

Saint Petersburg State Establishment of Health Care City Hospital No 40

**HIGH TECHNOLOGY METHODS
OF TREATMENT AND REHABILITATION**

THEORY AND PRACTICE

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The current edition is a collection of works on theory and practice performed by physicians of the City Hospital No 40, Saint Petersburg, Russia, in 2010. The book consists of a preface and 8 chapters grouped in two sections. The first section is dedicated to theoretical problems of rehabilitation. The 1st chapter brings us the semantic analysis of the term “verticalization”. It is shown that it would be judicious to avoid the usage of this term in the sense of designation of the process or principle of rehabilitation to escape the semantic confusion and ambiguity. In the 2nd chapter on the basis of analysis of the latest achievements of gravitational biology there have been brought to light the potentially important applications of the latter in rehabilitology and gerontology and formulated the notions of *disgravitational syndrome* and *g_{-z} rehabilitation*. The second section is concentrated on the practical issues of rehabilitation of the patients after stroke, spinal cord injury, and ischemic heart disease with the use of modern high-technology methods. In particular, it is a matter of assisting robot *Lokomat* (chapters 3–5) and cardiac shock wave therapy (chapters 6–7). The concluding, 8th chapter, analyses the new international standard of clinical trials CONSORT 2010.

The chapter abstracts in Russian and English are situated before the corresponding chapters, bibliography – at the end of each chapter.

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CHAPTER 1

Verticalization. Etymology and semantics of the term

Scherbak S.G., Golota A.S., Krassii A.B., Lisovets D.G., Popov A.E., Sarana A.M., Tereshin A.E.

The semantic analysis of the term “verticalization” has revealed that this term is steadily used in many branches of human activities and comprises the broad range of meanings. In medicine the term “verticalization” is also common and has been used for a long time, although in quite a narrow sense, that is, “the transition of the body or its parts from the horizontal to vertical position”. The term “verticalization” in the meaning of “a process or method of restoration of the ability of a convalescent to independent or assisted maintenance of the vertical position of the body and ambulation” in the analyzed sources has not been found. That is why the usage of the term in its latter meaning should be thoroughly and convincingly argued. However, it is reasonable to avoid the usage of that term in the above mentioned meaning at all in order to escape the semantic confusion and ambiguity of the meaning.

Key words: rehabilitation, semantics, verticalization.

MeSH terms: Semantics, Rehabilitation.

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Bibliography: 70 items.

CHAPTER 2

Gravitational biology. The current state and medical applications.

Review of the foreign scientific medical Internet publications

Scherbak S.G., Golota A.S., Krassii A.B., Lisovets D.G., Popov A.E., Sarana A.M., Tereshin A.E.

The aim of the current review is to acquaint the broad medical community with certain achievements in the sphere of gravitational biology which could have important applications in medicine, in particular, in rehabilitology and gerontology. For that purpose there have been adduced some modern data from general and special gravitational biology and investigations in the field of simulated microgravity. The review is based on the works of 2008–2010. The earlier publications have been used mostly for the background. The extrapolation of the bibliographical data over the clinical situation demonstrates that the hospitalized patient very early develops the profound changes on molecular biological level which entirely link to patient's position across the vector of gravity. This triggers the oxidative stress. If the patient continues to stay in the horizontal position the antioxidant processes quickly become extinct. To block the replication of the damaged genome such substances as p53, p16, NF- κ B p50, p55 initiate apoptosis. It is of principle importance that so far there is no way to restrict the above mentioned pathogenetic chain reaction except moving the patient into the orthostatic position with weight load on the legs. And it should be done as soon as possible because, perhaps, the situation deteriorates from hour to hour. Further, the review confirms the essential role of the regular vertical walking as one of the key preventive measures for premature aging of the organism. The striking isomorphism of the processes which take place in the patient in the state of zero gravity and the patient lying in bed allows to

formulate the notion of *disgravitational syndrome*. The latter inevitably arises as soon as the evolutionary established principles of interaction between the organism and Earth's gravitational field are impaired. The mode of rehabilitation which takes into consideration the key role of correct orientation of patient's body in Earth's gravitational field is designated as *g-z-rehabilitation*.

Key words: 3-methylhistidine, apoptosis, bone tissue, disgravitational syndrome, DNA, endothelium, genome stability, genome, gerontology, glutathione peroxidase, glutathione, gravitational biology, gravitational field, gravity, gravity persistence signal genes, g-z-rehabilitation, hypodynamia, hypogravity, IL-6, IL-8, inflammation, lymphocyte, microgravity, molecular biology, muscle tissue, NF- κ B p50, osteoporosis, oxidative stress, p16, p53, p65, parathyroid hormone-related protein, rehabilitation, rehabilitology, robot-assisted locomotology, simulated microgravity, space medicine, superoxide dismutase, The Flight Analogs Project, vector of gravity, β -galactosidase.

