

The Russian Academy of Medical Sciences
Siberian Branch
Scientific Centre for Clinical and Experimental Medicine

Academika Timakova Str., 2
Novosibirsk, 630117

Tel.: (3832) 32-43-39
Tel/fax: (3832) 33-68-22

Of 26.06.00 NO 131-2

Approved by _____
Head physician of the clinic
at the Scientific Centre for Clinical and
Experimental Medicine
Of the Siberian Branch of the Russian
Academy of Medical Sciences
V.B. Barsky

14, June, 2000

Proceedings
Of the clinical testing on application
Of the FRTD-01 Respiration Simulator
by bronchial asthmatic patients

Clinical testing plan on application of the FRTD-01 personal respiration training device in a complex therapy of the bronchial asthmatic patients.

1. Bronchopulmonary system diseases are one of the main causes of decrease in working ability, as well as total disability; especially serious complications are registered in cases of bronchial asthma. According to F. Lieberman and L. Crawford (1986) bronchial asthma ranks third among the main causes of working capacity limitation with patients under 35 and fifth among the serious reasons for such limitation with the patients of all ages on the whole. Approximately 9m of the Americans suffer from bronchial asthma, it accounts for about 90000-500000 days of invalidity, out of which nearly 35000 the patients spend in bed rest. 27m bronchial asthmatic patients visit doctors annually, which makes up around one third of idiopathic hypertension patients and about half of those suffering from diabetes mellitus. P. Barnes (1987) furnishes evidence that bronchial asthma affects 5 to 10% of the English population, mortality caused by this disease rises in industrial countries and, in Australia and New Zealand in particular, bronchial asthma is the most prevalent cause of death among young people. Constant expansion of medicamentous therapy, appearance of new drugs and new methods of physical therapy do not solve the problem of effective cure of these diseases.

In the recent years with the purpose of helping the bronchopulmonary pathology patients, those suffering from bronchial asthma included, various systems of respiratory exercises found widespread application, such as respiratory gymnastics by A. N. Strelnikova, K.P. Buteiko ("volitional liquidation of deep breathing" method), by N.A. Agadzhanian and V.V.Gnevushev (voluntary optimal diminishing of minute respiratory volume), as well as various apparatus methods (hypoxicators, hypercapnicators etc.), separate pranayama complexes by yoga system cure.

It happens not infrequently that, for various reasons, performing of respiratory exercises according to these methods is made difficult, in particular it concerns bronchial asthmatic patients owing to disturbance of the pattern of breathing, presence of obstructive effects and dyspnea. However, as the experience of administering of these methods proved, respiratory exercises have a positive influence on gas exchange and ventilation, cause improvement of respiratory muscles function and can considerably complement basic drug therapy.

In the recent years the FRTD-01 respiration training device and breathing exercises procedure with this trainer found wide application, which presupposes combined respiratory training, i.e. breathing with the hypoxic-hypercapnic mixture under resistance to inspiration and expiration with gradual increase in duration of the expiration phase.

It is assumed that this kind of respiratory exercises can be effectively administered in a complex therapy of bronchopulmonary diseases, bronchial asthmatic patients included.

2. The purpose of testing

- 1) To study the influence of the respiratory exercises with the individual training simulator FRTD-01 on the respiratory system within realization of the complex therapy with the bronchial asthmatic patients.
- 2) To compare the effectiveness of the conventional therapy and the complex approach, which includes application of the FRTD-01 in combination with drug treatment of bronchial asthmatic patients.
- 3) To estimate the influence of hypercapnic training with the FRTD-01 simulator on the clinical signs of bronchial asthma, condition of pulmonary ventilation and gas exchange.
- 4) To test the recommended procedure of administering the FRTD-01 within the complex therapy of bronchial asthma of medium seriousness process in the phase of unstable remission (remitting exacerbation).

- 5) To ascertain whether this method is safe when administered to the patients of this category within the complex therapy of bronchial asthma.
- 6) To determine the best clinical criterion of effectiveness and safety.

