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## THE EFFECTS OF PREVENTIVE COUNSELING FOLLOWED BY REMOTE SUPPORT VIA TELEPHONE ON THE MOTIVATION TO CHANGE LIFESTYLE IN PATIENTS WITH HIGH AND VERY HIGH CARDIOVASCULAR RISK

<i>Aim</i>	To evaluate effectiveness of preventive telephone counseling with a nutritional component and distance support for three months with respect of motivation for lifestyle modification in patients with high and very high cardiovascular risk (CVR).
<i>Material and methods</i>	This prospective, controlled, randomized clinical study in two parallel groups included patients with high and very high CVR (5–9% and ≥10% according to the SCORE scale) who had at least two criteria of metabolic syndrome. Patients were randomized to the main and control groups in a 1:1 ratio with age and gender stratification. The main group received comprehensive preventive counseling with a nutritional component and distant support via telephone once in two weeks for three months (total 6 consultations). Patients of the control group received standard counseling by a health center physician. Patients’ motivation for lifestyle changes was evaluated with a questionnaire at baseline and at 6 and 12 months.
<i>Results</i>	The study included a total of 100 patients (mean age, 59.85±4.47 years, 80% females). At baseline, 81% of patients had high and 19% of patients had very high CVR. Patients of the study groups did not differ in major demographic and clinical characteristics. At 6 month of follow-up, the main group showed a significantly more pronounced positive changes in motivation and healthier lifestyle (50% in the main group vs. 12% in the control group, p<0.01). At 12 months of follow-up, the number of such patients somewhat decreased to 38%. In this process, a vast majority of patients in the control group (82%) continued theoretically considering the expediency of lifestyle modification.
<i>Conclusions</i>	Preventive counseling with nutritional component and further distance support via telephone for three months for patients with high and very high CVR provided increased motivation for healthier lifestyle and positive behavioral changes.
<i>Keywords</i>	Motivation for lifestyle modification; preventive counseling; metabolic syndrome
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Patients with metabolic disorders are exposed to an increased risk of diabetes mellitus (DM), cardiovascular diseases (CVDs) of atherosclerotic origin, and nonalcoholic fatty liver disease [1]. New strategies are needed to reduce the total cardiovascular risk by increasing patient adherence to a healthy lifestyle and controlling the major CVD risk factors (RFs). Combined preventive interventions to change patients’ lifestyles, including training and counseling on healthy eating and being more physically active, are useful tools for managing metabolic disorders [2, 3].

At the same time, poor patient adherence to participation in preventive care programs and incom-

plete implementation of these programs (due to both organizational difficulties and lack of screening of subjects) reduce their efficacy in clinical settings [4]. Patient adherence to treatment and preventive care is mostly determined by personal motivation [5, 6]. It was shown in several studies that the likelihood of higher levels of physical activity and healthier eating behaviors increases if patients are initially motivated to change their behavioral habits [2, 6–9]. The patient’s efforts are more likely to lead to a long-term change in behavior if they are well aware that changes are reasonable and chooses consciously to achieve their goals. A systematic review [1] showed that the success of preventive care programs

depends on the patient's motivation for change rather than the quality of counseling. The authors of that review concluded that active interventions and remote feedback using the phone and electronic communications improve patient motivation and may increase the efficacy of a preventive program.

With this background, the objective of the study was to assess the efficacy of preventive and nutritional counseling and long-term remote, over-the-phone support of motivation for lifestyle changes in patients exposed to high and very high cardiovascular risks after 12 months of follow-up. This is the third publication resulting from this study. Previous publications [10, 11] presented a comparison of changes in behavioral and metabolic RFs and patient awareness of cardiovascular risks between study groups.

