

## Evaluation of the effectiveness and safety of the "Reflexology method for reducing excess body weight and body shaping (Mukhina MM)". Post 2:

### Dynamics of the health status of patients

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The reflexology method for reducing excess body weight and body shaping (Mukhina M.M.) consists in correcting the psychoemotional and physiological state of overweight persons using auricular and corporal reflexotherapy in combination with a reduction diet (against the background of leveling the motivational and behavioral characteristics of eating behavior personality) [4, 9, 10].

Previously, we have substantiated the criteria for assessing the effectiveness and safety of this method [2]. A previous publication [3] was devoted to the study of the effectiveness of the method. Since the main indicators of the safety of the method is the absence of deterioration in the state of health of patients against the background of its application, the purpose of this study was to study the main indicators of the health of patients in accordance with our proposed criteria for assessing the safety of the method under study.

### Materials and methods

The study was carried out on the basis of the Federal Scientific Clinical and Experimental Center for Traditional Methods of Diagnostics and Treatment of the Federal Service for Healthcare of the Russian Federation (FNCECTMDL of Roszdrav) in the period from April 14 to October 17, 2005 (a total of 5 reflexotherapy sessions). The study group consisted of 33 people, including 30 women and 3 men. The age of the patients ranged from 19 to 60 years and was less than 20 years in 1 patient, from 21 to 30 years - in 8, from 31 to 40 years - in 10, from 41 to 50 years - in 9, from 51 to 60 years - in 6 patients. The average age of patients in the study was  $38.3 \pm 3.9$  years. The duration of observation of one patient averaged  $158.1 \pm 12.3$  days.

In accordance with our proposed criteria [2], to objectify the data obtained in order to assess the safety of the studied method were used: 1) physical examination of patients; 2) diagnostic method of electropunctural diagnostics (EPD) according to the method of R. Voll (to assess the functional state of organs and body systems); 3) dispersion mapping method using the CardioVisor-06s device (to assess the functional state of the myocardium); 4) the method of spirometry; 5) psychological research (according to the Spielberg-Khanin reactive and personal anxiety scales, as well as the SAN test - well-being, activity, mood).

Research according to R. Voll's method, spirometry, psychological testing and physical examination were performed in patients before each session of IRT (4-5 times in total). All the results in the article are given in absolute numbers, since with a small number of objects of observation, the presentation of data using relative indicators (shares, percent) reduces the reliability of the results.

### Research progress and results

In the course of the study, the dynamics of changes in the main indicators of EPD by the method of R. Voll could be assessed in 28 out of 33 patients, since 5 patients underwent this examination only once (Table 1).

When analyzing the results of the examination by the method of R. Voll, 1.5 and 3 months after the start of the study, the majority of patients showed a deterioration in mean values by

most meridians, which can be explained by the exacerbation of latent pathology against an unfavorable premorbid background associated with a sharp change in eating behavior and metabolism.

After 6 months, the average values returned to the initial values on the gastric meridian; there was an improvement in the average values on the remaining meridians, however, the tendency to lower values compared to the baseline remained, which may be due to the relatively short observation period, during which most of the disturbed metabolic processes could not have time to return to normal. At the same time, the application of the investigated method could be a stress factor for the organism, which requires a longer period of time to overcome.

Table 1

Dynamics of average EPD values according to R. Voll's method in patients compared with initial (n = 28)

Меридианы ЭПД по методу Р. Фолля	Время от начала исследования		
	1,5 мес.	3 мес.	6 мес.
Лимфатической системы	↓↓	↓	↓
Аллергии	=	=	↑
Легких	↓	↓	↑
Сердца, системы кровообращения	↓↓	↓	↓
Толстой кишки	↓	↓↓	↑
Тонкой кишки	↓	↓↓	↑
Поджелудочной железы	↓	↓	↑
Печени, желчного пузыря	=	=	↑
Желудка	↓↓	↑	=
Почек	↓	↓	↑
Мочевого пузыря	↓↓	↓	↓
Нервной дегенерации	↓↓	↓	↑
Органной дегенерации	↓	↓	↑
Суставной дегенерации	↓↓	↓	↑
Соединительно-тканной дегенерации	↓↓	↓	↓
Кожной дегенерации	↓↓	↓	↓

↓ – ухудшение, ↑ – улучшение, = – возвращение к исходным значениям

Of the 33 patients included in the study, 9 people never showed up for an appointment with a therapist, i.e. the state of health of these patients could not be assessed using physical examination methods. The dynamics of the state of the remaining 24 patients during the study was assessed by comparing the clinical data with the EPD data according to the method of R. Voll. As a result: subjective improvement of the general condition in the course of the study was noted by 18 out of 24 people, 4 patients did not notice the dynamics, and 2 - noted a deterioration in well-being.