In the course of the study a continuous (90-94 days) daily application of respiratory exercises with the FRTD-01 is performed.

The recommended non-drug treatment method is based on the using of the physiological method of stimulation and development of adaptive and sanogenetic processes in the lung tissue and elements of cardiovascular system.

It is expected to achieve positive influence of the combined respiratory training with the FRTD-01 on the state of bronchial asthmatic patients.

It is expected to improve ventilation and gas exchange values, which would make it possible to reduce drug dosage and heighten the quality of life of the patients.

3. Plan of testing

In the course of the study the so called parallel plan is used.

The patients first of all take a training course in learning the respiratory exercises with the FRTD-01 trainer under a physician's surveillance in a hospital, performing the treatment daily and making notes in the self-observation journal (see Appendix 1). After being discharged from the hospital, the patients continue daily respiratory training with the FRTD-01 at home, visiting the hospital for periodical control examinations.

The total observation period is 90-94 days.

The data collection is carried out by means of the examination of the patients at the hospital and at an out-patient clinic, which includes physical examination, functional testing (external respiration function – dynamic spirometry, pneumotachometry, X-ray examination, bronchial permeability index (BPI), the determination of respiratory and cardiovascular system response to physical load by Skibinskaya (ISK), the tension condition of sympathetic and parasympathetic vegetative nervous system by Stange and Gench, the Kerdo index (VKI), electrocardiography, cardiotospectral analysis with the separation of VLF, LF, and HF frequencies, laboratory and clinical examination methods, including blood count).

Control trial, which includes 10-minute respiration with the FRTD-01 after the physiological examination.

The active simultaneous monitoring involving the patients undergoing the traditional treatment without respiratory exercises was conducted.

Concealment of the information from the patients under study is made difficult because the patient performs the breathing exercises himself, the effectiveness of the treatment depends on the accuracy, exactness of the breathing technique, therefore the patients are explained only the technique of the respiration exercises.

Information on the acting mechanism of this method of cure, as well as on the possibility of positive results (improved cenesthesia, reduction of dosage of the administered drugs), is concealed from the patients, which is considered necessary. The patients are not informed of the results of the study either.

In order to ensure the objectiveness of the testing the doctors participating in the testing are informed only of the technique of the respiratory exercises with the FRTD-01, and not of the acting principle and possible results.

The doctors performing functional and laboratory examination are completely ignorant as to what patients perform the breathing exercises with the FRTD-01 and who of them is subjected only to the conventional drug therapy.

The procedure of the breathing exercises is offered to every patient admitted to the department and is administered on the condition of their voluntary consent. The group under study includes persons willing to use the respiratory exercises with the FRTD-01 within the complex treatment.

The treatment is ordered on the 10th-14th day of staying at the hospital after the necessary examination and prescription of the drug treatment. The simple randomization method is used.

4. The description of the group of patients under study.

The study is to take place on the basis of the pulmonology department of the Clinical base of the Scientific Center for clinical and experimental medicine of the Siberian Branch of Russian Academy of medical sciences.

The group under study will consist of 59 patients subjected to hospital treatment of bronchial asthma; after the hospital treatment is completed, follow-up observation and cure are carried out at the out-patient department.

Testing is conducted at the hospital and out-patients' clinic. When selecting the patients the main criteria of insertion are as follows:

- Age: 40-49
- Sex: male/female
- A person should be employed
- A person should have an apartment with modern conveniences

- A person should not have concomitant diseases
- A person should give his consent to be subjected to this sort of treatment

The patients inserted in the group should be those subjected to drug treatment, having stable course of bronchial asthma, their disease should be of medium degree of seriousness, their illness period should be 8 to 10 years. This group of patients corresponds almost completely to the main characteristics of the bronchial asthmatic patients, represents the great bulk of the bronchial asthmatic patients, undergoing hospital treatment.

