Primary care in the treatment of obesity: a strategy for maintaining long-term weight.

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Context: Poor maintenance of weight loss in obesity.

Objective: To determine if a medical/behavioral program improves maintenance of weight loss; to identify behavioral and psychological factors that predict weight maintenance.

Design: A one- to four- year retrospective study investigating weight status of successful weight losers followed on a monthly basis, or not.

Setting: Primary care clinic.

Subjects: Obese subjects (32 males, 148 females; BMI: 31.1 ± 0.5 kg/m2; weight: 83.1 ± 1.5 kg; age: 47 ± 1 yrs) whose weight and BMI post treatment were 63.7 ± 0.8 kg and 23.9 ± 0.2 kg/m2, half of which attended a monthly follow-up program.

Methodology: Weight, BMI and number of months post-treatment were analyzed according to gender, initial weight, percent of initial weight lost, energy restriction of treatment, percent of weight loss maintained and scores from questionnaires identifying behavioral and psychological traits.

Results: With follow-up, no subject returned to initial weight compared with 29% without; at year 1, 95 \pm 2% of weight loss was maintained compared with 47 \pm 4% at year 1 and at year 4 81 \pm 6% compared with 6 \pm 7%. Improvement in eating behaviors, motivation and the use of food as reward related to better weight maintenance. Subjects who showed initially greater self-confidence, less aggressivity and stress attended the follow-up program which increased their probability of maintaining weight.

Conclusion: Our results confirm that primary care physicians can provide motivation and support during brief but frequent contacts to assist post-obese individuals in maintaining improved eating behaviors and weight.

Key words: Obesity, weight loss, weight maintenance, obesity treatment, weight regain.

Introduction

Obesity defined by a body mass index greater than 27 kg/m2 has reached epidemic proportions in some populations (1,2). It is one of the most preventable conditions and causes of morbidity and mortality (3). It has been estimated that obesity and multiple diet-related factors have contributed to 300,000 deaths every year in the United States in relation to problems such as cardiovascular disease, type 2 diabetes mellitus, high blood pressure and cancer (4). This is equivalent to 1,000 deaths a day, six days a week.

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Despite the reported 15 to 35% of Americans trying to lose weight at any given time of the year (5,6), obesity continues to rise (7).

Up to now, the medical community has shown little interest in the management of this multi-faceted condition. It has been recognized as one of the most common presenting conditions found in family practice yet not adequately treated (3). Reported reasons for this are the reluctance of physicians to counsel on health behaviors due to lack of time, training and support (8), negative attitudes toward obesity, and the poor long-term success rate of treatment (9). Substantial weight loss is obtained with treatments for obesity whether through dietary, means such as the very-low-energy diet (9), or behavioral interventions (10). However, the long-term success in the maintenance of weight loss of various single techniques to reduce weight have generally been poor. Behavioral programs for obesity have shown some limitations in maintaining weight loss accomplished through treatment to the point that weight regain represents a significant clinical problem (11). The search for innovative methods has led to the assembly of a large sample of individuals who have successfully maintained weight loss, in order to identify the variables associated with success (12). This study confirmed that individuals can succeed in not regaining weight. We questioned whether the combinations of techniques, such as behavior modification, diet, exercise and nutrition information, offered after weight reduction within a long-term follow-up may improve long-term outcome of weight-loss therapy. It has been suggested that poor maintenance of weight loss may be the result of a lack of motivation to sustain adherence to new acquired habits and cognitive skills (13,14).

It is feasible for primary care physicians to provide brief counselling to patients with obesity, using behavioral and motivational techniques (3). In order to maximize the number of patients seen, such interventions must be cost-effective and realistic in the amount of time spent with individual patients. We have found that the use of information technology to assess patients' readiness, and eating and lifestyle habits, has allowed us to achieve these goals. Our program (Slim Within, Weight Loss Medical Clinic) had shown efficacy in teaching the skills, and providing support, to weight-losing patients for them to achieve their predetermined weight goals (15). Having helped our patients to lose weight, we offered a follow-up program that implied a monthly visit to our clinics to assist them in maintaining their weight. In order to evaluate the efficacy of this weight maintenance program, we retrospectively analysed the weight changes of patients who had attended the program, and compared their results to those of patients who chose not to attend. Our results include data from one to four years post-weight loss treatment. Furthermore, we analyzed the results of computerized questionnaires that identified behavioral and psychological factors to see if they predicted weight maintenance. Parts of results have been published in abstract form (16).