## Materials and Methods

A prospective, controlled, randomized clinical trial was conducted in two parallel groups of 100 total patients exposed to high and very high cardiovascular risks (5–9% and  $\geq 10\%$  by the Systematic COronary Risk Evaluation (SCORE) score) having any two metabolic syndrome criteria (waist circumference [WC]  $\geq 94$  cm in male and  $\geq 80$  cm in female patients, blood pressure  $\geq 140/90$  mmHg, triglycerides  $\geq 1.7$  mmol/L, high-density lipoprotein levels  $< 1.0$  mmol/L in male and  $< 1.2$  mmol/L in female patients, low-density lipoprotein levels  $> 3$  mmol/L, fasting glucose  $\geq 6.1$  mmol/L, glucose  $\geq 7.8$  and  $\leq 11.1$  mmol/L after glucose tolerance test).

The exclusion criteria were clinical manifestations of atherosclerosis (coronary artery disease [CAD], cerebrovascular diseases, peripheral atherosclerosis); DM; life-threatening arrhythmias; heart, kidney, and liver failure; cancer; asthma; mental diseases; alcohol; drug and other addictions; patient's inability to fill out questionnaires in Russian.

All patients signed informed consent forms. During the clinical interview, case report forms were filled in for each patient. They included sociodemographic characteristics (sex, age, education, marital status, working status, disability, subjective assessment of income), information on behavioral RFs: dietary habits (consumption of sodium chloride, animal fats, fish, vegetable and fruits, refined carbohydrates), consumption of alcohol, smoking, physical activity. Anthropometric (height, body weight, WC), and blood pressure (BP) (Omron M6 automatic digital tonometer) measurements were taken. Excess body weight and obesity were determined under generally accepted criteria (body mass index [BMI] of 25.0–29.9 and  $\geq 30$  kg/m<sup>2</sup>, respectively). WC  $\geq 94$  cm in male and  $\geq 80$  cm in female patients was described as

abdominal obesity (AO), and  $\geq 102$  cm in male or  $\geq 88$  cm in female patients as severe AO. The target BP level was  $< 140/90$  mmHg. Patients who smoked one or more cigarettes a day were treated as smokers. The individual level of alcohol consumption was estimated in standard doses. One standard dose was 13.7 g (18 mL) of ethanol. Physical activity was characterized using the International Physical Activity Questionnaire (IPAQ) [12]. Metabolic equivalents (MET) were calculated to assess physical activity (1 MET = 3.5 mL O<sub>2</sub>/kg of body weight/min). Fewer than 600 MET minutes/week corresponded to low physical activity.

The motivation for raising awareness and changing a lifestyle was assessed using a questionnaire tested previously [13]. The questionnaire asked about the patient's desire to learn more about their health and treatment/prevention care and to help clarify which aspects of lifestyle and treatment the patient would like to learn more about (nutrition, alcohol use, physical activity, reducing emotional strain and stress, quitting smoking, drug therapy), and assessed the patient's motivation for lifestyle changes and the results achieved during the study.

The included patients were randomized using random numbers and stratified by sex and age (below and above 55 years old) into the intervention and control groups (1:1). One hundred twenty-nine patients met inclusion criteria; 118 of them signed the informed consent forms and were randomized into the study groups (58 patients in the intervention group and 60 patients in the control group). During the 12-month follow-up, 18 individuals discontinued their participation in the study, predominantly due to loss of interest in the program or a change of address. One hundred individuals completed the study and were included in the final analysis. In the control group, patients received standard advice from a health center physician. In the intervention group, patients received preventive care and nutrition counseling aimed at favoring a healthy diet, increasing physical activity, managing overweight and obesity, and achieving the target levels of other RFs. Counseling was provided by a qualified physician who was not attending any of the patients in the study and underwent specialized training in nutrition. Moreover, patients in the intervention group had remote over-the-phone counseling once every 2 weeks during the first 3 months after the inclusion (six consultations in total). The healthcare professional providing remote, over-the-phone consultations was pretrained in motivational counseling (open questions, careful listening, ambivalence, summing up). The remote, over-the-phone consultations included a patient survey about the patient's health in the previous period (especially nutrition), clarified the most relevant questions for the

feedback, provided counseling that took into account the information received, and identified new goals. During each remote consultation, the patient informed the healthcare professional about their general well-being, BP levels, any cases of seeking outpatient or emergency care, hospitalizations, success in quitting smoking (for smokers), and adherence to the recommended treatment.