MeSH terms: Aerospace Medicine, Apoptosis, Bone and Bones, Cyclin-Dependent Kinase Inhibitor p16, DNA, Galactosidases, Genome, Genomic Instability, Geriatrics, Glutathione Peroxidase, Gravitation, Hypogravity, Hypokinesia, Interleukin-6, Interleukin-8, Lymphocytes, Molecular Biology, Muscle Tissue, Osteoporosis, Oxidative Stress, Parathyroid Hormone-Related Protein, Rehabilitation, Superoxide Dismutase, Transcription Factor RelA, Tumor Suppressor Protein p53, Weightlessness.

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CHAPTER 3

Assisting robots in rehabilitation: The current state of the problem.

Review of the foreign scientific medical Internet publications

Scherbak S.G., Golota A.S., Tereshin A.E., Volodina S.T., Makarenko S.V., Volkonina T.E., Urazov S.P., Berezhkova N.I., Popov A.E.

The current review is dedicated to the modern state of the problem of the employment of assisting robots for rehabilitation of patients with impairments of the function of locomotion. The issues of robot therapy of motion impairments of the upper extremities are not considered. The review is made on the basis of medical scientific 2008–2010 publications. The earlier works are used infrequently for the elucidation of the history of the issue. The first section analyzes how common the use of robotic rehabilitation is and outlines the diseases in rehabilitation of which the robots are used most frequently. The second section is devoted to the results of clinical trials of robotic therapy effectiveness. The third section looks into certain advantages and disadvantages of usages of locomotive robots. The fourth section considers prospects for employment of robotic engineering in rehabilitation. In conclusion it is noted that despite the modest results demonstrated so far by assisting robots in physical therapy of motion impairments the locomotive robotics is a rather promising direction in rehabilitation. By the present time we have been being at the very beginning of the epoch of robotic therapy. That is why the main task now is to systematically accumulate and analyze the scientific data rather than to pursue the more expensive and sophisticated devices. The main text is followed by two appendices. The first contains the general information about the apparatus *Lokomat* and its manufacturing firm *Hocoma*. The second

possesses the data about the first experimental over-ground gait assisting robot *ZeroG*.

Key words: cerebral palsy, head injury, *Lokomat*, motion impairments, multiple sclerosis, Parkinson disease, physical therapy, rehabilitation assisting robots, rehabilitation, spinal injury, stroke, *ZeroG*.

MeSH terms: Cerebral Palsy, Craniocerebral Trauma, Exercise Movement Techniques, Multiple Sclerosis, Parkinson Disease, Rehabilitation, Robotics, Spinal Injuries, Stroke.

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Bibliography: 38 items.

CHAPTER 4

Comparative effectiveness of rehabilitation after stroke employing assisting robot *Lokomat* in the modes of comfort and submaximal loading: Plan of the clinical trial

Tereshin A.E., Golota A.S., Volodina S.T., Makarenko C.V., Volkonina T.E., Urazov S.P., Berezhkova N.I., Popov A.E.

Introduction to the theme. The stroke morbidity in Saint Petersburg is 4,5‰ which makes approximately 25 000 cases annually. Stroke is the leading cause of disability. The robot-assistant systems allow to conduct rehabilitation sessions by a single-handed technician with accurate dosing of weight and speed loading in safe for a patient conditions. Despite 15 years history of assisting robots employment, there has not yet existed the common opinion not only on particular details of their clinical application but on appropriateness of their usage altogether.

Aim and goals. Aim: to define more accurately the appropriateness of employment of the assisting robot rehabilitation of the function of locomotion in stroke patients. Goals: to elucidate whether: (1) the assisting robot rehabilitation of the function of locomotion after stroke in the mode of submaximal loading is more effective in comparison with the mode of comfort loading and, not to mention, (2) rehabilitation without the assisting robot.

Materials and methods. Design: prospective, interventional, treatment, randomized, partially blinded, active control, phase II trial. Three groups of stroke patients, 150 people in each group: (1) rehabilitated employing the assisting robot in the mode of submaximal loading, (2) rehabilitated employing the assisting robot in the mode of comfort loading, (3) rehabilitated without the assisting robot *Lokomat*. In all three groups

everyone receives 36 sessions of locomotive training three sessions a week. The primary end points: one minute walk distance, 10 meter walk time; the secondary end points: “The Stroke Specific Quality of Life Scale”, ECG stress-test, and 5 biochemical parameters of blood serum.