Method

One hundred and eighty subjects (31 men and 149 women, ranging in age from 21 to 73 years) who had voluntarily joined a medical/behavioral weight loss clinic (Motivation Medical Weight Control Center) and reached their desired weight, were reassessed one to 4 years post treatment in order to evaluate the effectiveness of attending monthly visits at the clinic for weight maintenance. Their characteristics are given in Table 1. Informed consent was obtained from each subject when weight was reassessed at follow-up.

Initial weight averaged 83 ± 2 kg and body mass index (BMI) 31 ± 2 kg/m2. Initial evaluations included a medical history, physical examination, and fasting blood profile. All subjects had a BMI above 26 kg/m2. They were free of major health problems such as hypothyroidism, uncompensated diabetes, active cancer, severe heart and blood circulation disease, hepatic, renal, pulmonary and cardiac insufficiency that could be aggravated by and/or jeopardize their weight loss and maintenance.

Diet was personalized to meet individual preferences; some were given: a) a Low Energy Diet [4.2 - 6.3 MJ, > 100g of carbohydrates, 1 g of protein/kg of ideal body weight from food and supplemented if desired by protein supplements - (Bariatrix International Inc.®, Lachine, Canada)], b) a Very Low Energy Diet (3.6 MJ, < 40 g of carbohydrates, 1.5 g of protein/kg of ideal body weight from food and/or protein supplements). The choice of diet was determined according to subjects' lifestyle, past experience and expectations. 63% of subjects chose to lose weight with a very low energy diet (see Table 1).

During their first visit, 88 subjects answered a 60 question computerized questionnaire that evaluated eating behavior, motivation, stress, emotional status, and body image. Thirty-two behavioral and psychological traits were identified. These were eating behaviors (speed of eating, leaving food on the plate, response to external food cues, food preferences, alcohol intake, night eating), use of food as comfort in presence of emotional

distress, use of food as reward, reactive hypoglycemia, level of physical activity, motivation to lose weight, life goals, guilt feelings, trust in achieving weight loss, self-esteem, self-confidence, paranoid trends, aggressivity, physical symptoms of stress, levels of perfectionism, viewing things as black-or-white, tendency to dramatize and to exaggerate problems, assertiveness in expressing needs and feelings, state of boredom, solitude, depression. More than 100,000 questionnaires have been answered and the validity of the scoring system confirmed by internal and external validation tests. A personalized printed report was given to each subject, identifying on a scale of 0 to 100 the specific behavior, habits and attitudes to be addressed and improved upon. A 0 score corresponded to a major problem and 100 % to absence of a problem. The report also included the subject's *Mental Weight*® program results, a number in kg which corresponded to the summation of 5 variables, corrected for each individual's ideal body weight. This relates to the maximum weight an individual may theoretically reach if current behavior is maintained. The *Mental Weight*® program was conceived to help a subject identify and relate behavior to the overweight problem. It is a tool that was developed to quantify change in behavior over time just like a scale shows change in body weight. The *Mental Weight*® program is a measure independent of body weight and its change is independent of body weight loss.

This personalized report also included a prescription for the coming month, describing strategies and motivational tools to use in order to change one or two specific habits and self-defeating thoughts related to weight and eating. The habit most easily changed was targeted first in order to ensure success initially and build-up confidence. The motivational tools comprised a series of 15 audio-cassettes called "Slim Within" relating to different habits and attitudes, such as: how to acquire a positive motivation, how to master stress and emotions, how to be more assertive, how to eliminate guilt and perfectionism, etc. Patients were encouraged to listen for 12 minutes per day to the tapes that covered motivational material and techniques applicable to their particular needs. Reading material that described testimonies of obese individuals with deviant behaviours and attitudes was recommended to help identify the psychological blocks responsible for the weight problem, to give motivational strategies, to help master stress and emotions and to build-up self-esteem. Weekly behavioral documents such as a food diary, a personal journal to control emotions, a diary for binge eating, a behavior feedback sheet, a collaboration contract were also provided.

