

# Efficacy of Lifestyle Change Psychological Intervention in Coronary Risk Reduction

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## Summary

**Objective:** To evaluate the efficacy of a program of lifestyle change through psychological intervention, combined with pharmacological therapy, for coronary risk reduction in uncontrolled hypertensive patients with overweight and dyslipidemia over 11 months of follow-up.

**Methods:** A randomized controlled trial with 74 patients assigned to three different treatment programs. One group (CT) only received conventional pharmacological treatment. Another group (OG) received pharmacological treatment and participated in a guidance program to control cardiovascular risk factors. A third group (LSPI) received pharmacological treatment and participated in a brief psychological intervention program for reduction of stress levels and changing of eating behavior. The main measure was the Framingham risk index.

**Results:** CT patients presented an average reduction of 18% ( $p = 0.001$ ) in coronary risk; OG patients elevated the risk by 0.8% (NS) and the LSPI group showed an average reduction of 27% on the Framingham risk index ( $p = 0.001$ ).

**Conclusion:** Pharmacological treatment combined with psychological intervention for reduction of stress level and changing of eating behavior resulted in additional benefits in coronary risk reduction. (Arq Bras Cardiol 2007;88(6):624-628)

**Key words:** Hypertension; dyslipidemias; weight loss; primary prevention; behavioral medicine.

## Introduction

Cardiovascular diseases are the leading cause of death in developed and developing countries<sup>1,2</sup>. Previous studies have shown that the joint approach of treatment with medication and a program of multiple risk factor intervention through educational guidance<sup>3,4</sup> or behavioral intervention<sup>5,6,7</sup> may promote additional benefits on cardiovascular morbidity and mortality rate reduction, compared with pharmacological treatment alone.

This study evaluates the effect of a program of lifestyle change through psychological intervention combined with pharmacological therapy for stress reduction and eating behavior change compared to pharmacological treatment alone and a guidance program for coronary risk reduction in uncontrolled hypertensive patients with overweight and dyslipidemia who underwent treatment for 11 months.

## Methods

**Study design** - The study was a randomized trial designed to compare the effects of a lifestyle psychological intervention (LSPI) for stress reduction and eating behavior change combined with pharmacological therapy with a conventional

intervention for coronary risk reduction lasting 11 months. The 42-week study was conducted at an outpatient hypertension clinic and divided into an 18-week intervention phase and a 24-week result consolidation phase. The team consisted of four physicians, one psychologist and two psychology students. The study protocol was approved by the ethics committee of the Federal University of São Paulo, School of Medicine.

**Sample** - Inclusion criteria were: 1) hypertensive patients under antihypertensive medication who presented mean diastolic blood pressure (DBP) between 90 and 109 mmHg or systolic blood pressure (SBP) between 140 and 179 mmHg in two screening visits taken two months apart and conducted by the same physician; 2) both genders, age 35 to 63 years; 3) body mass index (BMI) 25 to 34.9 kg/m<sup>2</sup>; 4) LDL-cholesterol  $\geq$  130 mg/dL, and HDL-cholesterol  $\leq$  40 mg/dL. Exclusion criteria were patients with history or ECG evidence of myocardial infarction, stroke, peripheral arterial obstruction, kidney failure, diabetes (fasting glucose  $\geq$  126 mg/dL), and BMI over 35 kg/m<sup>2</sup>. Also excluded were patients who scored 7 or higher on the scale for psychiatric disturbance screening<sup>8,9</sup> Self-Report Questionnaire 20 (SRQ 20), were intellectually impaired, had a history or current diagnosis of psychosis, or were alcohol (serum gamma-glutamyl transferase activity was assessed as a marker of alcohol consumption) or drug addicts.

Consent was obtained from every patient after oral and written information was given. A centralized computer

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program randomly distributed patients into three groups: the conventional treatment group (CT, n = 21), orientation group (OG, n = 29), and lifestyle psychological intervention group (LSPI, n = 24).

Patients were duly informed that they could not miss more than three visits throughout the study, whether medical consultations or group interventions.

Eligibility for participation in the study was evaluated in hypertensive patients belonging to a cohort that was a representative sample of the clinic population.

