphasized the importance of a low-fat diet and regular physical activity to achieve modest weight reduction [3]. In both studies, intensive lifestyle modifications were associated with the greatest reductions in the risk of DM.

These interventional programs conducted in developed countries might be not feasible for the developing world due to economical limitations. To achieve effectiveness, DM prevention programs should be tailored to the reality of public health systems. Independent of the region of the globe, behavioral changes in population are a common challenge for professionals and health authorities.

The epidemiological transition and emergence of chronic diseases raise the attention of health policies also to the subjective well-being of population [4]. In addition to metabolic outcomes, measures of QoL should be used to assess the effect of intervention programs.

Psychiatric disorders are known to deteriorate the control of chronic diseases such as DM and metabolic syndrome [5–9]. Particularly concerning DM, associations of eating disorders and depression are frequently reported [8, 9]. Although mechanistic relationships are still under debate, it is known that depression and/or binge eating have deleterious effects on the homeostasis of glucose metabolism [10, 11].

Benefits induced by behavioral interventions on lifestyle have shown to be more pronounced than pharmacological interventions [3, 12]. Changing behavior may be aggravated by the presence of psychiatric disorders, which have been associated with decreased adherence to treatments [13]. Metabolic beneficial effects of interventional programs are commonly reported [2] but not the psychological benefits, an important component of QoL.

Among the instruments available to measure QoL, the Medical Outcome Study 36-Item Short-Form Health Survey (SF-36) is one of the most applied for comparisons of groups or interventions [14]. Eight domains of functional health and well-being scores, as well as psychometrically based physical and mental health summary measures, are provided [15]. The Primary Care Evaluation of Mental Disorders (PRIME-MD) allows the assessment of the main mental disorders [16]. Its modules—mood, anxiety, somatoform, alcohol, and eating disorders—were based on diagnostic criteria of the American Psychiatric Association [17] described in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV). The Beck Depression

Inventory (BDI) is self-report questionnaire, which has been widely used for screening depression in clinical practice and research [18]. In combination with a semi-structured clinical interview, the BDI assures the diagnosis of depression. The Binge Eating Scale (BES) has been used to evaluate 3 dimensions of this eating behavior: frequency of binge, amount of food intake, and degree of feelings at the time of binging [19]. The SF-36, PRIME-MD, BDI, and BES were validated in Brazilian population samples.

This study hypothesized that an interdisciplinary intervention, including a psychologist, would represent to individuals at risk of DM an opportunity to change behavior, self-care, and lifestyle, which would result in improvement in metabolic profile, psychological status, and QoL. The main objectives of this study was to evaluate whether an intervention program on lifestyle, including an intensive interdisciplinary approach for 9 months, in individuals at risk for DM results in better QoL and in lower frequencies of depression and BED. In addition, predictive factors of non-adherence to the intensive intervention were assessed.

## Methods

A total of 438 individuals seen by the public health system of the Sao Paulo city, Brazil, were screened. Inclusion criteria were adults of both sexes aged 18 and 79, at high risk for type 2 DM. High risk was defined by the presence of prediabetic conditions (impaired fasting glucose or impaired glucose tolerance) or the metabolic syndrome without DM, considering the 4.6-fold increased risk of developing type 2 DM [20, 21]. American Diabetes Association and International Diabetes Federation diagnostic criteria were used [22, 23]. Exclusion criteria were: (1) to live out of São Paulo metropolitan area; (2) pregnant women; (3) neurological or unstable psychiatric problems; (4) antidiabetic agents or medications for weight control; and (5) neoplasias, chronic communicable diseases, hepatic or renal failure, and untreated thyroid dysfunctions.

Two hundred and forty-four individuals were eligible, and 177 agreed to participate. The proportion of men was higher among non-participants. The Institutional Ethics Committee approved the study (protocol COEP 210/08), and written consent was obtained from all participants.

In this longitudinal study, individuals were randomly assigned to one of two intervention programs of lifestyle modifications (dietary habits and physical activity), which each lasted 9 months. Traditional intervention (control condition) consisted of 3 medical visits during the time frame, in which participants received written guidelines on changes in diet and physical activity, based on primary care model advocated at the Brazilian public health system. The



intensive intervention (interdisciplinary condition) consisted of these visits plus an individual appointment with a dietitian and 2-h group sessions for up to 17 participants, led by an interdisciplinary team, with frequency fading from 4 sessions in month 1 to 2 sessions in month 2 and 1 monthly session until month 9. Participants under intensive intervention also received print materials including hints to reach a healthier lifestyle in all sessions and telephone calls between sessions to motivate and enhance the patientprofessional link. Interdisciplinary team included an endocrinologist, psychologist, nutritionist, and physical educator. These psychoeducative sessions deal with issues related to their daily habits focusing in diet, physical activities, and stressful situations. Short targets were recommended to the participants in order to motivate changes in their routine, which were discussed in the subsequent session. Adherence to the intensive intervention was defined by attendance up to 70% of the group sessions.