A second self-administered computerized questionnaire was given to identify if psychological factors such as sexual conflicts, fear of success, fear of failure, guilt, self-punishment, fear of sickness associated with weight loss, significant association between food and happiness, being out of touch with one's body, interfered with weight control and blocked the ability to change. The underlying causes of these blocks such as: negative upbringing (rejection, psychological, physical and sexual abuse), and personal failures (financial, marital, sexual, intellectual, professional) were also identified.

Weight loss phase:

During weight loss, patients were first seen by a physician experienced in weight control and behavior therapy and were asked to answer the computerized questionnaires; this visit lasted about an hour. Then the patients were seen weekly for about 15 minutes by the same physician. Weight, blood pressure and pulse were measured. Medical condition was assessed and treatment given if needed. Diet was evaluated, behavior analyzed and strategies suggested; the behavioral documents given as homework were surveyed and goals set for the coming week. A subgroup of 42 subjects completed the computerized questionnaires at the end of the weight loss.

Post weight loss phase:

The patients who reached their weight goal and whose results were analyzed in this study were not taking any medication that would affect weight loss and weight maintenance. They were prescribed a transition and maintenance diet and asked to come back monthly to be seen by the same physician. During the follow-up visit, the physician assessed physical health and vital signs. Behavioral issues were reviewed, feedback about dietary and exercise lapses given, high-risk situations for relapse identified, and support for improving self-image and enhancing motivation provided. The physician would spend about 10 minutes reviewing progress in changing eating and exercise habits since the last visit.

Experimental design of the retrospective study:

To evaluate the long-term effect of the weight loss program and that of the follow-up visits for weight maintenance, weight, number of months after weight loss, gender, initial weight, weight achieved, body mass index, type of diets followed, and scores for computerized questionnaires on behavioral and psychological variables were recorded for each subject presenting themselves at their regular visit to four different Slim Within weight loss medical clinics in Canada between December 96 and March 97. A second group of subjects who had once reached their weight goal following the same behavioral and weight loss program as the first group, but who had not attended the monthly maintenance follow-up program, were identified in two ways to serve as controls: a) when they came back between December 96 and March 97, for consultation concerning weight; b) by telephone, going through the clinic files, using the alphabetical order. Actual weight, number of months since the weight goal was reached, gender, initial weight, BMI, type of diet followed and scores of computerized questionnaires were recorded for these subjects as well.

Statistical Methods

Descriptive statistics were used to compare the outcome between groups. Analysis of variance was used to assess differences in percent of weight loss maintained by attendance at monthly visits, gender, age, initial weight and BMI, duration of follow-up, magnitude of energy restriction of the weight-loss treatment. Scores obtained on initial and post-weight loss computerized questionnaires, and magnitude of change between them were correlated to the percent of weight loss maintained and as predictors for being in the group that chose to attend a follow-up program. Calculations were made using SPSS for MS Windows release 6.1 software package (SPSS Inc., Chicago, IL.). Significant differences were identified at p<0.05. Linear-regression analysis was done using Pearson correlation coefficients. Data in text, figures and tables are presented as mean \pm SEM unless indicated otherwise.

Results

The subjects chosen for this study who had achieved the weight they had initially defined as their goal, did so independently of the severity of the energy restriction used (< 3.3 or > 4.2 MJ/day) and of the inclusion of protein supplements. Mean weight lost was 19.4±1.0 kg and ranged from 6 to 102 kg. It represented 21.6±0.6 % of initial weight, a range of 8 to 53%. The magnitude of weight loss correlated with the initial BMI (r2= 0.807, p<0.05, n= 186). Follow-up visits occurred during a range of one to more than four years. At the time of data collection, mean BMI was 26.4±0.3 kg/m2 which was significantly less than initial BMI (p< 0.05). The BMI of subjects who attended follow-up visits was significantly less than that of those who did not (24.3 compared with 28.6 kg/m2, p< 0.001) and the percent of weight loss maintained was greater (87±3 compared with 28±5%, p< 0.001). Of the subjects who attended the monthly follow-up visits, 98%,100%,90% and 85% had lost more than 10% of their initial weight after 1,2,3 and 4 year post-treatment periods, respectively. Of the subjects who did not attend the monthly follow-up visits, 87%,43%,36% and 27% had lost more than 10% of their initial weight after 1,2,3, and 4 year post-treatment periods, respectively. Table 2 reports BMI and percent of weight loss maintained in both groups of subjects divided into sub-groups according to the number of years post-treatment they were assessed. At year four of monthly follow-up visits, weight, compared to initial weight, ranged from a gain of 7.7 kg to a loss of 100 kg and BMI from 19 to 31 kg/m2. After one year of monthly follow-up visits, only one person had regained weight beyond initial weight, 28 (36%) had maintained the weight achieved post treatment or had lost more weight such that total weight loss was 19±2kg and weight regained 2.4±0.5 kg. Table 3 reports the percent of initial weight lost at post treatment and after 1,2,3 and 4 years of follow-up in subjects attending the monthly visits and those who did not. Percent of initial weight lost did not differ between groups post treatment. Already at one year, without the monthly visits, the percent of initial weight lost was significantly lower than in the group which attended monthly visit. With monthly visits, none had returned to initial weight pre-treatment, compared to 27 (29%) in the group not attending monthly visits.