The psychological intervention and the orientation program were developed by a therapist other than the one who evaluated the patients. Both were documented in manuals for reference during the study. Study sample was formed as follows: 82% of the patients were women and 38% were white; mean age was 50 (8.5) years; mean systolic and diastolic blood pressures were 136 (15) and 87 (11) mmHg, respectively (as documented by ambulatory blood pressure monitoring – ABPM); mean BMI 28.4 (3.4) kg/m<sup>2</sup>; mean LDL-C 138.6 (29.6) mg/dL; mean HDL-C 42.3 (10.5), 55% suffered from stress, 80% were considered physically inactive, and 5% were smokers.

*Evaluation methods and procedures* - The following parameters were measured at baseline and between weeks 18 and 42: serum total cholesterol, high-density lipoprotein cholesterol and triglyceride concentrations (evaluated by enzymatic technique), low-density lipoprotein cholesterol (according to Friedewald's formula), body mass index (BMI - kg/m<sup>2</sup>), creatinine (colorimetric evaluation), ambulatory blood pressure monitoring (ABPM- Spacelabs, model 90207, Ecafis), glucose test (venous blood was drawn after an overnight fast) and ECG.

The following parameters were evaluated at baseline and on week 42: Framingham risk index for each individual (Wilson et al 1998); adherence to antihypertensive medication through an anonymous questionnaire (patients were considered adherent if they reported taking their medication at least five days a week); physical activity (those who responded a brief questionnaire as practicing three times a week for at least 30 minutes were considered physically active); Stress Symptom Inventory (SSI) (Lipp et al 1994), and smoking habits (examined with a brief questionnaire who considered any cigarette smoked during the last month).

Patients with LDL-C  $\geq$  160mg/dL received a simvastatin prescription.

*Conventional treatment (n=21)* - All patients were monitored in the conventional manner by the same doctor every two to three months. For all groups the aim was to reduce systolic and diastolic blood pressures to levels below 140 and 90 mmHg, respectively. Overweight or hypercholesterolemic patients were treated according to the normal clinical practice.

*Orientation group (n=29)* - In addition to conventional treatment, patients participated in a Guidance Program conducted by a psychologist. This program was developed to inform patients about cardiovascular risk factors and their associations with coronary disease and to stimulate lifestyle changes in two phases. In the *intervention phase*

the patients received information during 18 weekly 60-minute sessions. A maximum of 10 participants was allowed per session. Information on hypertension, adherence to pharmacological treatment and coronary disease, cholesterol, alcohol consumption limits, smoking, salt restrictions, stress control, weight control and sedentary lifestyle were included in the program. In the *result consolidation phase* the same information was emphasized during 60-minute sessions held once a month over six months.

*Lifestyle psychological intervention group (n=24)* - In addition to conventional treatment, all patients participated in a brief dynamic psychological intervention (Hobbs 1996, Sifneos 1989), planned in advance and conducted by the same psychologist. The goals were: 1) to provide the same information given to the OG group; 2) to increase adhesion to antihypertensive treatment, to reduce stress levels, weight loss of at least 5% of BMI (Hutton et al 2004), and walk at least three times a week for 30 minutes; 3) to identify and approach psychological conflicts involved in the difficulties of changing lifestyles and reaching the goals above.

The *intervention phase* took place during 18 eighteen 60-minute meetings held once a week as with the OG. Three groups of eight patients were formed. Based on the group work, common stress generation factors were identified so as to provide proper guidance. Psychological issues involved in excessive food intake and sedentary lifestyle were likewise addressed. Each patient committed to goals of stress and weight reduction and physical activity increase.

The *result consolidation phase* followed, and consisted of 60-minute group meetings held once a month. The objectives were to maintain the newly acquired behavior patterns and to reach unachieved goals. Notes were taken after each session for later analysis.

*Statistical methods* - All data were analyzed according to the intention-to-treat principle. We used all available data. For baseline comparisons we used analysis of variance, repeated-measures analysis of variance and Chi-square, whether the data had normal distribution or not. For within-group analyses, paired t-test, repeated-measures analysis of variance or when data had uneven distribution, the Wilcoxon signed rank and Fisher tests were used.

We used the Pearson correlation coefficient for each group to compare initial and final differences of the Framingham risk index, DBP and SBP, and HDL and LDL-cholesterol values. The chi-square test was used to test associations between increased HDL-C levels and simvastatin, physical activity and weight loss.

Only *p* values < 0.05 were considered statistically significant.