5. Description of the treatment course with the FRTD-01

Treatment course, involving respiratory exercises with the FRTD-01 begins on the 10th – 12th day of patient's stay at the hospital after the examinations have been completed and drug treatment administered. Before the beginning of the course begins, the patients of the group under study will be informed of the procedure of breathing exercises with the FRTD-01 training device, the doctors' and patients' consent to the testing is to have been obtained. The total duration of the course – 80 days.

At the hospital the patients of the group under study perform the respiratory exercises with the FRTD-01 under surveillance of a medical specialist in the remedial gymnastics room, daily, at 11.30 am. The overall time of the procedure in the first three days is 10 minutes; beginning with the fourth day the training time increases by 1 minute every two days until it reaches 30 minutes, subsequently not exceeding that period. In the process of the exercises hydraulic pressure of 20mm H₂O is used as respiration resistance. Respiration act duration (RAD) is supposed to increase constantly in the course of the training. The patients will be supposed to make daily notes in the self-observation journal.

6. Detailed description of the treatment.

After every treatment trial at the hospital (subsequently – at the out-patients' clinic) the patient is examined by a physician, his condition and cenesthesia are estimated. A physician cancels the treatment on the grounds of the dynamic observation of the patients, their condition, examination, general clinical and functional examination data analysis.

To determine the condition of the patients that fail to appear at the follow-up examinations, an active home nursing will be organized, as well as outpatient record analysis. The patients are banned from the testing in case they refuse to perform respiratory exercises, they perform the treatment irregularly, they do not follow the breathing training technique, and they fail to see the physician during the outpatient course.

7. Data collection during the patients' examination.

To study the condition of the respiratory system, special instrumental examination methods, such as spirometry, pneumotachometry, bodyplethysmography, as well as determination of the carbon monoxide transfer factor (pulmonary diffusion capacity) in the regimen of stable condition, using such apparatuses as "Transferscreen-2" and "Bodyscreen-2" by a German firm "Erich Jaeger" will be conducted.

General clinic monitoring and electrocardiography are planned to be conducted.

Besides it is presumed, for the purpose of determining the effectiveness of using the FRTD-01 by bronchial asthmatic patients, in combination with laboratory and X-ray examinations, to conduct dynamic studies of the indicants, characterizing the recovery of bronchi permeability using the bronchi permeability index (BPI), to study the response of cardiovascular and perspiration systems to physical load using the Skibinskaya index (ISK), as well as tension condition of vegetative nervous system using the Kerdo, Stange and Gench indices.

Data analysis is conducted within the process of statistical analysis by means of analysis of variance method, using the Student's t – criterion.

8. Information on researchers

The pulmonology department head – Ljudmila Nikolajevna Toporkova, is a higher category certified physician, graduated from a medical college in 1977, has been working for 11 years at the pulmonology department at the clinic base of Scientific Center for clinical and experimental medicine at the Siberian Branch of Russian Academy of Medical Sciences.

Chamber physician – Ljudmila Michailovna Muzichenko, holder of a Ph. D. in medical sciences, higher category physician, graduated from a medical college in 1976, has been working for 14 years at the pulmonology department at the clinic base of the Scientific Center for clinical and experimental medicine at the Siberian Branch of the Russian Academy of Medical Sciences, is the founder and leader of "Asthmacenter".

9. Determination group includes

To estimate the influence of the respiratory training on the external breathing function the following set of parameters is to be determined.

TLC – total lung capacity

VC – vital capacity

RV – residual volume

FEV1 – forced expiration volume within 1 second

MEF75 – maximum expiration force (maximum volume rate at the moment of expiration) 75% of Forced Vital Capacity;

MEF50 – 50% of FVC

MEF25 – 25% of FVC

TFst – carbon monoxide transition factor in stable condition

ECG – electrocardiography was conducted in tranquil state in lying position using 3 standard, 3 reinforced derivations from the limbs and 6 derivations from chest.

Stange's and Gench's respiration tests reflect the condition of respiratory and blood circulation functions. They are performed in a sitting position, the patient is asked to do a deep inspiration and to hold the breath at its height; the time of the holding is checked with a stop-watch or spirogram. Gench's test is performed in an analogous manner, but the breath is held at the end of expiration.