The dynamics of changes in the main subjective complaints of patients during the study is presented in Table 2.

Thus, in the course of the study, many patients had complaints characteristic of asthenia syndrome (weakness, fatigue - in 12 people, emotional lability - in 9, sleep disturbances - in 4), and most patients subjectively noted an improvement in their condition at the time of the end of the study, especially in the emotional sphere. Quite often, patients complained of headaches of various nature (10 people), and during the study, there was no positive dynamics in

patients with migraine-like (2 people) and tension headaches (4 people). By the end of the study, 2 patients with arthrosis subjectively noted a significant decrease in the intensity of pain, which can be associated with a decrease in the load on the musculoskeletal system during weight loss.

During the study, complaints of patients from the gastrointestinal tract were widespread (nausea, discomfort in the epigastric region - 8 people, chronic constipation - 12 people). Moreover, a positive trend was observed only in half of patients with complaints of discomfort in the epigastric region and a third of patients with constipation. At the same time, 4 patients developed nausea, a feeling of discomfort in the epigastric region, 6 patients showed an increase or appearance of constipation, and 4 - the appearance of flatulence.

table 2

Distribution of patients depending on changes in the main clinical complaints (n = 24)

Основные жалобы пациентов	Улучшение	Без изменения	Ухудшение	Появление
Слабость, утомляемость (n = 12)	7	4	1	0
Эмоциональная лабильность (n = 9)	6	3	0	0
Нарушения сна (n = 4)	2	2	0	0
Периодические головные боли* (n = 10)	4	5	1	1
Эпизоды головокружения* (n = 6)	1	4	1	0
Боли в крупных суставах (n = 5)	2	3	0	1
Боли в различных отделах позвоночника (n = 3)	1	2	0	0
Дискомфорт в эпигастральной области, тошнота (n = 8)	4	4	0	4
Боли в эпигастральной области (n = 2)	1	1	0	2
Боли в области правого подреберья (n = 4)	2	2	0	0
Изжога, отрыжка после приема жирной, жареной пищи (n = 4)	4	0	0	1
Запоры (n = 12)	4	5	3	3
Метеоризм (n = 2)	0	2	0	4

\* The table shows the total number of patients who complained of headaches and dizziness, without taking into account their nature and etiology.

When interviewing patients who noted worsening of the gastrointestinal tract during the study, it was found that they did not follow the recommendations for taking a sufficient amount of fluids, enterosorbents and carminatives. As a result, in these patients, we observed a pronounced symptom complex of autointoxication, provoked, in the opinion of the method developers, by intense lipid catabolism. The distribution of patients depending on the dynamics of the physical examination data is presented in Table 3.

Against the background of the application of the method under study, we observed a positive dynamics of blood pressure figures and a decrease in the frequency of episodes of its increase in patients with essential hypertension, as well as in patients with periodic increases in blood pressure against a background of various factors.

(Table 4).

In order to study the influence of the investigated method on the course of common somatic diseases, a group-by-group analysis of the dynamics of the state of patients with various chronic diseases of the digestive system, respiration of the urinary system was carried out. In the course of the study, the presence of chronic somatic diseases in patients was confirmed using EPD according to the method of R. Voll, which, along with clinical data, made it possible to assess the dynamics of the course of diseases.

To assess the effectiveness of the studied technique in patients with chronic diseases of the gastrointestinal tract, out of 24 patients, 2 patients with duodenal ulcer, 6 patients with chronic gastritis, 3 patients with chronic non-calculous cholecystitis and 1 patient with chronic pancreatitis were selected.