## Results

The study sample comprised 74 patients, 5% of whom were smokers. Mean SBP and DBP were 148mmHg and 94mmHg, taken during screening visits.

Six patients dropped out of the study during the first month of treatment (five in the CT and one in the OG). The statistical loss was irrelevant (*p* = 0.729) as 92% completed the study

with no more than three absences.

Sample demographic characteristics at study entry are shown in Table 1. There were no significant differences among the three groups at baseline (Tables 1, 2 and 3), except for triglyceride values, higher in the CT group, and for the greater number of sedentary patients in the LSPI group. Blood pressure values in the Table 2 were obtained by ambulatory blood pressure monitoring (ABPM).

The CT did not achieve SBP and DBP below 140 and 90 mmHg, respectively (Table 2). CT adherence to antihypertensive medication as informed by the patients remained constant at 21%. Within-group analyses revealed reductions in total cholesterol levels of 6% and LDL-cholesterol of 12%, in addition to an increase in HDL-cholesterol of 13% (Table 2). Simvastatin was prescribed for two patients (10%) at baseline and seven patients (33%) at the end of the study ( $p = 0.017$ ). The two smokers continued their habit throughout the study period. The CT group presented a significant reduction of 18% on the Framingham risk index ( $p = 0.001$ ) (Table 3), and 50% of the patients were able to reduce the coronary risk (Figure 1).

The OG group did not achieve SBP and DBP below 140 and 90 mmHg, respectively (Table 2). Within-group comparisons (Table 2) showed that the indices of antihypertensive medication adherence rose from 18% to 24% ( $p < 0.001$ ). There was a tendency for HDL-cholesterol to rise ( $p = 0.066$ ). Simvastatin was prescribed for two patients (6%) at baseline and four patients (13%) at the end of the study (NS). A significant reduction was found in the number of physically inactive patients: 20 patients in the beginning and 12 ( $p = 0.008$ ) at the end. The two smokers continued their habit during the entire study period. Thus, the OG group did not achieve a significant reduction in the Framingham risk index (Table 3).

The LSPI group did achieve SBP and DBP below 140 and 90 mmHg, respectively, but only DBP dropped significantly ( $p = 0.026$ ) (Table 2). Within-group analyses (Table 2) showed that indices of antihypertensive medication adherence rose from the initial 34% to 55% at the end of the study ( $p = 0.002$ ). Total serum cholesterol concentrations dropped 5% as did LDL-cholesterol (11.6%), while HDL-cholesterol rose 10%. Simvastatin was prescribed for two patients (10%) initially and for three (13%) by the end of the study (NS). Body mass index (BMI) was reduced by 5% or more in 50% of the patients, and

75% had become physically active (Table 2). We observed an expressive reduction on the mean percentage obtained in the ISS test (Table 2). LSPI presented a 27% decrease of Framingham risk index ( $p = 0.001$ ) (Table 3) and 75% of the patients had their coronary risk reduced (Figure 1).

From the psychological standpoint, the following aspects were recurrent in all groups: denying hypertension (“why take any medication if I don’t feel anything?”, “my blood pressure is already under control and medication is no longer necessary”); denying excessive food intake (“my purpose is not gaining weight when I eat”, when patients are evidently overweight or obese); aspects related to voracity (eating until there’s an uncomfortable sense of fullness, eating in a hurry to have a second helping); denying obesity (“I’m not obese,

