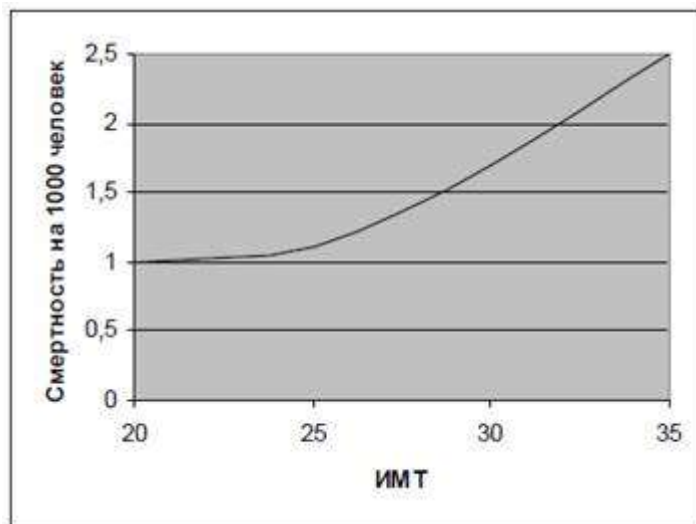


Development of criteria for assessing efficiency and safety  
"Reflexology method for overweight reduction and correction  
figures (Mukhina M.M.) "

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The World Health Organization (WHO) has recognized obesity as a new non-infectious "epidemic of the 21st century" [15]. According to the latest WHO estimates, more than a billion people on the planet are overweight, and among them the proportion of people of working age is constantly increasing, accounting for up to 60% of the adult population [2, 14, 17].

The factor of overweight is well known as a predictor of the development of atherosclerosis, hypertension, coronary heart disease, cerebral circulation disorders, diabetes mellitus and other diseases [1, 2, 10, 11, 13, 16, 17]. At the same time, obesity is already considered as an independent risk factor, which is not inferior in importance to such factors as arterial hypertension or smoking [2, 13, 15-17]. A graphic interpretation of the relationship between body mass index (BMI) and the relative risk of mortality (according to WHO data) is shown in Fig. 1.



Rice. 1. The relationship of body mass index (BMI) with the relative risk of mortality [15]

It has now been proven that a person suffering from overweight, as a rule, cannot independently achieve a steady decrease in weight,

since the motivation inherent in his consciousness of excessive consumption of high-calorie foods is constantly reinforced by the macro- and microsocial environment [3, 14]. The existing conservative methods of obesity treatment (hypocaloric diet, nutritional supplements, increased physical activity, suggestion and coding methods, massage, etc.) are practically ineffective.

The use of surgical methods for weight loss is also limited by their cost and the number of contraindications [4, 6]. Under these conditions, acupuncture (IRT) is considered as the optimal method for correcting excess body weight, allowing, with a minimum number of contraindications, to carry out therapy taking into account the patient's constitution [4, 6, 7]. Our two previous publications are devoted to the following issues: the essence of the new technique for reducing excess body weight and body shaping [6] and the psychoemotional aspects of the impact of this technique on the patient's body [7].

The method of reducing excess body weight and body shaping (the technique of 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 the eating behavior of the individual) [5–7]. The method was approved for medical use by the RF Ministry of Health in 2004 [4], its priority is confirmed by RF patents [8, 9].

A feature of the method is the creation of concretized motives of sustainably eating behavior of a person suffering from increased body weight [5–7]. The essence of the method was published in the open press [6, 7] and is designed as a manual for doctors, approved by the Ministry of Health of the Russian Federation in the prescribed manner [4]. The logistical support of the method is standard for auricular and corporal IRT.

Since the effectiveness of the method was declared by its authors as high, and the results of treatment of patients were very successful, on behalf of the Ministry of Health of the Russian Federation, pre- and post-registration studies of the effectiveness of the Mukhina M.M. method. were 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.

The task of the research was, first of all, to assess the safety, and then to objectify the effectiveness of the method under study. In this regard, at the first stage of research to assess its effectiveness and safety, it was necessary to develop appropriate objectification criteria.

In the course of the research, only those methods and equipment were used that are approved for use in medical practice on the territory of the Russian Federation.

The purpose of this publication is to justify the choice of criteria objectification of the effectiveness and safety assessment of the "Reflexology method for reducing excess body weight and body shaping (Mukhina M.M.)"

Considering that the method of Mukhina M.M. is based on the reflexological effect on the body, which is one of the traditional methods of treatment, to objectify its effectiveness and

safety, a combination of methods of both traditional and academic medicine has been used.

1. In order to assess the effectiveness of the method, all patients within the research systematically (before each IRT session) measured body weight and basic body volumes: chest circumference, waist / abdomen, hips, shoulder and thigh circumference.