Follow-up visits in the treatment and control groups were made in 6 and 12 months from the date of randomization.

The independent ethics committee of the State Research Center for Preventive Medicine approved the study protocol in 2015.

Statistical analysis of the study data was carried out in the SAS system (Statistical Analysis System, SAS Institute Inc., USA). The distribution of quantitative traits was analyzed using the Kolmogorov-Smirnov test. Mean values, standard deviations, and standard errors of the mean were calculated for the quantitative variables measured using the interval scale. The rate of detection in percentage or the rate of registration of different rank estimates were determined for categorical indicators measured using the nominal scale and ordinal variables measured using the rank scale, respectively. The causality between variables was estimated using contingency tables and by calculating several modifications of the chi-square test and Cramer's contingency coefficients. The Student's T-test was calculated for independent samples in the analysis of intergroup differences measures using the interval scale according to the corresponding formulas. The differences were statistically significant at  $p < 0.05$ .

## Results

Sociodemographic, clinical, and behavioral characteristics of patients in the treatment and control groups are given in Table 1. There were more female patients among those included in the study. The educational level of the subjects was high. The absolute majority of patients in both groups were exposed to high cardiovascular risk at the time of randomization, and one in five patients were exposed to very high cardiovascular risk. About 90% of subjects had hypertension; 80% or more had hypercholesterolemia. At the time of inclusion, only 28% of patients with hypertension in the intervention group and 32% in the control group achieved the target BP levels.

The rate of behavioral RFs was high in both groups. The absolute majority of patients in both groups were overweight and/or obese (96% and 94%, respectively). AO was diagnosed in absolutely all patients, severe AO in the majority of subjects (70% and 72%, respectively). Insufficient physical activity was reported in 40% of

patients in the intervention group and 24% in the control group.

With regard to behavioral habits, it should be noted that, at the time of randomization, one in five patients exposed to high or very high cardiovascular risks smoked, and 8% of patients in the intervention group and 2% in the control group regularly consumed alcohol; the mean number of standard alcohol doses in a row did not exceed two doses (see Table 1). Therefore, patients in both groups had a high baseline RF burden and did not differ in main sociodemographic, clinical, and behavioral characteristics.

Table 2 provides data on the assessment of patient motivation to receive medical information during randomization. All subjects (100%) expressed their desire to receive more information about high and very high cardiovascular risks, metabolic disorders, treatment, and prevention of complications. The patients were most interested in nutrition, drug therapy, and physical activity. One in three patients in the intervention group and one in four patients in the control group were interested in information on reducing stress. Although one in five included patients smoked, the motivation to receive information on quitting smoking was low. However, the findings demonstrated a generally high motivation to increase medical awareness in patients exposed to high or very high cardiovascular risks.

Table 3 shows the motivation to change a lifestyle in patients in both study groups and the results achieved during the follow-up period.

The majority of patients in both groups had high baseline motivation to improve lifestyle (62% in the intervention group and 86% in the control group;  $p < 0.01$ ); 32% of patients in the intervention group and 12% of the control group said that they would gladly change their lifestyle if they knew how ( $p < 0.05$ ). Only very few patients had achieved changes in lifestyle in both groups before their inclusion in this study (6% and 2%, respectively, with insignificant differences between the groups).