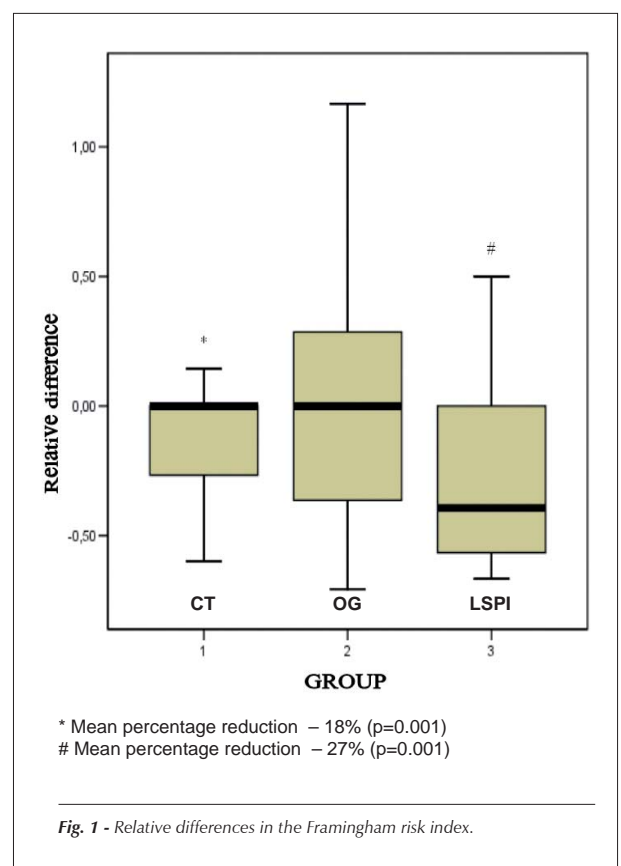


Fig. 1 - Relative differences in the Framingham risk index.

Table 1 - Distribution of demographic characteristics

Characteristics	CT (n= 21)	OG (n= 29)	LSPI (n = 24)	p
<b>Gender (%)</b>				
Female	15 ( 71)	27 (93)	19 (80)	0.122
Male	6 (29)	2 (7)	5 (20)	
<b>Ethnic group (%)</b>				
White	9 (43%)	12 (41)	7 (30)	
Black/mixed race	12 (57%)	17 (59)	17 (70)	0.564
<b>Age (mean ± DP)</b>	48 ± 9.8	50 ± 8.19	53 ± 8	0.143

Table 2 – Cardiovascular risk factors at baseline and after 18 and 42 weeks

		TO	T18	T42	p T0vsT42
<b>SBP (ABPM)</b>	CT (n = 21)	140 ± 16.0	138 ± 14.4	142 ± 14.7	0.67
	OG (n = 29)	136 ± 18.7	135 ± 19.5	140 ± 18.6	0.456
	LSPI (n=24)	132 ± 11.3	130 ± 12.9	127 ± 13.8	0.062
<b>DBP (ABPM)</b>	CT	90 ± 11.1	88 ± 9.0	91 ± 7.6	0.927
	OG	88 ± 13.0	88 ± 13.9	91 ± 13.4	0.58
	LSPI	84 ± 8.2	84 ± 8.6	80.5 ± 8.8	0.026
<b>Total Cholesterol (mg/dL)</b>	CT	204 ± 34	195 ± 22	192 ± 35	0.014
	OG	205 ± 32	208 ± 46	204 ± 38	0.868
	LSPI	217 ± 42	208 ± 40	206 ± 30	0.024
<b>HDL-C (mg/dL)</b>	CT	38 ± 8.9	43 ± 14	44 ± 12.9	0.004
	OG	43 ± 11.5	48 ± 12.8	51 ± 17	0.066
	LSPI	46 ± 11.2	51 ± 10.7	57 ± 13	< 0.001
<b>LDL-C(mg/dL)</b>	CT	133 ± 25	121 ± 21.5	117 ± 36.3	0.003
	OG	136 ± 30	130 ± 32	125 ± 33.7	0.203
	LSPI	147 ± 34	132 ± 33.4	130 ± 31.6	<0.001
<b>Triglycerides (mg/dL)</b>	CT	171 ± 109.4	154 ± 89.3	148 ± 85.6	0.069
	OG	137 ± 64.4	145 ± 88	139 ± 64.8	0.928
	LSPI	120 ± 80	123 ± 55	116 ± 41	0.368
<b>Fasting Glucose (mg/dL)</b>	CT	91 ± 8.1	99 ± 21.2	89 ± 8.2	0.433
	OG	95 ± 12.0	96 ± 10.1	94 ± 15.7	0.654
	LSPI	91 ± 14.3	91 ± 11.4	91 ± 12.7	0.916
<b>Body Mass Index (kg/m2)</b>	CT	27.8 ± 3.5	27.3 ± 2.7	27.3 ± 2.7	0.706
	OG	28.4 ± 3.7	28 ± 3.8	28.2 ± 3.8	0.557
	LSPI	29.0 ± 3.0	27.8 ± 2.8	27.4 ± 2.8	<0.001
<b>Waist / Hip (cm)</b>	CT	0.91 ± 0.06		0.89 ± 0.06	0.332
	OG	0.88 ± 0.06		0.88 ± 0.05	0.722
	LSPI	0.90 ± 0.06		0.86 ± 0.06	0.013
<b>Stress [% on SSI Test]</b>	CT	15.9 ± 22.9		13.5 ± 21.1	0.54
	OG	21.3 ± 26.5		17.5 ± 25.4	0.625
	LSPI	18.4 ± 23.2		6.6 ± 12.5	0.003
<b>Sedentary Lifestyle (n)</b>	CT	14		13	0.187
	OG	20		12	0.008
	LSPI	24		6	<0.001