The outcomes of programs were the improvement in the metabolic profile, including plasma glucose and lipids concentrations and blood pressure levels. The goals were weight loss  $\geq 5\%$ , dietary fiber intake  $\geq 20$  g per day, saturated fat  $\leq 10\%$  of total energy, and moderate physical activity  $\geq 150$  min per week.

## Study protocol

Individuals were examined and submitted to laboratory procedures at baseline and after 9 month of follow-up. The long version of the International Physical Activity Questionnaire [24, 25] was applied, and three 24-h recalls were obtained by trained specialists. Dietary data were processed using the software Nutrition Data System for Research [26].

The Medical Outcome Study 36-Item Short-Form Health Survey (SF-36) was used to assess quality of life. A single examiner applied the SF-36. This questionnaire includes questions focusing on the limitations on physical and social activities due to physical or emotional concerns, limitations on daily activities, pain, mental disturbances, and vitality. Additional information about the SF-36 and the interpretation of results are available on the SF-36 web page (http://www.sf-36.org). Quality of life was assessed by each of its 8 domains and also by 2 summary measures, focusing on "physical" or "mental" aspects. The domain scaled scores (0–100) are physical function, physical role, bodily pain, general health, vitality, social functioning, emotional role, and mental health. The scores from the 8 domains were individually weighted into physical and mental components and combined to calculate the SF-36 physical component summary (PCS) and mental component summary (MCS) health scales [14]. The module "mood" of the PRIME-MD and the Beck Depression Inventory (BDI) was applied to diagnose depression as a dichotomous variable [27]. By the PRIME-MD, depression was diagnosed when individuals had minor or major depressive disorder or dysthymia. BDI is composed of items relating to symptoms of depression such as hopelessness and irritability, cognitions such as guilt or feelings of being punished, as well as physical symptoms such as fatigue, weight loss, and lack of interest in sex. Overall scores are obtained by the sum of responses to 21 questions ranging from 0 to 63. Cutoff points used to classify the depression severity were as follows: 0 to 11—minimal; 12 to 19-light; 20 to 35-moderate; and 36 to 63-severe [28]. In this study, the cutoff point  $\geq 12$  was used to define depression. Binge eating disorder was assessed by the Portuguese version of the BES [29]. This is a 16-item questionnaire whose questions are based on behavioral and the emotional characteristics (guilt or shame). Each question punctuated from 0 to 3, and the final score is obtained by the sum, ranging from 0 to 46. Scores less than 17 are considered non-binging, from 18 to 26 moderate binging, and 27 and greater severe binging. For the purpose of this study, the cutoff point  $\geq 18$  was employed to define the presence of BED.

Fasting blood samples were taken, and a 75 g oral glucose tolerance test performed. Samples were immediately centrifuged, and analyses made in the local laboratory. Plasma glucose was measured by the gluco-oxidase method and lipoproteins enzymatically by automatic analyzer.

## Statistical analysis

Data are reported as means  $\pm$  standard deviation for numerical variables or as number and percent for categorical variables (depression and binge eating). Paired and unpaired Student's t tests were used to compare continuous variables with normal distribution. Those with skewed distributions were transformed using their natural logarithms. Differences of frequencies were tested by chisquare test. Agreement of diagnosis of depression using both instruments (PRIME-MD and BDI) was measured by the kappa coefficient. Correlation between changes in variables was tested by the Pearson or Spearman coefficient. Sensitivity analyses were conducted since use of antidepressants could interfere in variables of interest.

To identify independent predictors of non-adherence (attendance to group sessions <70%) to intensive intervention, logistic regression was employed. Differences in baseline variables between adherent and non-adherent participants at significance level up to 0.20 in the univariate analysis were entered into the logistic regression final model, taking depression and binge eating as variable of main interest. Statistical analyses were performed using



SPSS 17.0 software [30]. The significance level was set at P < 0.05.

## Results

The total sample was composed of 177 individuals (32.2% men), with mean age of  $55.4 \pm 12.5$  years. Fifty-two percent were married, 54% had up to 8 years of schooling, and 49% had body mass index  $\geq$  30 kg/m<sup>2</sup>. Table 1 shows the characteristics of the participants allocated to the interventions. Groups stratified according to the type of intervention had similar proportions of women (73.3% in the intensive and 63.8% in the traditional intervention) and did not differ at baseline according to clinical, OoL score, and frequencies of depression and BED. From those 177 individuals, 135 completed the 9-month follow-up (mean lost to follow-up of 23%), totalizing 60 individuals in the traditional intervention and 75 in the intensive one. The main reason for drop was to live far from the health center. Comparing individuals who completed or not the followup, subsets did not differ according to sociodemographic, anthropometric, and metabolic data and to the frequencies of psychiatric disorders. Participants were followed up from March 2008 to January 2009. Sixty-four percent of the participants were considered adherent since they achieved 70% of attendance to the group sessions.