Although patients in the intervention group had lower baseline motivation to improve lifestyle versus the control group (62% vs. 86%, respectively,  $p < 0.01$ ), within 6 months of follow-up, significantly more evident positive changes were observed in the intervention group in terms of increasing motivation and improving lifestyle, in which preventive and nutritional counseling was carried out and long-term remote, over-the-phone support was provided; every other (50%) patient pointed out that they had improved their lifestyle (only 12% in the control group;  $p < 0.01$ ). The number of such patients decreased slightly and was 38% after 12 months of follow-up (Table 3).

**Table 1.** Primary sociodemographic, clinical, and behavioral characteristics of patients in the treatment and control groups at the time of randomization

Parameter	Intervention group (n=50)	Control group (n=50)
<b>Social and demographic characteristics</b>		
Age, mean ± SD, years	59.7 ± 4.9	60.1 ± 3.9
Male patients, %	18	22
Higher education, %	58	68
<b>Clinical characteristics</b>		
Hypertension, %	94	90
Systolic BP, mean ± SD, mmHg	148 ± 19.9	147 ± 18.9
Diastolic BP, mean ± SD, mmHg	85.50 ± 9.5	84.80 ± 8.8
Heart rate at rest, mean ± SD, bpm	71 ± 8.9	70 ± 8.6
Risk of CVCs, SCORE, mean ± SD	6.8 ± 2.7	7.4 ± 5.8
High CVR (SCORE 5–9%), %	78	84
Very high CVR (SCORE ≥ 10%), %	22	16
TC ≥ 5 mmol/L, %	80	82
Hyperglycemia ≥ 6.1 mmol/L, %	4	8
<b>Lipid exchange</b>		
BMI, mean ± SD, kg/m <sup>2</sup>	30.6 ± 4.1	30.3 ± 3.4
Overweight, %	40	40
Obesity, %	56	54
Abdominal obesity, %	100	100
Severe abdominal obesity, %	70	72
<b>Behavioral characteristics</b>		
Smoking, %	22.0	20.0
Regular alcohol consumption, %	8.0	2.0
Number of standard alcohol doses consumed at a time, mean ± SD	2.0 ± 2.1	1.7 ± 1.4
Low level of physical activity, %	40	24

The data are expressed as the mean ± SD or a relative value (%). SD, standard deviation; BP, blood pressure; CVCs, cardiovascular complications; CVR, cardiovascular risk; TC, total cholesterol; BMI, body mass index; SCORE, Systematic COronary Risk Evaluation. The differences between the study groups are statistically insignificant for all parameters.

**Table 2.** Motivation for obtaining medical information from patients exposed to high and very high cardiovascular risks in two study groups during randomization

Issues about which patients wanted to learn more	Intervention group (n=50), %	Control group (n=50), %
Information on high cardiovascular risks, metabolic disorders, treatment, and prevention of complications	100	100
Nutrition	84	64*
Drug therapy	82	72
Physical activity	38	46
Stress reduction	34	24
Smoking cessation	6	4
Alcohol consumption	0	0

\* – p < 0.05.

The absolute majority of patients in the control group continued to think about making changes to lifestyle (78% and 82% in 6 and 12 months of follow-up, respectively); only 12% of patients succeeded in this direction at both stages of follow-up.

A lower percentage of patients with low physical activity in the intervention group versus the control group is an example of better RF management with preventive counseling with remote, over-the-phone support (Figure 1). The IPAQ questionnaire revealed that the proportion of sedentary patients decreased significantly in the intervention group at 6 and 12 months of follow-up; there were no such trends in the control group.

## Discussion

The study revealed high baseline motivation to obtain medical information and improve lifestyle in patients exposed to high and very high cardiovascular risks. That may be due to the fact that patients were enrolled in a health center where they sought medical advice on their own and were initially more responsible for their health.