The percent of weight loss maintained was not affected by the extent of dietary restriction used for weight loss in either group. At year one post-treatment, in the group with follow-up, $87\pm4\%$ of weight lost was maintained in the subjects whose diet was more than 4.2 MJ/d (n=42) compared with $89\pm5\%$ in those whose diet was less than 3.3 MJ/d (n=49) NS; in the group without follow-up, it was $37\pm17\%$ with 4.2 MJ/d (n=7) compared with $55\pm9\%$ with 3.3 MJ/d (n=8), NS. By analysis of variance, there was only an effect of group i.e. attendance to the monthly visit intervention, that significantly increased the probability of maintaining weight loss post treatment (p<0.0001). Initial BMI and weight, age, sex, duration of post-treatment and energy intake during weight loss had no significant effect. There was a 2-way interaction between the number of years post-treatment when data were collected and the energy intake during treatment (p=0.049) indicating a trend for patients and/or therapists to choose less severe energy-restricted diets for losing weight in recent years.

The scores obtained for all the psychological and behavioural variables assessed in the computerized questionnaires given at baseline, before weight loss, were compared between groups to identify if any characteristics were significantly associated with a greater probability of attending follow-up visits and maintaining weight loss. Table 4 shows the scores obtained initially of the variables that were significantly different between groups. The subjects who chose not to attend the follow-up program obtained lower scores that indicated more frequent reports of reactive hypoglycemia, lack of self-confidence, aggressivity and stress, compared to the subjects who later chose to return for monthly follow up. Table 5 shows the variables whose scores significantly improved during the weight-loss treatment in both groups. *Mental Weight®* program results decreased in both groups. Eating behaviors, use of food as comfort, motivation and weight loss expectations improved in both groups. Reactive hypoglycemia, trust in achieving weight loss and levels of stress which showed lower scores in the group that chose not to attend follow-up, improved significantly only in that group. Level of depression also only improved in that group. There were improvements in scores for using foods as a reward and in response to emotional distress and reports of boredom only in the group who attended the follow-up program.

There were no significant correlation between the scores of all the variables assessed initially before weight loss and the percent of weight loss maintained. However, the scores obtained post-weight loss for eating behaviors and reward with food correlated positively with the percent of weight loss maintained (Figure 1A and B). Motivation nearly reached significance (p=0.06). We performed stepwise multiple regression analysis with percent of weight loss maintained as dependent variable and eating behaviors, reward with food and motivation as independent variables and found that eating behaviors and motivation explained 39% of the outcome (r=0.626, p=0.0001, n=42).

The changes in scores between the two questionnaires performed before and after weight loss were also correlated with the percent of weight loss maintained. We found a significant correlation with the following variables: change in eating behaviors (r=0.324, p=0.036); change in feelings of boredom (r=0.362, p=0.018); change in *Mental Weight*® program (r=-0.321, p=0.038); change in weight goal (r=-0.411, p=0.008). We performed stepwise multiple regression analysis and found that a decrease in weight loss expectations to more realistic goals (Figure 2A) and an improvement in feelings of boredom (Figure 2B) explained 26% of the variation in the percent of weight loss maintained.