I'm just slightly overweight"); denying consequences of obesity ("thin people are also going to die, so I'd rather die as a fat person"); denying coronary risk ("I feel you are overstating my risk of heart attack", "if I have a heart attack, I'm sure I'll recover quickly").

As far as stress control is concerned, the following behavior was noted: anxiety and hastiness when performing tasks; strictness when reviewing deadlines and priorities, tendency for over-accumulating tasks and responsibilities, and tendency

to over- or underestimate the ability to solve problems.

Pearson correlation among relative differences observed both in HDL-cholesterol and coronary risk was - 0.61 (p = 0.003) for CT, - 0.46 (p = 0.01) for OG and - 0.62 (p = 0.001) for LSPI. Rises in HDL-cholesterol were related to the introduction or increase of simvastatin dosage (p = 0.017) in the CT, to physical activity increase (p = 0.016) in the OG and to weight loss (p < 0.001) in the LSPI.

Table 3 – Ten-year risk of coronary event

Treatment	Baseline	After 42 weeks	P value
	Mean (%)	Comparative mean Reduction (%)	
CT	9.95	18	0.001
OG	7.65	—	NS
LSPI	9.25	27	0.001

## Discussion

The patients in the Conventional Treatment group achieved an average reduction of 18% on the Framingham risk index. This was correlated to an increase in HDL cholesterol that was associated to the introduction or increase in simvastatin dosage. The importance of low levels of HDL cholesterol as a cardiovascular risk factor was reported in the studies of Planas et al (1980) and Orso et al (1982). Although this therapeutic approach may be effective, associate treatment costs are high and drug side effect risks are increased (Pezzilli et al 2004).

Patients require guidance to change their life habits and increase their adherence to treatment. In the orientation group, however, guidance was unable to change behavior that could reduce the Framingham risk factors. Other studies with a similar methodology and a one-year follow-up have presented controversial results (Ebrahim et al 2000). Other longer studies of this type lasting five years have led to positive results (Ebrahim et al 2000).

Although the final percentage of sedentary individuals in the orientation group was high (43%), the increase in physical activity was associated to the increase in HDL-C. This finding is compatible with the results of the meta-analysis conducted by Thompson et al., in 2003.

The patients in the lifestyle psychological intervention group showed an average reduction of 27% on the Framingham risk index, and 75% of patients showed a reduction in risk. This coronary risk reduction was correlated to an increase in HDL-C, obtained by changes in lifestyle as it was associated to weight loss. Ginsberg et al. (2000) pointed out this effect. Ten percent of the patients went from overweight to normal-weight ( $\leq 24.9$  kg/m<sup>2</sup>), and 20% of the patients initially considered as obese (IMC  $\geq 30$  kg/m<sup>2</sup>) ended the study with a body mass

index classified as overweight (25 to 29,9Kg/m<sup>2</sup>).

Conventional treatment alone seems to have been useful to patients with a profile of adherence to the pharmacological treatment, while medical treatment associated with psychological lifestyle intervention was useful for hypertensive patients with two or more cardiovascular risk factors, such as overweight/obesity and hyperlipidemia, as this strategy was capable of changing a greater number of risk factors, reducing exposure to medication side effects.

The psychological factors that may have contributed are: reduced anxiety in the entire group; addressing the relationship between stress and increasing food intake; identification of voracious eating; addressing maniac defenses such as denying reality, and considering oneself immune to consequences arising from this condition. This was observed as denial of hypertension, excessive food intake and obesity.

This study suggests that patients with abovementioned psychological characteristics need not only a medical approach, but also an emotional approach, as these characteristics may constitute an obstacle to successful treatment.

New studies along this line of investigation may lead to enhanced therapeutic strategies for the different patient subgroups that present moderate to high coronary risks.

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### Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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### Study Association

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