The study showed that in-depth preventive and nutritional counseling and further remote, over-the-phone support within 3 months increased motivation for improving lifestyle, led to positive behavioral shifts, and improved RF management, based on the follow-up

**Table 3.** Changes in motivation to improve lifestyle in patients exposed to high and very high cardiovascular risks in the study groups over the follow-up period

Attitude to lifestyle improvement	Intervention group (n=50), %			Control group (n=50), %			pΔ between groups	
	Baseline	In 6 months	In 12 months	Baseline	In 6 months	In 12 months	In 6 months	In 12 months
Not ready to improve lifestyle	0	0	0	0	2	0	<0,01	<0,05
I often think that I need to improve my lifestyle	62	40	46	86	78	82		
I would improve my lifestyle if I knew what to do	32	10	16	12	8	6		
I wanted to and have already improved lifestyle	6	50	38	2	12	12		



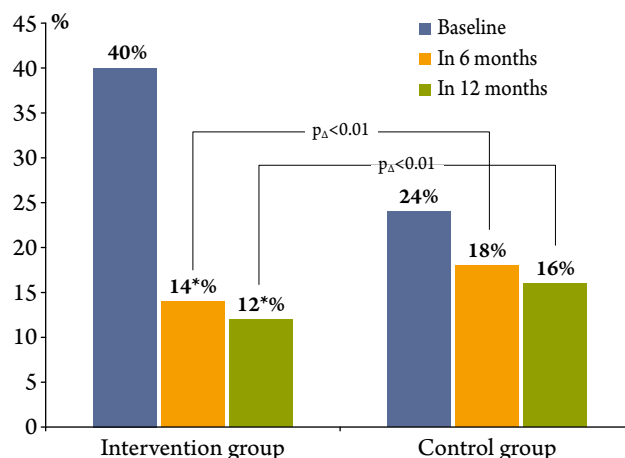
results. The efficacy of training has been shown in several studies. For example, Livia et al. [6] assessed changes in motivation to improve lifestyle in overweight/obese patients during active preventive care that combined a healthy diet and increased physical activity. At baseline, patients were willing to improve their lifestyle. The results of the study showed that, by the end of follow-up, patient motivation, adherence to new healthier habits, and increased physical activity, in particular, increased.

Information technology solutions can be useful tools for increasing patient motivation. Preventive care programs using remote support methods proved useful for managing behavioral RFs [1]. The most evidence in remote counseling has been gathered for over-the-phone interventions. For example, in the most recent systematic review with meta-analysis to estimate the efficacy of interventions to manage behavioral RFs in patients with coronary heart disease (CHD) [14], of 25 studies using at-home preventive interventions, 14 studies used only phone calls, and the other 2 studies used a combination of phone calls and messaging via the Internet. Nine of these studies showed statistically significant improvements in the estimated parameters in the intervention groups.

The comparison of different support methods (e.g., intensive, active over-the-phone counseling and regular emailing) showed that over-the-phone counseling was more effective – that is, real-life communication between patient and healthcare professional is more beneficial. Methods of increasing motivation to improve lifestyle and seek medical care using remote technologies and personalized feedback were shown to be effective in different patients, patients with metabolic syndrome and patients with confirmed CVDs in particular [15, 16].

The study had some limitations: the study sample is a particular population of patients who sought medical advice at health centers on their, often had higher baseline motivation to improve lifestyle, and, thus, differed from other patients exposed to high and very high cardio-

**Figure 1.** Proportion of patients with low physical activity according to IPAQ in the study groups during the follow-up period



\*, differences within a group in 6 and 12 months,  $p < 0.001$ ;  $p_{\Delta} < 0.01$ , differences between groups in 6 and 12 months of follow-up.

vascular risks. Another limitation of this study could be the small size of the intervention and control groups (50 patients each).

## Conclusion

The study showed high motivation to obtain medical information and improve lifestyle in patients exposed to high and very high cardiovascular risks. It was established that in-depth preventive and nutritional counseling and 3-month remote, over-the-phone support of patients exposed to high and very high cardiovascular risks increased motivation to improve lifestyle, led to positive behavioral shifts, and improved RF management, based on the follow-up results.

*No conflict of interest is reported.*

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