The objectivity of respiration tests rises if oxyhemometria is performed simultaneously. Normally blood (hemoglobin) saturation (SO₂) is in the range of 96 to 98%. Three stages of hypoxemy are differentiated: 1 – SO₂ is reduced to 90%; 2 – down to 89-80%; 3 – down to 79-60%.

Oxygen content is an objective indicant of the condition of compensation mechanisms of the external respiratory function under physical load.

Combined estimation of respiratory and cardiovascular system condition according to Skibinskaya index (ISK) is the most adequate and specific test for determining the effectiveness of the treatment with the inclusion of the specific regulation respiratory exercises with the FRTD-01.

$ISK = (VC : 100) \times \text{breath holding time in seconds}$

systole frequency (SF)

Decoding: 5 – very bad; 5-10 – unsatisfactory; 10-30 – satisfactory; 30-60 – good; over 60 – excellent

Stroke volume (SV) can be calculated using the Starr formula:

$SV = 100 + 0.5p - 0.6d - 0.6a$ (Decoding: p – pulse pressure; d – diastolic pressure; a – age of the tested)

Minute volume (MV): $MV = SV \times SF$

Average dynamic pressure (ADP) using the Chikem formula:

$ADP = (- PD : 3) = \text{diastolic pressure}$

Peripheral resistance (PR):

$PR = (ADP \times 1333 \times 60) : MV$ (decoding: 1333 is a coefficient for conversion of the testing results into dynes)

The state of excitability of the sympathetic part of vegetative nervous system was determined by means of the orthostatic trial: the patient lies down on the couch, and in 3-4 minutes the pulse rate is counted within 15 seconds, after the patient has changed his position to vertical the pulse rate is counted again. Pulse rate increase within 1 minute should not exceed 12-18 beatings, which would indicate the normal excitability tone of the sympathetic part of vegetative nervous system. Pulse rate increase by less than 12 and more than 18 beatings is indicative of lowering or heightening of the tone, accordingly.

The parasympathetic part of vegetative nervous system is studied by means of the clinorthostatic test, that is when the patient changes his position from vertical to horizontal.

Reduction of the pulse rate by 12-14 beatings per minute is indicative of normal excitability. More pronounced pulse rate reduction indicates its heightened excitability.

Aschner-Dainini test, or eye-heart reflex, can also define the activity of the parasympathetic part of vegetative nervous system. With the patient in lying position, his pulse rate is counted; with the cushions of a first and index finger pressure on the eyeballs is applied for 5-10 seconds; the pulse rate is measured again. The test is considered to be positive if the pulse rate reduced by 4-12 beating, if the pulse rate remained unaltered, the test is considered negative and is indicative of a lowered excitability of the parasympathetic nervous system (PNS). Pulse reduction by more than 12 beatings is indicative of a distinctly positive test and increase in PNS excitability.

Dermography also allows determining the activity of the sympathetic and parasympathetic sections of vegetative nervous system. After drawing a blunt object over the skin there remains red, white or convex red stripe. Protracted red stripe is indicative of capillary dilatation and heightened activity of the parasympathetic nervous system. White dermography indicates hypodermic capillary constriction and is a sign of a heightened excitability of the sympathetic innervation of dermal vessels.

Vegetative Kerdo index (VKI) allows to determine the degree of influence of parasympathetic innervation activity on cardiovascular system.

$VKI = 1 - (DP_{min} : SF) \times 100$ decoding: DP_{min} – minimal diastolic pressure, SF – systole frequency

Positive VKI value indicates the predominance of the sympathetic part, negative value – of the parasympathetic section of vegetative nervous system.

FRTD-01 is an individual respiration training device (patent NO 1790417, US patent # 5,755,640 of 26.05.98).

Respiratory training consists of respiratory exercises and breathing training.