In both interventions, similar reductions in total energy intake were found (Intensive:  $1,833 \pm 638-1,491 \pm 485$  kcal/day, P < 0.01 and Traditional:  $1,710 \pm 602-1,497 \pm 624$  kcal/day, P < 0.01). Only in the intensive intervention had significant increase in fiber intake (II:

 $9.1 \pm 3.7$ – $11.1 \pm 4.3$ , P < 0.01; TI:  $9.6 \pm 3.6$ – $9.2 \pm 3.1$ , P > 0.05). Mean percent decrease in total fat and added sugar intake were higher in individuals the intensive intervention (data not shown).

The proportion of individuals spending  $\geq$ 150 min/week of physical activity increased more in the intensive intervention (59.6–87.7%, P=0.001) compared with the traditional one (53.8–61.5%, P=0.78).

After intensive and traditional interventions, respectively, the mean values of body mass index and waist circumference decreased and HDL-cholesterol increased (Table 2). However, only individuals submitted to the intensive intervention had mean blood pressure levels and fasting and 2-h plasma glucose reduced. Comparing differences between the two interventions, individuals of the intensive intervention had greater decreases in waist circumference and blood pressure. Mean values of BDI and BES scores were similar at baseline and decreased after both interventions.

Intensive intervention was associated with significant improvement in the majority of QoL domains and the summary measures (Table 3). Comparing the increments in QoL induced by both interventions, they were higher in intensive intervention regarding to the domains of physical functioning and role-emotional than the traditional one (Fig. 1). Sensitivity analyses, taking into consideration the use of antidepressants, did not change the results.

At baseline, kappa coefficient ( $\kappa = 0.49$ ) for the diagnosis of depression using both instruments showed a good agreement. The frequencies of depression decreased at the end of both interventions (Table 4). However, frequency of BED showed significant reduction only in the intensive

Table 1 Sociodemographic, psychological, and clinical data at baseline, according to the type of intervention

	Intensive $n = 97$	Traditional $n = 80$	P
Age (years)	$56.1 \pm 11.4$	$53.8 \pm 13.3$	0.23
Body mass index (kg/m <sup>2</sup> )	$31.5 \pm 5.7$	$30.5 \pm 5.6$	0.23
Waist circumference (cm)	$103.3 \pm 11.9$	$100.0 \pm 12.8$	0.08
Systolic blood pressure (mmHg)	$136.4 \pm 17.5$	$135.7 \pm 17.5$	0.80
Diastolic blood pressure (mmHg)	$83.6 \pm 10.3$	$80.7 \pm 9.7$	0.06
Fasting plasma glucose (mg/dL)	$99.6 \pm 12.2$	$99.0 \pm 11.1$	0.74
LDL-cholesterol (mg/dL)	$126.8 \pm 36.5$	$126.5 \pm 42.0$	0.97
HDL-cholesterol (mg/dL)	$42.5 \pm 11.7$	$40.3 \pm 10.3$	0.19
Triglycerides (mg/dL)	$151.7 \pm 66.8$	$155.0 \pm 67.5$	0.74
Quality of life			
Physical summary measure	$48.0 \pm 8.7$	$49.0 \pm 9.0$	0.47
Mental summary measure	$44.2 \pm 11.9$	$45.1 \pm 13.2$	0.66
Depression* (%)	46.3	46.8	0.95
Binge eating disorder (%)	26.3	22.1	0.52

Data expressed as means  $\pm$  standard deviation or percent

<sup>\*</sup> Diagnosed by Beck Depression Inventory



Qual Life Res (2012) 21:105-113

Table 2 Mean values (±standard deviation) of clinical variables at baseline and after 9 months of follow-up according to the type of intervention