Discussion

Obesity has been considered a refractory and chronic condition, the general perception being that all medical treatments have a failure rate of up to 95% after 5 years (17). The major finding of this study is that adherence to monthly visit follow-ups that provide brief behavioral, motivational, nutritional and exercise counselling by primary care physicians dedicated to the treatment of the obese person, is a significant factor for sustaining newly acquired habits and cognitive skills. Primary care physicians are privileged persons to diagnose and treat the obese persons. Their advice and support can influence significantly the efforts of the obese in sustaining behavior changes for a healthier lifestyle and weight. With the use of information technology, self-help tools (books, audiocassettes), and reinforcement through brief and repeated contacts, our data indicate that patients can succeed in losing weight and maintaining weight loss.

This study confirms the findings of other studies (13,14) that suggest that long-term follow-up contacts using a multicomponent approach is crucial to the success of obesity treatment. We found that a once-a-month visit to a medical clinic of a 10-minute duration, on the average, can suffice to help patients maintain motivation and newly acquired habits. Others (13,14) have shown that maintenance strategies such as small group boosting sessions, client-therapist contact by mail and telephone also have succeeded in helping maintaining weight.

This study stresses the importance of motivation which can be induced, and increased during weight loss and sustained through repeated contacts with medical therapists to achieve weight maintenance. Furthermore, weight was maintained in subjects independently of whether it was lost using severe or moderate energy restrictions. This finding challenges the belief that rapid weight loss with protein sparing fast decreases the probability of maintaining weight loss in the long term because of its effect on metabolic rate, or absence of effect on eating behaviors (18). Weight regain after weight loss has been related to the magnitude in the decrease in resting energy expenditure at the end of a severe energy restriction (19). A low ratio of fat to carbohydrate oxidation i.e. as high respiratory quotient (20,21) especially at the end of a very low energy diet, has also been associated with weight regain (22). As reported by others (23,24) we found no significant effect of gender and age on weight maintenance. Although the heavier patients lost more weight, initial body weight did not predict better or worse

weight maintenance (25). An increase in the cognitive restraint scores during dieting has been suggested among psychological variables, as predictors for successful weight maintenance (26). Less probability to maintain weight loss was also observed in women with a history of dieting (19). These women were also characterized by greater preoccupation with weight and body shape.

We have compared one group of obese subjects who had successfully lost weight and chose to continue to be seen in our medical clinics to another group of obese subjects who achieved the same weight loss but never returned to our clinics. Because the subjects who did return maintained better weight, we analyzed the questionnaires and the psychological data collected from these patients before and after weight loss and found significant differences between the answers and the traits of both groups. The differences may provide insight as to what characterizes post-obese subjects more at risk for weight regain and in need of support to achieve permanent changes in eating behaviors and attitudes. We found that the subjects with the best scores in eating behaviors and motivation obtained at the time when their desired weight was achieved, predicted 39% of the variation in the maintenance of weight loss. Those who, during weight loss, improved significantly their state of boredom and decreased their expectations in regard to the weight goal also maintained weight loss. Among the variables that characterized the subjects who chose to visit our clinics for support after weight loss, we found better self-confidence, less stress and aggressivity and less frequent reactive hypoglycemia. The latter may partly explain greater food consumption to counteract this symptom.

Our results indicate that obese subjects who successfully lose weight and maintain weight loss over time show personality, behavioral and psychological traits that differentiate them from subjects who regain weight after weight loss. Computerized questionnaires to identify those traits and continuous support from physicians to induce permanent changes in eating behaviors and motivation increase the probability of the maintenance of healthy weight in obese subjects who achieve weight loss successfully. Furthermore, the fact that only 14% of all dieters regained as much or more of the weight lost is encouraging and supportive of comprehensive weight loss programs.

We conclude that a combined behavioral and medical program using information technology to convey exercise and nutritional information results in sustained weight maintenance over a 4 year period, when offered for brief visits on a monthly basis.

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Table 1. Subject Characteristics

	who monthly visits	attended follow-up		not attend follow-up	P
n	15M, 75F		16M, 74F		
age (yr)	$46 \pm 1*$		48 ± 1		NS
Initial weight (kg)	84 ± 2		83 ± 2		NS
Initial BMI (kg/m2)	31.2 ± 0.7		31.0 ± 0.6		NS
Post treatment weight (kg)	63 ± 1		64 ± 1		NS
Post treatment BMI (kg/m2)	23.6 ± 0.2		24.1 ± 0.3		NS
% of initial weight lost	23 ± 1		21 ± 1		NS
Treatment diet 3.6 MJ (n)	48		66		
Treatment diet 4.2 MJ (n)	42		26		

Table 2.