RAD – respiratory act duration, expressed in seconds, is measured from the beginning of inspiration to the end of expiration during the present respiratory cycle.

Clinical Testing Statement Of the FRTD-01 Individual Respiration Stimulator

The testing was conducted in the period from 31.01.2000 to 02.05.2000 at the clinical base of the Scientific Center for clinical and experimental medicine at the Siberian Branch of the Russian Academy of Medical Sciences.

The purpose of testing:

1. To study the influence of the individual training device FRTD-01 on the respiratory system when conducting the complex therapy of the bronchial asthmatic patients.
2. To compare the effectiveness of the conventional therapy and that of the complex approach, which includes application of the FRTD-10 in combination with the drug treatment of the bronchial asthmatic patients.
3. To determine the influence of the hypercapnic training with the FRTD-01 simulator on the clinical signs of bronchial asthma, pulmonary ventilation condition, gas exchange.
4. To test the recommended procedure of the FRTD-01 application in the complex treatment of bronchial asthma of medium seriousness process in the stage of unstable remission (remitting exacerbation).
5. To ascertain if this method is equally safe or still safer.
6. To determine the best criterion of effectiveness and safety.

A medical specialist, who is an expert at the procedure, directed the instruction on the respiration exercises technique with the FRTD-01.

The treatment procedure with the FRTD-01 was offered to all the patients, admitted to hospital treatment. The course of medical treatment began on the 10th – 12th day of staying at the hospital, after the physicians and the patients had given their consent, after the examination had been conducted and drug treatment administered.

Concealment of the information was conducted (as stated in paragraph 3. (Clinical Testing Plan)).

The examination of the patients was conducted at the hospital (of the clinical base of the SCCEM SB RAMS) on the 10th – 12th day of staying at the pulmonology department, after elimination of acute signs of bronchial asthma, discontinuance of application of short-term course of systemic glucocorticoids, parenteral introduction of sympathomimetics and xantine derivatives. Thus, the patients on the moment of initial examination and the beginning of application of the perspiration simulator FRTD-01 in the principal group were in the stage of unstable remission, and in this connection all the observed patients continued intake of inhalant glucocorticoids (primarily inhacort in daily dose of 1 500 mg), bronchodilators of short-term effect (berotec, ventoline in daily dose of 600-800 mg), prolonged theophylline (theopec 0,3 g twice a day).

The initial condition of the respiratory system in the principal and the control groups was estimated in the remitting exacerbation stage of the prior disease (on the 10th – 12th day since the admission to the hospital), from that time in the principal group in combination with the pathogenetic and symptomatic therapy a remedial program was conducted with the application of the FRTD –01 simulator during the subsequent stay at the hospital. The control group patients were subjected only to the conventional therapy, including inhalation administration of sympathomimetics, glucocorticoids and intake of prolonged theophyllines.

To estimate the influence of the respiratory training on the external respiration function a set of parameters was determined:

TLC – total lung capacity

VC – vital capacity

RV – residual volume

FEV1 – forced expiration volume within 1 second

MEF75 – maximum expiration force (maximum volume rate at the moment of expiration) 75% of Forced Vital Capacity;

MEF50 – 50% of FVC

MEF25 – 25% of FVC

TFst – carbon monoxide transition factor in a steady condition

During the initial examination of the respiratory system of the principal and control group patients a moderate ventilation disturbance of obstructive type with structural shifts in TLC was observed, accompanied by increase in RV (hyperinflation), which caused significant ventilation-perfusion inadequacies, manifested in the reliable reduction of CO transition in steady condition (TFst). During the initial examination of the patients of the principal and control groups statistically significant differences between rate and volume values and gas exchange values were not revealed. To study the respiratory system condition specific instrumental examination methods with the application of such apparatuses as "Transferscreen-2" and "Bodyscreen-2" by a German firm "Erich Jaeger" were conducted. These methods included spirometry, pneumotachimetry, bodyplethysmography and the determination of the carbon

monoxide transition factor (pulmonary diffusion capacity) in a steady condition regimen.