	Intensive intervention $(n = 75)$				Traditional intervention $(n = 60)$			
	Baseline	9 months	P	Difference	Baseline	9 months	P	Difference
Body mass index (kg/m <sup>2</sup> )	$31.7 \pm 5.6$	$30.9 \pm 5.7$	< 0.001	$-0.8 \pm 1.5$	$29.9 \pm 5.0$	$29.1 \pm 5.3$	< 0.001	$-0.7 \pm 1.2$
Waist circumference (cm)	$104.0 \pm 12.0$	$100.7 \pm 11.3$	< 0.001	$-3.4 \pm 5.6$	$99.4 \pm 12.2$	$97.4 \pm 12.2$	< 0.001	$-1.8 \pm 3.5*$
Systolic BP (mmHg)	$136.4 \pm 17.7$	$131.0 \pm 17.0$	< 0.001	$-5.4 \pm 15.3$	$135.8 \pm 17.6$	$136.2 \pm 19.2$	0.85	$0.6 \pm 18.3*$
Diastolic BP (mmHg)	$84.0 \pm 10.7$	$76.8 \pm 12.5$	< 0.001	$-6.0 \pm 9.2$	$80.5 \pm 9.9$	$80.0 \pm 8.2$	0.63	$-0.7 \pm 8.5*$
Fasting plasma glucose (mg/dL)	$98.9 \pm 12.0$	$95.3 \pm 12.1$	< 0.001	$-3.6 \pm 13.4$	$99.7 \pm 11.1$	$98.8 \pm 12.3$	0.61	$-2.0 \pm 13.8$
Post-load plasma glucose (mg/dL)	$123.3 \pm 28.3$	$114.1 \pm 28.5$	< 0.001	$-9.2 \pm 27.8$	$116.1 \pm 26.2$	$113.8 \pm 29.0$	0.52	$-2.4 \pm 26.9$
Total cholesterol (mg/dL)	$203.8 \pm 41.9$	$198.3 \pm 39.9$	0.23	$-5.5 \pm 39.5$	$200.6 \pm 46.3$	$195.2 \pm 47.7$	0.40	$-3.1 \pm 50.4$
LDL-cholesterol (mg/dL)	$128.5 \pm 37.6$	$122.3 \pm 33.8$	0.19	$-6.1 \pm 38.9$	$129.5 \pm 42.8$	$118.6 \pm 42.1$	0.08	$-8.4 \pm 50.4$
HDL-cholesterol (mg/dL)	$43.6 \pm 12.3$	$47.3 \pm 12.6$	< 0.001	$3.6\pm10.4$	$39.1 \pm 10.1$	$44.9 \pm 11.3$	< 0.001	$4.9 \pm 12.3$
Triglycerides (mg/dL)	$150.6 \pm 59.5$	$141.9 \pm 51.6$	0.19	$-8.7 \pm 57.2$	$165.2 \pm 71.1$	$165.2 \pm 89.7$	0.99	$3.0 \pm 62.8$
BDI score	$12.2 \pm 9.4$	$8.4 \pm 7.7$	< 0.001	$-3.8 \pm 6.6$	$9.3 \pm 7.5$	$5.2 \pm 5.1$	< 0.001	$-4.1 \pm 6.6$
BES score	$9.9\pm8.8$	$6.8 \pm 6.4$	< 0.001	$-3.2 \pm 5.9$	$8.0 \pm 8.5$	$6.3 \pm 7.5$	0.003	$-1.8 \pm 4.5$

BP blood pressure, BDI Beck Depression Inventory

**Table 3** Mean values (±standard deviation) of quality of life assessed by the SF-36 at baseline, after 9 months of follow-up, and differences from baseline, according to the type of intervention

SF-36 domains	Intensive intervention				Traditional intervention			
	Baseline	9 months	Р	Difference	Baseline	9 months	Р	Difference
Physical functioning	$76.0 \pm 19.7$	87.1 ± 16.9	< 0.001	$11.1 \pm 14.0$	$82.4 \pm 20.0$	87.7 ± 17.1	< 0.001	5.3 ± 13.0*
Role-physical	$75.7 \pm 34.6$	$81.7 \pm 32.4$	0.18	$6.0 \pm 38.7$	$78.0 \pm 33.8$	$84.5 \pm 26.0$	0.16	$6.5 \pm 34.6$
Bodily pain	$58.3 \pm 22.8$	$65.9 \pm 21.9$	0.02	$7.7 \pm 27.1$	$65.4 \pm 23.8$	$67.8 \pm 21.2$	0.50	$2.3 \pm 26.2$
General health	$70.8 \pm 20.4$	$80.1 \pm 17.7$	< 0.001	$9.3 \pm 17.0$	$72.4 \pm 19.4$	$79.5 \pm 17.3$	< 0.001	$7.0 \pm 17.4$
Vitality	$57.9 \pm 23.0$	$69.6 \pm 20.4$	< 0.001	$11.7 \pm 21.5$	$63.6 \pm 19.0$	$70.9 \pm 20.2$	< 0.05	$7.3 \pm 19.2$
Social functioning	$71.2 \pm 27.2$	$82.3 \pm 21.5$	< 0.001	$11.2 \pm 27.5$	$78.9 \pm 24.6$	$84.5 \pm 21.0$	0.08	$5.6 \pm 23.6$
Role-emotional	$60.4 \pm 40.5$	$80.9 \pm 33.9$	< 0.001	$20.4 \pm 40.2$	$69.7 \pm 38.1$	$75.9 \pm 36.8$	0.29	$6.2 \pm 43.8*$
Mental health	$63.9 \pm 21.8$	$74.7 \pm 17.5$	< 0.001	$10.8 \pm 20.3$	$67.2 \pm 21.9$	$75.4 \pm 22.1$	< 0.001	$8.3 \pm 19.5$
Summary measures								
Physical component	$48.0 \pm 8.6$	$50.4 \pm 8.6$	< 0.05	$2.4 \pm 8.1$	$49.6 \pm 8.8$	$51.2 \pm 6.6$	0.14	$1.5 \pm 7.6$
Mental component	$44.3 \pm 11.3$	$50.8\pm9.9$	< 0.001	$6.5 \pm 10.7$	$47.0 \pm 12.1$	$50.5 \pm 11.5$	0.02	$3.5 \pm 11.2$

<sup>\*</sup> P < 0.05 difference in intensive versus traditional intervention

one. When number of individuals showing decreases in BES score was considered, intensive intervention was associated with greater percent of reductions than the traditional one (85.7% vs. 50.0%, P=0.04).