During the study, we observed exacerbations of diseases of the gastrointestinal tract in only 3 patients with chronic gastritis in the form of the appearance of a constant sensation of discomfort and hunger pains in the epigastric region of varying intensity, which were stopped by taking antacids. However, on the basis of EPD in these 3 patients at the end of the study, there was no evidence for "dysfunction of the stomach". The study did not reveal a negative effect of the studied method on the course of diabetes mellitus (1 patient), bronchial asthma (2 patients), chronic bronchitis (3 patients), chronic sinusitis (4 patients), urolithiasis (2 patients), chronic pyelonephritis ( 2 patients) and glomerulonephritis (1 patient).

Table 3

Distribution of patients depending on the dynamics of physical examination data (n = 24)

Симптомы, признаки	Улучшение	Без изменения	Ухудшение	Появление
<b>Кожный покров</b>				
Витилиго (n = 2)	0	2	0	0
Стрии на коже живота (n = 5)	0	5	0	0
Аллергическая сыпь на лице (n = 3)	2	1	0	0
Отеки в области голеней (n = 13)	3	10	0	0
<b>Опорно-двигательный аппарат</b>				
Ограничение объема активных и пассивных движений в крупных суставах (n = 5)	0	5	0	0
Ограничение объема активных и пассивных движений в различных отделах позвоночника (n = 2)	0	2	0	0
<b>Система органов дыхания</b>				
Сухие хрипы в нижних отделах легких на фоне жесткого дыхания (n = 3*)	0	3	0	0
<b>Система органов кровообращения</b>				
Расширение границ относительной тупости сердца влево (n = 3**)	0	3	0	0
Глухость сердечных тонов (n = 5)	0	5	0	0
Нарушения ритма сердца (n=5)	0	5	0	0
<b>Система органов пищеварения</b>				
Болезненность в эпигастральной области (n = 7)	3	2	2	0
Болезненность в области правого подреберья (n = 7)	4	3	0	1
Положительные пузырьные симптомы (n = 4)	3	1	0	0
Болезненность при глубокой пальпации в различных отделах толстого кишечника (n = 9)	3	3	3	5

\* 2

the patients had a smoking experience of more than 10 years and suffered from chronic obstructive bronchitis, 1 the patient has suffered from bronchial asthma since 2001.

\*\* patients with GB II stage

Table 4

Patient distribution by baseline BP and episode frequency raising it

Уровень АД и частота эпизодов его повышения у пациентов	Улучшение	Безизменения	Ухудшение
Постоянный повышенный уровень АД* (n = 3)	3	0	0
Регулярные повышения АД без четких провоцирующих факторов (n = 4)	3	1	0
Эпизоды повышения АД под воздействием стрессовых факторов на фоне исходных нормальных показателей (n = 5)	1	4	0

\* SBP> 140, DBP> 90 mm Hg. Art.

When analyzing the data of a spirographic study carried out in 25 patients from

33 (8 patients performed the study once), we did not note the dynamics of indicators of external respiration function in patients with ventilation disorders caused by chronic respiratory diseases (2 patients with chronic obstructive bronchitis) and bronchial asthma (2 patients). At the same time, there was an improvement in spirometry indices with a leveling of obstructive disorders in 2 out of 5 patients without a history of diseases of the bronchopulmonary system (Table 5).

Table 5

Distribution of patients depending on the results of spirometric research  
(n = 25)

Вентиляционные нарушения	Улучшение	Без изменения	Ухудшение
Нормальные показатели ФВД (n = 16)	-	16	0
Умеренные вентиляционные нарушения по обструктивному типу (n = 5)	2	3	0
Выраженные вентиляционные нарушения по обструктивному типу (n = 3*)	0	3	0
Вентиляционные нарушения по смешанному типу (n = 1**)	0	1	0

\* 2 patients had a smoking experience of more than 10 years and suffered from chronic obstructive bronchitis, 1 patient has suffered from bronchial asthma since 1998.

\*\* The patient has suffered from bronchial asthma since 2001.

In the course of the study, the dynamics of changes in the main indicators of the functional state of the myocardium and the cardiac conduction system [2] was assessed in 29 out of 33 patients, since 4 patients underwent examination on the CardioVisor-06c™ device once. The dynamics of changes in the main indicators of the functional state of the myocardium and the cardiac conduction system in patients according to the results of examination on the CardioVisor-06c™ device is presented in Table 6.