The group under study (the studied group)

The group under study included the patients with the bronchial asthma of moderate seriousness process. The total number of patients in the group under study – 59 (29 males and 30 females) aged 40-49 (average age – 46,4), disease period 6-10 years (mean value – 5,9).

All the patients were subjected to examination and interlocution concerning the respiratory exercises. Training sessions were performed daily, according to the clinical testing plan (paragraph 5), the patients made daily notes in the self-observation journal.

In the beginning of the course an adaptation period (the first three days) was singled out, in the course of which the respiratory exercises duration was 10 minutes a day. Subsequently the training time increased by 1 minute every two days, reached 30 minutes, and remained the same in order to exclude unforeseen circumstances.

Respiration act duration (RAD) was 5-6 seconds (average value 5,4 sec), increased with the physical fitness; on reaching 30 seconds RAD did not increase on researchers' recommendation with the purpose of stabilizing the physiological adaptive processes, in order to ensure the reliability of the observations in view of partial cancellation of medicaments as a means of prophylaxis of unexpected circumstances.

Control inspection of the patients undergoing treatment with the FRTD-01 was conducted by an attending physician and a medical specialist, an expert at the method, at the hospital daily after the performance of the treatment, on the outpatient inspection days on the 20th, 50th and 80th day of the cure.

All the patients of the group under study were subjected to syndrome, pathogenetic therapy with the application of drugs administered during the previous hospitalization. The patients of the group under study ended the treatment on the 25th – 30th day of hospitalization, the average duration of their stay at the hospital made up 26,4 days. Laboratory examination data are offered in the table (Appendix 2).

In view of the systematic exercises with the FRTD-01, the patients of the group under study on the 5th – 8th day of the training observed considerable improvement of cenesthesia, sleep, diminishing of dyspnea, cough fits, improved expectoration.

The conducted examinations ascertained that as a result of the supplementary application of the respiratory exercises with the FRTD-01 the bronchial asthmatic patients already on the 7th – 9th day of the treatment observe improved cenesthesia,

reduction of dyspnea, asphyxia attacks regress completely or their duration and frequency of occurrence diminishes. Positive dynamics of auscultative effects were observed, which are manifested by regression or considerable reduction of dry and moist rale.

An increased quantity of leukocytes and erythrocyte sedimentation rate (ESR) is reduced 8 – 10 days earlier compared to the control group patients. Positive dynamics of X-ray inspections are observed – infiltration shadows. Congestion effects in (прикорневая зона/near the root zone) regress on the 14th – 16th day, whereas in the control group such effects are observed only near the end of the treatment.

VC is reliably increases from 82-68% to 88-90% and more of the due value, maximum pulmonary ventilation from 70-48 to 83-87%. Bronchial permeability index (BPI) and the FEV/VC ratio is more than 22-32%. Positive dynamic of cardiovascular system response to the physiologic load according to ISK (from 10-26 to 60 and more).

Reliable increase in tone of the sympathetic part of the vegetative nervous system of bronchial asthmatic patients according to VKI (vegetative Kerdo index) is observed. Reduction of cure time and dosage of the administered drugs was observed.

Subsequently, after discharge from the hospital, the patients performed respiratory training at home, gradually increasing the training time and RAD values, all the patients of the studied group were recommended to appear for the first control inspection (on the 20th day of the treatment course). There appeared 57 patients out of 59, which accounted for 94,9%.

Positive changes of the external respiratory function in the principal group were accompanied by positive clinical facts, which manifested in reduction of dyspnea occurrence in the course of 24 hours' time, improved sleep (reduction of night attacks of asphyxia), increase in tolerance to physical load, heightening of subjective dyspnea perception threshold (2 patients made repeated unaided successful attempts of arresting of difficult breathing with the FRTD-01 simulator). The above mentioned clinical changes and positive dynamics of functional indicants made it possible for us, after a repeated address of the patients, to reduce the dosage of inhalant glucocorticoids from 1 500 mg to 1 000mg and decrease the number of takings of sympathomimetics.