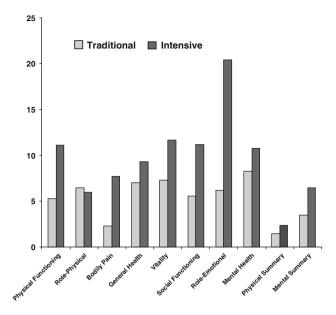
Depressed individuals at baseline (n=58) who decreased symptoms after 9 months (n=29) had their fasting plasma glucose reduced, while those who maintained depression symptoms had levels elevated  $(-4.3 \pm 12.6 \text{ vs. } 7.3 \pm 9.0 \text{ mg/dL}, P = 0.015)$ . Similarly, the former group improved physical component of QoL  $(5.0 \pm 8.3 \text{ vs. } -5.6 \pm 8.9, P = 0.002)$  but not the latter.

In univariate analysis, comparison of subsets of adherent and non-adherent individuals according to clinical and laboratory data, no difference was observed (data not shown). Final logistic regression including depression and BED as independent variables male sex was independently associated with non-adherence to the intensive intervention but not the psychiatric disorders (Table 5). Men had a 5.4-fold increase in non-adherence compared with women.

The changes in the scores of QoL of both interventions were inversely correlated to the changes in some clinical variables. For the total sample, vitality was correlated to body mass index (r = -0.168, P = 0.05), role-emotional domain to waist circumference (r = -0.190, P = 0.03), and mental summary measure to fasting and post-load glycemia (r = -0.208, P = 0.016 and r = -0.213,



<sup>\*</sup> P < 0.05 for difference in intensive intervention



**Fig. 1** Mean changes in the scores of the SF-36 domains and summary measures of individuals submitted to 2 types of intervention (traditional or intensive) for 9 months

**Table 4** Frequencies of binge eating and depression (by two instruments) at baseline and after 9 months of follow-up according to the type of intervention

	Intensive	intervention	Traditional intervention			
	Baseline	9 months	P	Baseline	9 months	P
Depression						
PRIME- MD	52.0 (39)	36.0 (27)	0.04	39.7 (23)	19.0 (11)	0.04
BDI	46.7 (35)	29.3 (22)	0.04	39.7 (23)	12.1 (7)	0.01
Binge eating	28.0 (21)	4.0 (3)	<0.001	13.7 (8)	8.6 (5)	0.38

PRIME-MD Primary care evaluation of mental disorders, BDI Beck Depression Inventory

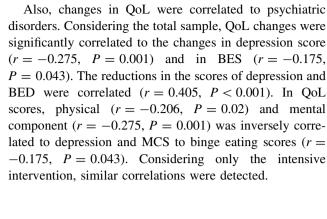
Data expressed in percent and number of individuals in parentheses

**Table 5** Final model of logistic regression for the association with non-adherence (<70% of attendance to group sessions) to intensive intervention

	OR	95% CI	P
Male sex	5.48	0.022-0.574	0.02
Depression	0.47	0.139-1.563	0.22
Binge eating	1.62	0.450-5.809	0.46

Adjusted for age, schooling, marital status, occupation, and body mass index

P = 0.014, respectively). Stronger coefficients were detected in the intensive intervention, in which changes in role-physical domain were inversely correlated to fasting (r = -0.305, P = 0.008) and post-load glycemia changes (r = -0.231, P = 0.047).



## Discussion

Our study supports the hypothesis that this intensive intervention on lifestyle with an interdisciplinary approach to individuals at risk of DM results in greater benefits in metabolic profile, accompanied by improvement in QoL, when compared to a traditional intervention. The beneficial effects on blood pressure and plasma glucose levels may contribute to reduce cardiometabolic risk in long term.

Our setting and program had some unique characteristics. This was tailored to the public health system of a developing country using limited resources, in contrast to programs conducted in the developed world [2, 3]. Both interventions followed international guidelines for DM prevention differing mainly in relation to the contact time with several health providers. The health team included professionals, which are normally available in Brazilian health units. This context results in adequate adherence to the program reverting and favorable effects. The slight changes verified in their dietary habits and physical activities were sufficient to induce reduction in anthropometric variables. It is known that small weight loss is associated with cardiometabolic benefits [31, 32]. Even more important at the patient viewpoint was the improvement in QoL and welfare. Higher discipline regarding diet and physical activity was not seen as an inconvenience but a motivation for a healthier life. For those with depression or BED, symptoms were attenuated, which is relevant considering that the management of these disorders may favor weight control and metabolic homeostasis [5, 33].

The enhancement in physical and emotional aspects of the QoL of individuals submitted to our 9-month intensive intervention was greater than that of the traditional one. Similar results were previously found in the Diabetes Prevention Program—DPP [34]. After a 12-month period, greater benefits on QoL of the individuals allocated to intensive lifestyle modifications were found as compared to those under traditional or pharmacological intervention. Association of QoL and weight loss was found in studies, ours and DPP, independent of the type of intervention.