	With follow-up		Without follow-up			
Post	n	BMI	% of weight loss maintained	n	BMI	% of weight loss maintained
one year		23.9 ± 2.7**	C		$27.8 \pm 4.9*$	C
two years	16	24.0 ± 2.4	81 ± 17	26	28.6 ± 5.0*	40 ±34*
three years	10	23.6 ± 1.8	77 ± 21	13	28.9 ± 3.5*	14 ± 51*
four years	20	25.4 ± 4.1	81 ± 50	29	28.7 ± 4.4*	9 ± 60*

^{*} means \pm SEM

$$2.9 \pm 2.2$$
 90 24.3 ± 2.9 87 ± 30 92 $28.5 \pm 4.6*$ $28 \pm 49*$ (all subjects)

Table 3. Percent of initial weight lost

	Post-wt loss Rx	with follow-up	Post-wt loss Rx	without follow- up
at yr 1	(44) 21.4 ± 1.0**	20.0 ± 1.0	$(24)\ 23.0 \pm 8.7$	11.7 ± 8.2*
at yr 2	$(16)\ 20.3 \pm 1.8$	16.5 ± 1.9	$(26)\ 19.8 \pm 7.6$	$7.6 \pm 8.8 *$
at yr 3	$(10)\ 22.7 \pm 3.8$	18.5 ± 4.3	$(13)\ 19.1 \pm 1.9$	$4.1 \pm 8.4*$
at yr 4	$(20)\ 27.4 \pm 3.0$	23.2 ± 3.6	$(15)\ 21.0\pm2.1$	$4.4 \pm 14.0*$
at 2.9 ± 2.2 yr	(90) 22.6 \pm 9.7	20.1 ± 10.6	$(92)\ 20.8 \pm 8.5$	7.1 ± 10.6*
(all subjects)				

() = number of subjects per group

 $Table \ 4. \textit{Mental weight} \& program \ and \ scores \ of \ behavioral \ variables \ that \ differed \ significantly \ between groups \ before \ weight \ loss$

	with follow-up (n=39)	without follow-up (n=49)	p
Mental Weight® program (kg)	$78 \pm 4*$	88 ± 3	0.051
Reactive hypoglycemia %	93 ± 2	86± 3	0.038
Trust in succeeding %	69 ± 4	55 ± 3	0.009
Aggressivity %	62 ± 3	54 ± 3	0.025

^{*} P=0.001 vs corresponding values observed with follow-up

^{**} means \pm SD

^{* =} p<0.001 vs post-weight loss treatment and vs with follow-ups

^{** =} means \pm SEM

Table 5. *Mental Weight*® program results in kg and scores of behavioral variables that improved significantly during the weight-loss treatment in both groups.

	with follow-up (n=21)			without follow- up (n=21)		
	Initial	post- weight loss	p	Initial	post-weight loss	p
Mental Weight® program (kg)	81 ± 6**	66 ± 4	0.012	90 ± 5	74 ± 4	0.0007
eating behaviors	55 ± 2	73 ± 3	0.0003	52 ± 3	66 ± 3	0.001
reactive hypoglycemia	92 ± 3	93 ± 3	NS	86 ± 5	99 ± 1	0.013
food as comfort	61 ± 4	79 ± 4	0.007	62 ± 6	74 ± 5	0.016
motivation	76 ± 4	87 ± 2	0.006	70 ± 3	82 ± 4	0.002
goals in life	59 ± 6	72 ± 5	0.051	58 ± 6	73 ± 5	0.016
trust in succeeding	72 ± 6	75 ± 4	NS	$48 \pm 5 *$	61 ± 4*	0.018
stress	76 ± 2	80 ± 2	NS	70 ± 2	81 ± 3	< 0.0001
depression	83 ± 5	89 ± 3	NS	83 ± 5	93 ± 3	0.007
food as reward	51 ± 5	66 ± 5	0.027	42 ± 5	51 ± 5	NS
motivational level	54 ± 3	64 ± 3	0.031	53 ± 2	58 ± 3	NS
boredom	88 ± 4	98 ± 1	0.024	98 ± 2	95 ± 2	NS

^{*} p = <0.05 vs corresponding value in the group with follow-up

 $^{* =} means \pm SEM$

^{**} means \pm SEM