Table 6

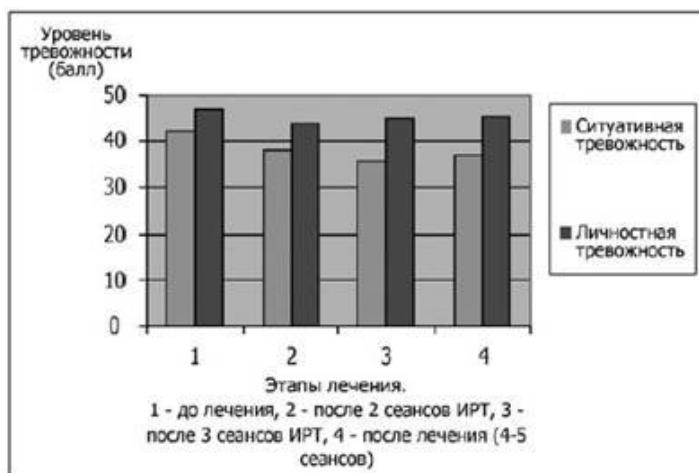
Основные показатели функционального состояния миокарда и проводящей системы сердца	Улучшение	Без изменений	Ухудшение	Появление
Интегральные показатели функции миокарда (n = 29)	9	13	8	-
Интегральные показатели ритма сердца (n = 29)	4	17	8	-
Функциональное состояние миокарда по «портрету сердца» (n = 29)	7	15	8	-
Признаки гипертрофии ЛЖ (n = 4)	2	2	0	1
Напряжение механизмов адаптации (n = 4)	3	1	0	8
Начальные проявления гипоксии миокарда (n = 3)	2	0	1	1
Признаки ишемии различных отделов миокарда (n = 6)	2	3	1	2
Нарушения процессов реполяризации миокарда желудочков (n = 4)	1	2	1	1
Нарушения ритма сердца: тахикардия (n = 8)	7	1	0	0
Нарушения ритма сердца: брадикардия (n = 5)	1	4	0	2
Нарушения AV-проводимости (n = 3)	2	0	1	0

Dynamics of changes in the main indicators of the functional state of the myocardium and the cardiac conduction system in patients according to the results of examination on the CardioVisor-06s™ device (n = 29)

When analyzing the results of examinations of patients using the CardioVisor-06c™ device, it was possible to establish that the majority of patients (13 people) did not show any dynamics of integral indicators of myocardial function and rhythm. Along with this, 9 patients showed an improvement in myocardial function indicators. A similar trend was observed when comparing the data on the state of the myocardium according to the "portrait of the heart", according to which 15 patients had no changes in the myocardium, and 7 patients showed improvement. At the start of the study, signs of left ventricular hypertrophy were detected in 4 patients, including 3 patients with stage II hypertension. It is important to note that in 2 patients with hypertension stage II, based on the data of the CardioVisor-06c™ device,

Deterioration of integral indicators of myocardial function, rhythm and picture of the "heart portrait" was observed in 8 patients. When studying the indicators of myocardial adaptation in these 8 patients, activation of stress mechanisms with a pronounced violation of adaptation mechanisms in combination with the appearance of signs of ischemia in various parts of the myocardium was revealed in 3 patients. Stress, as a generalized nonspecific adaptive response of the body aimed at maintaining homeostasis, in patients was probably triggered by weight loss during the study and was realized through the activation of the neuro-endocrine system with the start of the synthesis of glucocorticoids and catecholamines, the main stress hormones [1].

In the course of the study, it was possible to assess the indicators of psychoemotional status in 28 out of 33 patients who completed the number of questionnaires required for analysis. Statistical processing of the Spielberg-Khanin test results revealed a significant ( $p < 0.05$ ) decrease in the levels of personal and situational anxiety in all patients (Fig. 1).