Cost-effectiveness analysis of the DPP concluded that interventions are recommended considering long-term outcomes in the prevention of DM. In agreement to our findings, in a 4-year prospective study conducted in individuals with type 2 DM, the subset submitted to group sessions had more favorable effects in glycemic control and QoL than that followed exclusively by medical visits [35].

Binge eating may reach high prevalence rates particularly in individuals with DM or in weight loss samples [11, 36], in which this behavior represents a difficulty for weight control [37]. An intervention including psychosocial treatment for binge eating in diabetic individuals showed that the control of the BED occurred concomitantly with reduction in HbA1c [38]. In our study, high dropout rate (47%) was found in the traditional intervention. At least in part, high dropout and unsuccessful weight loss treatment may dependent of a lack of psychological approach. This is supported by our finding of reduced frequency of BED in the intensive intervention but not in the traditional one. We speculate that the interdisciplinary program played an important role for this result. A limitation of this analysis is related to the contrasting numbers of individuals with this disorder in each intervention at baseline; however, when percentages of decrease in BES score were considered, the analysis provided consistent results (data not shown). Based on the correlation between changes in BES and QoL, we suggest that binge eaters may have improved their QoL in part due to their successful attempt in weighting loss. Concordantly, other investigators have previously found that individuals with BED submitted to behavioral interventions improved QoL in parallel weight maintenance [10].

Scores of BED and depression were correlated in our study. It was previously reported that individuals with eating disorders have 60% more psychiatric comorbidities compared with general population [39]. Despite the recognized association of these disorders [40, 41], more studies are needed to clarify the underlying mechanisms these disorders [42]. Concomitant to reduction in the frequency of BED, depression was reduced, which may be contributing to the improvement of QoL of the individuals under intensive intervention on lifestyle. At baseline, the high frequency of depression (47%) among our participants was similar to that found in other intervention studies [43]. Interestingly, depression symptoms decreased also in our traditional intervention, suggesting that a simple 30-min medical care may be effective to improve depression symptoms even not directed to this psychological disorder. In fact, in a randomized trial including 51 patients with type 2 DM allocated to cognitive behavior therapy or to non-specific treatment to depression, the latter induced a reduction of 27.3% of depression symptom [44].

A recent longitudinal study found that depression symptoms increased the risk of type 2 DM [45]. It is recognized that the role of the hyperactivity of the hypothalamic–pituitary–adrenocortical axis for visceral adiposity in turn increases the risk of glucose metabolism disturbances [46]. Therefore, the additional benefits of lifestyle interventions on psychiatric disorders could enhance the protective effects in the prevention of type 2 DM.

Finally, in terms of public health, it was of interest to investigate factors associated with non-adherence to intensive intervention. Also, we hypothesized that psychiatric disorders could impair adherence. Using a strict criterion to define adherence (>70% of attendance in group sessions), over a third of the program participants were not exposed to the full intervention. Considering that their reasons for non-attendance were mainly related to work concerns, transportation, and economic limitations, we call attention to the necessity of politics to facilitate assessment to health visits and to enhance employers' comprehension. Multivariate analysis showed that the presence of BED or depression was not associated with non-adherence, but the male sex. Lower rates of men demanding medical visits are widely observed, which have been attributed to their occupational activities. Although our findings did not support that these psychiatric disorders interfere in adherence to psychoeducation groups, further studies, including bigger samples, are still necessary.

In conclusion, intensive intervention on lifestyle with interdisciplinary approach for individuals at risk for type 2 DM induced greater improvements in QoL than a traditional one, in parallel to better benefits on cardiometabolic profile. Additional favorable effects on BED and depression may contribute to such QoL improvement. These disorders seem not to be predictive of non-adherence to behavioral intervention. Strategies for lifestyle changes should be revised to improve adherence by male sex.

#### References

- King, H., Aubert, R. E., & Herman, W. H. (1998). Global burden of diabetes, 1995–2025. Prevalence, numerical estimates and projections. *Diabetes Care*, 21, 1414–1431.
- Tuomilehto, J., Lindstrom, J., Eriksson, J. G., Valle, T. T., Hamalainen, H., Ilanne-Parikka, P., et al. (2001). Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. New England Journal of Medicine, 344, 1343–1350.
- Knowler, W. C., Barrett-Conner, E., Fowler, S. E., Hamman, R. F., Lachin, J. M., Walker, E. A., et al. (2002). Diabetes Prevention Program Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *New England Journal of Medicine*, 346, 393–403.
- 4. WHO-World Health Organization. (1946). Constitution of the World Health Organization. Genebra: World Health Organization.