Two of the patients (1 male and 1 female) failed to appear at the examination and were inspected during the active home nursing. It was ascertained that they discontinued respiratory exercises in view of satisfactory cenesthesia for private reasons on the 30th – 31st day and refused to continue training sessions and to participate in the testing on grounds of good general state (cenesthesia).

During the first examination the patients for reasons of safety were recommended not to exceed 30 seconds of the Respiratory Act Duration (RAD) duration, and to restrict the training time to 30 minutes. It was recommended to appear on the 50th day for the 2nd control inspection.

For the 2nd control examination there reported 54 patients (27 males and 27 females), which accounted for 91,5% of the initial composition. All the tested revealed the right performance of the breathing technique, mentioned a considerable improvement of health condition. The obtained positive results of the physiologic inspection made the reduction of drug therapy possible and from the 51st day the patients took approximately 60% of the initial quantity of drugs.

All the patients were recommended to report at the 3rd control inspection to the end of the course of the treatment (80th day), continuing daily 30-minute training sessions in the evenings with 30 seconds RAD.

There reported 52 persons for the 3rd control inspection, which accounted for 88,1% of the initial setting of the group. All the patients of the studied group revealed the right breathing training technique with the FRTD-01, good cenesthesia, expressed their wish to continue the training sessions. The general positive dynamics of the laboratory indicants and cenesthesia made it possible to preserve the drug therapy at the level 50-60% of the initial. Three of the patients discontinued the training, having revealed signs of stable cenesthesia improvement.

In the sphere of the subjective perceptions the patients noted a substantial sleep and general state improvement, reduction of the frequency and seriousness of asphyxia attacks, cough cessation, general tone and working performance rise.

Physiological inspection data are presented in the table (Appendix 2)

The control group

In the course of the testing an active simultaneous inspection was conducted. The control group included 65 patients (31 males, 33 females) aged 40-49 (mean value 47,2), suffering from bronchial asthma, moderately serious, of stable course, with the period of the disease 4,9-8,6 years (mean value – 6,7).

The information was completely concealed from the patients of the control group, laboratory and clinical inspections during the 90-day course was explained to them as a schedule follow-up.

The patients of the control group were treated at the hospital, subsequently as out-patients without the application of the FRTD-01. The control group patients were undergoing drug treatment analogous to that of the studied group. Clinical observation and physiologic inspection was conducted, with the assessment of the

same parameters and within the same period of time as with the studied group patients.

In view of the active drug therapy there was observed definite positive dynamics in the cenesthesia and physiological indicants of the patients.

The control group patients were discharged from the hospital on the 28th - 30th day of cure, the average duration of staying at the hospital made up 28,4 days.

For the first control inspection there reported 60 patients (28males, 32 females), which accounted for 92,3% of the initial composition.

For the second control inspection there appeared 57 patients (27 males, 30 females) – 89,2%.

For the third inspection there reported themselves 51 patients – 78,4%.

For the fourth examination reported also 51 patient – 78,4% of the patients. The search for the patients that failed to appear revealed that all of them had satisfactory cenesthesia, underwent conventional treatment, administered earlier and saw no reason to appear at the examination.

Thorough examination and medical inspection allowed to achieve a definite improvement in the patients' condition and to correct the treatment course. The average reduction of the drug dosage with the control group patients made up 10% by the discharge day, approximately 20% of the initial dosage by the 50th (control) day (without the further reduction to the end of the testing).

Deductions:

Thus, the obtained results allow drawing preliminary conclusion that the influence of respiratory training with the FRTD-01 on the respiratory system of the patients with bronchial asthma of moderate seriousness in the stage of remitting exacerbation is positive. Therapeutic and rehabilitation effects of the procedure are as follows:

1. Bronchial permeability improvement and reduction of heightened lung inflation which is allegedly associated with the positive pressure in the expiration phase, created by means of the FRTD-01 simulator, preventing expiratory collapse of the minor respiratory tracts and reducing distinct signs of tracheobronchial dyskinesia.
2. Recovery of the disordered ventilation-perfusion relations and optimization of gas exchange.
3. In the process of the testing of the respiration simulator with bronchial asthmatic patients (medium degree of seriousness) cases of complication and side-effects, hazardous for health, were not registered. Observations of the patients proved safety of the proposed procedure.