2. As one of the main criteria for objectifying dynamics changes in body weight and nutritional status of patients, as well as determining the presence and degree of obesity in the course of the study, we chose the body mass index (BMI) most often used in international practice, or Quetelet-2 index, which is defined as the quotient of the division of body weight in kilograms per body length in meters squared:  $BMI = \text{weight (kg)} / \text{height}^2 \text{ (m)} \text{ [kg / m}^2\text{]}$ .

To assess the change in BMI and corpometry indicators, an individual comparison of the initial indicators and indicators during the study and at the time of the end of the program was carried out with the calculation of the percentage difference and statistical processing of the results.

3. In order to control the dynamics of the objective and subjective state the health of patients, the program included a regular physical examination, which was carried out according to generally accepted methods.

Taking into account the predominant composition of the group of patients with overweight or obesity, special attention was paid to changes in the functional state of the gastrointestinal tract, as well as in the level of blood pressure. We have developed a special form of an individual patient record, in which the therapist entered the anamnesis data (past illnesses and operations, reasons for weight gain) of the patient, as well as the patient's main complaints and the results of examination of organ systems at each appointment (before each IRT session).

Based on the experience gained in this study, it is advisable to note the high information content of the physical examination, which recently, from our point of view, is not always justified, has been replaced by instrumental methods. In addition, this clinical study made it possible to draw attention to the continuity of diagnostic methods of traditional medicine and diagnostic methods of the classical Russian therapeutic school.

4. Considering that the IRT method has a therapeutic effect, falling under the theory of traditional Chinese medicine, in order to objectify the assessment of the functional state of organs and body systems in the research program, it was decided to include the method of electropunctural diagnostics (EPD) by the method of R. Voll. To carry out EPD by the method of R. Voll, an automated computer system "IMEDIS-EXPERT" ("IMEDIS", Russia) was used. EPD was performed using acupuncture points described by R. Voll, grouped by meridians, some of which are used to determine the functions of organs (for example, the meridians of the heart, kidneys), some to determine the functions of systems (for example, the meridians of blood circulation, endocrine), and some to determine state of tissue or metabolism (meridians of connective tissue and fatty degeneration). Results of the

diagnostics were assessed in combination with the data of the physical examination of patients, which made it possible to trace the dynamics of the patient's condition with greater reliability.

5. According to the information received from the authors of the tested method, under its the influence significantly improves the gas exchange function of the lungs. Therefore, the study included spirographic research as a method reflecting the state of the external respiration system. Spirographic research combines the measurement of statistical lung volumes that make up the vital capacity of the lungs, dynamic lung volumes, as well as forced ventilation flows [3].

The analysis of the results of spirographic studies was carried out according to the calculated percent of deviation from the proper values using tables (nomograms) in order to determine the type of ventilation disorders (obstructive, restrictive) and control the dynamics of the state.

6. Given the high frequency of pathology of the circulatory system in persons with overweight, it was considered expedient to conduct a dynamic assessment of the functional state of the myocardium in patients.

The study used the CardioVisor-O6s™ device, the principle of which is based on the calculation and three-dimensional visualization of the electrical activity of the myocardium based on the parameters of the amplitude dispersion of a standard ECG signal from the extremities [12]. The device allows non-invasively and promptly (within 10-15 minutes) to carry out highly sensitive subthreshold monitoring of early functional changes in the myocardium, as well as to detect ischemic myocardial damage with a sensitivity of 90% and a specificity of 63% [12].

7. A very important point in increasing the effectiveness of treatment is taking into account personal psychological characteristics and the attitude of patients to obesity. According to the authors of the methodology, in the process of correcting excess body weight, the psychological parameters of patients, their psychological status, and the structure of the patient's personality are significantly improved [5, 6]. To assess the dynamics of the psychoemotional state of the subjects in the framework of this study, it was decided to use the generally accepted Spielberg-Khanin scales of reactive and personal anxiety and the SAN test - well-being, activity, mood.

Thus, we proposed and substantiated an algorithm for conducting research, and also developed scientifically substantiated criteria for objectifying the effectiveness and safety of the method under study:

- 1) physical examination of patients;
- 2) systematic measurement of body weight (with the calculation of BMI) and basic body volumes (corpometry method);
- 3) EPD according to R. Voll's method using the "IMEDIS-EXPERT" system;
- 4) dispersion mapping method using the CardioVisor device - O6s™;
- 5) the method of spirometry; 6) psychological research (according to scales Spielberg-Khanin and SAN test).

With the help of the criteria proposed in the course of the clinical study,

objectification of the results of the application of the "Reflexotherapy method for reducing excess body weight and body shaping (Mukhina MM)" in a clinical setting was carried out.

The results of the research will be presented in the following publications.

#### conclusions

1. The necessity of the combined application of the methods has been substantiated. traditional and academic medicine to objectify the effectiveness of safety "Reflexotherapy method for reducing excess body weight and body shaping (Mukhina MM)".

2. Criteria for evaluating the effectiveness and safety are proposed. the investigated method.

3. The algorithm of the clinical trial has been compiled.

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