- Lustman, P. J., Anderson, R. J., Freedland, K. E., de Groot, M., Carney, R. M., & Clouse, R. E. (2000). Depression and poor glycemic control. *Diabetes Care*, 23(7), 934–942.
- Katon, W. J., Rutter, C., Simon, G., Lin, W. H. B., Ludman, E., Ciechanowski, P., et al. (2003). The association of comorbid depression with mortality in patients with type 2 diabetes. *Diabetes Care*, 28, 2668–2672.
- Campayo, A., de Jonge, P., Roy, J. F., Saz, P., Camara, C., Quintanilla, M. A., Marcos, G., et al. (2010). Depressive disorder and incident diabetes mellitus: The effect of characteristics of depression. *American Journal of Psychiatry*, 167(5):496–497.
- Bogner, H. R., Post, E. P., Morales, K. H., & Bruce, M. L. (2007). Diabetes, depression, and death: a randomized controlled trial of a depression treatment program for older adults based in primary care (PROSPECT). *Diabetes Care*, 30, 3005–3010.
- 9. Young-Hyman, D., & Davis, C. L. (2010). Disordered eating behavior in individuals with diabetes: Importance of context, evaluation, and classification. *Diabetes Care*, *33*(3), 683–689.
- Cerrelli, F., Manini, R., Forlani, G., Baraldi, L., Melchionda, N., & Marchesini, G. (2005). Eating behavior affects quality of life in type 2 diabetes mellitus. *Eating and Weight Disorders*, 10(4), 251–257.
- Meneghini, L. F., Spadola, J., & Florez, H. (2006). Prevalence and associations of binge eating disorder in a multiethnic population with type 2 diabetes. *Diabetes Care*, 29(12), 2760.
- Williamson, D. A., Rejeski, J., Lang, W., Van Dorsten, B., Fabricatore, A. N., & Toledo, K. (2009). Impact of a weight management program on health-related quality of life in overweight adults with type 2 diabetes. *Archives of Internal Medicine*, 169, 163–171.
- Gensichen, J., Torge, M., Peitz, M, Wendt-Hermainski, H., Beyer, M., Rosemann, T., et al. (2005). Case management for the treatment of patients with major depression in general practices—rationale, design and conduct of a cluster randomized controlled trial—PRoMPT (Primary care monitoring for depressive patient's trial) [ISRCTN66386086]—Study protocol public health. 5:101. In: http://www.biomedcentral.com/1471-2458/5/101.
- 14. Ware, J. E., Jr., Gandek, B., Kosinski, M., Aaronson, N. K., Apolone, G., Brazier, J., et al. (1998). The equivalence of SF-36 summary health scores estimated using standard and country-specific algorithms in 10 countries: results from the IQOLA project. International Quality of Life Assessment. *Journal of Clinical Epidemiology*, 51, 1167–1170.
- Campolina, A. G., & Ciconelli, R. M. (2006). Qualidade de vida e medidas de utilidade: parâmetros clínicos para as tomadas de decisão em saúde. Pan American Journal of Public Health, 19(2), 128–136.
- Spitzer, R. L., Kroenke, K., Williams, J. B., Linzer, M., deGruy, F. V., Hahn, S. R., et al. (1994). Utility of a new procedure for diagnosing mental disorders in primary care. The PRIME MD 1000 study. *JAMA*., 272(22), 1749–1756.
- 17. APA—American Psychiatric Association. (2000). *Diagnostic and statistical manual of mental disorders* (4th ed.). DC: Washington.
- Lasa, L., Ayuso-Mateos, J. L., Vázquez-Barquero, J. L., Díez-Manrique, F. J., & Dowrick, C. F. (2000). The use of the Beck depression inventory to screen for depression in the general population: a preliminary analysis. *Journal of Affective Disor*ders, 57, 261–265.
- Gormally, J., Black, S., Daston, S., & Rardin, D. (1982). The assessment of binge eating severity among obese persons. *Addictive Behaviors*, 7, 47–55.
- Gami, A. S., Witt, B. J., Howard, D. E., Erwin, P. J., Gami, L. A., Somers, V. K., et al. (2007). Metabolic syndrome and risk of incident cardiovascular events and death: a systematic review and meta-analysis of longitudinal studies. *Journal of the American College of Cardiology*, 49, 403–414.