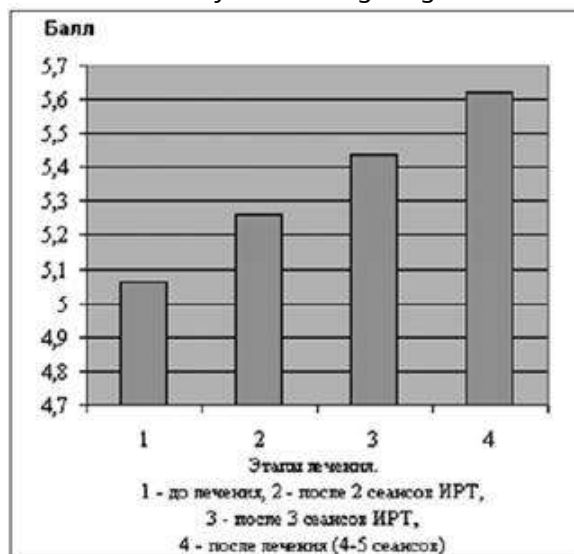
Rice. 1. Spielberger-Hannk test. The dynamics of the state of anxiety in patients during research

According to the results of the SAN test, all patients showed a clear trend towards a gradual improvement in well-being (Fig. 2). At the same time, a significant improvement in well-being ( $p < 0.05$ ) was found already in the middle of the course.

The discussion of the results

Against the background of the application of the method under study, in the majority of patients, we revealed a subjective improvement in their state, especially in the emotional sphere, which was probably associated with an increase in self-esteem during weight loss. The results obtained are in complete agreement with the results of psychological research. The normalization of the psychoemotional state was realized through a decrease in the level of anxiety, an improvement in well-being and mood, and an increase in the levels of activity and performance (Fig. 1, 2). Along with this, in the course of the study, we noted the disappearance of complaints characteristic of asthenovegetative syndrome in the majority of patients.

There was a subjective decrease in the intensity of pain in patients with arthrosis (in the absence of objective dynamics according to the results of EPD diagnostics), which can be associated with a decrease in the load on the musculoskeletal system during weight loss.



Rice. 2. SAN test. The dynamics of changes in the patient's well-being during the study



Against the background of the application of the method under study, we observed a positive dynamics of blood pressure values and a decrease in the frequency of episodes of its increase in patients with essential hypertension and in patients with periodic increases in blood pressure against the background of various factors.

In accordance with the results obtained, in order to objectify the influence of the studied method on the level of blood pressure, in our opinion, it is advisable to conduct an extended statistical study with a large sample of patients with hypertension. According to our observations, this study can be very promising for justifying the expansion of indications for the use of the investigated method in patients with hypertension.

Against the background of the application of the method under study, in half of the patients with chronic gastritis, we reliably recorded an exacerbation of the process, while the patients presented corresponding complaints. We did not observe exacerbations of other chronic diseases of the gastrointestinal tract. In the course of the study, we did not reveal the effect of the technique on the course of diabetes mellitus, bronchial asthma, chronic bronchitis, kidney and urinary tract diseases.

However, to obtain reliable data, more patients are needed. The intensification of lipolysis processes, according to the developers of the method, was reflected in the appearance in patients of a symptom complex of autointoxication (nausea, a feeling of discomfort in the epigastric region, constipation and flatulence), for the relief of the manifestations of which additional prescription of liquid, enterosorbents and carminative agents was required. The nature of the influence of lipolysis on the main metabolic processes requires further clinical and laboratory justification.

On the background of the study, there was an improvement in the skin condition in patients with allergic rashes, which can be explained by a decrease in the alimentary antigen load against the background of adherence to dietary recommendations.

At the same time, the study did not reveal a negative effect of this technique on the ventilation function of the lungs in patients.

#### conclusions

1. Conducted objectification of the results of the application of the method under study in the group patients, consisting of 33 people (in accordance with the research algorithm).

2. Taking into account the results obtained in this study, the developed Mukhina M.M. "Reflexology method for overweight reduction and body shaping" is effective and safe.

3. Taking into account the results obtained in this study, "Method reflexology to reduce excess body weight and body shaping (the method of Mukhina M.M.)" can be recommended for widespread use in practical health care, since as a result of this study, a positive trend has been noted in the condition of patients with metabolic disorders in the body, suffering from hypertension, diseases of the gastrointestinal tract and the musculoskeletal system. In addition, during and as a result of the study, the patients showed a normalization of the psychoemotional state and a decrease in the level of personal anxiety, a stable tendency towards the normalization of well-being and mood, a decrease in personal anxiety, and a significant decrease in the level of situational anxiety were revealed.

4. If it is necessary to obtain scientifically substantiated reliable data on medical the action of the method for each of the specific nosological forms of diseases will require an in-depth randomized study with the number of patients at least 60 (2 groups of 30 patients) for each nosological form of the disease or syndrome.

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