4. The most informative criteria of effectiveness and control in the treatment with the FRTD-01 are the following parameters: VC, FEV1, (ΠOC).
5. The treatment procedure of bronchial asthmatic patients with the application of the FRTD-01 simulator (moderate seriousness, stable course) is more effective, which is proved by a considerable improvement of the external respiration function indicants, reduction in the level of drug therapy with the studied group patients compared to the control group patients, subjected only to the conventional drug treatment.

We consider the application of the FRTD-01 apparatus in the treatment of bronchial asthma, especially accompanied by pulmonary emphysema, hyperventilation syndrome and, particularly, chronic obstructive bronchitis to be highly promising.

Executors:

Ward physician _____ L. Muzichenko

Department head _____ L. Toporkova

13, June, 2000

Appendix 1. A patient's self-observation journal

Date	Day, time of the training	Values: RAD, pulse, breathing frequency (BF) (before the training)	Values: RAD, pulse, breathing frequency (after the training)	General state (cenesthesia)
21.02.2000	22 nd day; 11.30 – 11.50	RAD – 14 s Pulse – 82 BF - 18	15 80 16	Good sleep, cough 3-4 times a day, expectoration easy, light in color To the end of the training feel tired of br. With FRTD-01 Take drugs 3 times a day (8 tablets), use the inhaler twice a day. Asphyxia fits 3-4 times

				in the daytime
13.03.2000	47 th day 21.00-21.30	RAD – 24 s Pulse – 80 BF – 16	25 78 14	Feel good, no cough, no dyspnea while walking, asphyxia 1-2 times a day The training is easy, can breathe longer and do more RAD. Take drugs in the mornings and evenings (5 tablets). Use the inhaler once-twice a day

Appendix 2. Lung function tests by the studied group patients

indicants	Initially	20 th day	50th	80 th
VC	83,3+-3,3	95,8+-3,4	98,6+-2,6	100+-1,6
TLV	151,4+-6,8	130,8+-2,9	122,2+-3,1	117,2+-7,1
TLC	107,7+-8,1	105,1+-4,8	104,6+-3,1	102,2+-4,5
FEV1	64,8+-4,2	76,9+-3,1	85,2+-2,1	89,8+-3,3
MEF75	50,6+-4,6	64,3+-2,9	69,8+-3,8	74,6+-2,6
MEF50	41,1+-3,9	53,2+-2,8	59,9+-3,1	65,3+-2,9
MEF25	39,2+-4,3	52,1+-3,1	58,1+-2,6	63,6+-3,3
TFst	64,1+-3,6	72,3+-2,7	80,1+-2,9	84,6+-3,1

Appendix 3. Lung function tests by the control group patients

indicants	Initially	20 th day	50th	80 th
VC	84,2+-5,2	87,9+-2,1	88,2+-2,2	89,1+-3,2
TLV	147,6+-3,8	142,7+-3,2	138,4+-2,5	136,4+-4,2
TLC	105,8+-5,8	105,0+-4,5	103,1+-3,8	102,2+-3,9
FEV1	66,0+-5,9	69,4+-3,1	72,5+-2,2	74,8+-2,1
MEF75	51,7+-2,8	54,3+-3,2	56,8+-2,1	58,9+-3,8
MEF50	38,0+-2,7	43,1+-2,9	45,4+-2,4	48,9+-2,0
MEF25	40,8+-3,6	45,3+-2,5	48,9+-2,5	52,1+-2,8

TFst

66,6+-5,1	68,1+-3,2	69,5+-1,8	71,8+-3,1
-----------	-----------	-----------	-----------