- Ford, E. S., Schulze, M. B., Pischon, T., Bergmann, M. M., & Boeing, H. (2008). Metabolic syndrome and risk of incident diabetes: findings from the European prospective investigation into cancer and nutrition-postdam study. *Cardiovascular Diabe*tology, 12, 7–35.
- ADA—American Diabetes Association (1997). Report of the expert committee on the diagnosis and classification of diabetes mellitus. *Diabetes Care*, 20, 1183–1197.
- 23. IDF—International Diabetes Federation (2006). *Diabetes Atlas*, (3<sup>a</sup>rd ed.,). Brussels: International Diabetes Federation.
- Craig, C. L., Marshall, A. L., Sjostrom, M., Bauman, A. E., Booth, M. L., Ainsworth, B. E., et al. (2003). International physical activity questionnaire: 12-country reliability and validity. *Medicine and Science Sports and Exercise.*, 35(8), 1381–1395.
- Florindo, A. A., Guimarães, V. V., Cezar, C. L., Barros, M. B., Alves, M. C., & Goldbaum, M. (2009). Epidemiology of leisure, transportation, occupational and household physical activity: prevalence and associated factors. *Journal of Physical Activity Health*, 6(5), 625–632.
- Nutrition Coordinating Center (NCC) (2005). Nutrition data system for research-NDS-R (computer program), University of Minnesota, Minneapolis.
- Beck, A. T., Steer, R. A., & Garbin, M. G. (1988). Psychometric properties of the Beck depression inventory: twenty-five years of evaluation. *Clinical Psychology Review*, 8, 77–100.
- Cunha, J. A. (2001). Manual da versão em português das escalas Beck. São Paulo: Casa do Psicólogo.
- Freitas, S., Lopes, C. S., Coutinho, W., & Appolinario, J. C. (2001). Tradução e adaptação para o português da Escala de Compulsão Alimentar Periódica. Revista Brasileira de Psiquiatria, 23(4), 215–220.
- 30. SPSS Incorporation (2009). Statistical package for the social science for windows student version/SPSS (computer program) release 17.0. Chicago: Marketing department.
- Heymsfield, S. B., Segal, K. R., Hauptman, J., Lucas, C. P., Boldrin, M. N., Rissanen, A., et al. (2000). Effects of weight loss with orlistat on glucose tolerance and progression to type 2 diabetes in obese adults. Archives of Internal Medicine, 160(9), 1321–1326.
- 32. Chiasson, J. L., Josse, R. G., Gomis, R., Hanefeld, M., Karasik, A., & Laakso, M. (2002). Acarbose for prevention of type 2 diabetes mellitus: the STOP-NIDDM randomised trial. *Lancet*, 359(9323), 2072–2077.
- Papelbaum, M., Moreira, R. O., Ellinger, V. C. M., Zagury, L., & Appolinário, J. C. (2001). Comorbidade psiquiátrica no paciente diabético. *Psiquiatria na Prática Médica*, 34(3), 82–85.
- Ackermann, R. T., Edelstein, S. L., Venkat, N. K. M., Zhang, P., Engelgau, M. M., Herman, W.H., et al. (2009). Changes in health state utilities with changes in body mass in the diabetes prevention program. *Obesity*, 17(12):2176–2181.
- Trento, M., Gamba, S., Gentile, L., Grassi, G., Miselli, V., Morone, G., et al. (2010). Rethink organization to improve education and outcomes (ROMEO): A multicenter randomized trial of lifestyle intervention by group care to manage type 2 diabetes. *Diabetes Care*, 33(4), 745–747.
- Spitzer, R. L., Yanovski, S., Waden, T., Wing, R., Marcus, M. D.,
   Stunkard, A. (1993). Binge eating disorder: Its further validation in multisite study. *International Journal Eating Disorder*, 13, 137–153.
- Schelling, S., Munsch, S., Meyer, A. H., & Margraf, J. (2011).
   Relationship between motivation for weight loss and dieting and binge eating in a representative population survey. *International Journal of Eating Disorders*, 44(1), 39–43.
- Kenardy, J., Mensch, M., Bowen, K., Green, B., & Walton, J. (2002). Group therapy for binge eating in type 2 diabetes: a randomized trial. *Diabetic Medicine*, 19(3), 234–239.



- 39. Bulik, C., Brownley, K. A., & Shapiro, J. R. (2007). Diagnosis and management of binge eating disorder. *World Psychiatry*, 6, 142–148
- Grucza, R. A., Przybeck, T. R., & Cloninger, C. R. (2007).
   Prevalence and correlates of binge eating disorder in a community sample. *Comprehensive Psychiatry*, 48, 124–131.
- Mather, A. A., Cox, B. J., Enns, M. W., & Sareen, J. (2009). Associations of obesity with psychiatri disorders and suicidal behaviors in a nationally representative sample. *Journal of Psychosomatic Research*, 66, 277–285.
- 42. Capuron, L., Poitou, C., & Machaux-Tholliez, D. (2010) Relationship between adiposity, emotional status and eating behaviour in obese women: role of inflammation. doi:10.1017/S00332917 10001984.
- Rubin, R. R., Ma, Y., Marrero, D. G., Peyrot, M., Barrett-Connor, E. L., Kahn, S. E., et al. (2008). Diabetes prevention program

- research group. Elevated depression symptoms, antidepressant medicine use, and risk of developing diabetes during the diabetes prevention program. *Diabetes Care*, 31(3):420–426.
- Lustman, P. J., Griffith, L. S., Freedland, K. E., Kisse, S. S., & Clouse, R. E. (1998). Cognitive behavior therapy for depression in type 2 diabetes mellitus. A randomized, controlled trial. *Annals* of Internal Medicine, 129(8), 613–621.
- 45. Demakakos, P., Pierce, M. B., & Hardy, R. (2010). Depressive symptoms and risk of type 2 diabetes in a national sample of middle-aged and older adults: The English longitudinal study of aging. *Diabetes Care*, 33(4), 792–797.
- Raison, C. L., Capuron, L., & Miller, A. H. (2006). Cytokines sing the blues: inflammation and the pathogenesis of depression. *Trends Immunology*, 27(1), 24–31.