Anticipated results and their discussion. The current clinical trial is called upon to answer the only question if the robot-assistant rehabilitation of post-stroke patients provides an additional positive effect in comparison with the traditional course without robot. Focusing of the current trial on the group of posts-stroke males of mainly before pension age (43–62 years old) defines the main practical and economic vector of this scientific investigation.

Key words: clinical trial, *Lokomat*, robot-assisted rehabilitation, stroke.

MeSH terms: Clinical Trial, Rehabilitation, Robotics, Stroke.

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Bibliography: 76 items.

CHAPTER 5

Comparative effectiveness of rehabilitation after spinal cord injury employing assisting robot *Lokomat* in the modes of comfort and submaximal loading: Plan of the clinical trial

Tereshin A.E., Golota A.S., Makarenko C.V., Urazov S.P., Berezhkova N.I., Popov A.E.

Introduction to the theme. The spinal injury morbidity in Russia is 0,08‰ with distinct tendency to grow. In Saint Petersburg it has been registered over 300 new spinal cord injuries annually. The robot-assistant systems allow to conduct rehabilitation sessions by a single-handed technician with accurate dosing of weight and speed loading in safe for a patient conditions. Despite the 15 year history of assisting robots employment, there has not yet existed the common opinion not only on particular details of their clinical application, but on appropriateness of their usage altogether.

Aim and goals. Aim: to define more accurately the appropriateness of employment of the assisting robot rehabilitation of the function of locomotion in spinal patients. Goals: to elucidate whether: (1) the assisting robot rehabilitation of the function of locomotion after spinal cord trauma in the mode of submaximal loading is more effective in comparison with the mode of comfort loading and, not to mention, (2) rehabilitation without the assisting robot.

Materials and methods. Design: prospective, interventional, treatment, randomized, partially blinded, active control, phase II trial. Three groups of spinal patients, 150 people in each group: (1) rehabilitated employing the assisting robot in the mode of submaximal loading, (2) rehabilitated employing the assisting robot in the mode of comfort loading, (3) rehabilitated without the assisting robot *Lokomat*. In all three groups

everyone receives 36 sessions of locomotive training three sessions a week. The primary end points: one minute walk distance, 10 meter walk time; the secondary end points: The Index of Life Satisfaction, ECG stress-test, and 5 biochemical parameters of blood serum.

Anticipated results and their discussion. The current clinical trial is called upon to answer the only question if the robot-assistant rehabilitation of spinal patients provides an additional positive effect in comparison with the traditional course without robot. Focusing of the current trial on the group of males after spinal cord injury of mainly below 50 years old defines the main practical and economic vector of this scientific investigation.

Key words: clinical trial, *Lokomat*, robot-assisted rehabilitation, spinal cord injury.

MeSH terms: Clinical Trial, Rehabilitation, Robotics, Spinal Injuries.

UDC: (615.4+616-089.227)(616.8:617.5)

Bibliography: 70 items.

CHAPTER 6

Cardiac shock wave therapy: The modern state of the problem and prospects of scientific research. Review of the foreign scientific medical Internet publications

Lisovets D.G., Golota A.S., Zelenina L.I., Larin K.E., Lebedeva S.V., Popov A.E.

The current review is dedicated to the modern state of the problem and prospects of scientific research in the field of cardiac shock wave therapy (CSWT). The review begins from the critical analysis of the sources themselves followed by the section of physical and technical characteristics of the equipment with the emphasis on the safety of the method. Then the supposed mechanism of action of CSWT is considered. 4 current clinical trials of the method of CSWT are analyzed. The role of visualization of the zone of myocardial ischemia in the method of CSWT is stressed. Separately, the employment of CSWT for the treatment of congestive heart failure due to ischemic heart disease is discussed. For the convenience of the readers the opponent mentions are combined together and presented in the last section. The review is summarized in the conclusion after which, taking into consideration the applied orientation of the review, the practical points are drawn. The review is completed by the list of the employed sources.

Key words: cardiac shock wave therapy, clinical trial, ischemic heart disease, myocardial revascularization.

MeSH terms: Clinical Trial, Myocardial Ischemia, Myocardial Revascularization.

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Bibliography: 55 items.

CHAPTER 7

Comparative effectiveness of treatment of stable angina with cardiac shock wave therapy and pharmacological methods: Plan of the clinical trial

Lisovets D.G., Golota A.S., Zelenina L.I., Larin K.E., Lebedeva S.V., Popov A.E.

Introduction to the theme. The modern Russia is a leading country in the world in ischemic heart disease mortality rate leaving others far behind. From the medical point of view that means that the existed standard methods of treatment of ischemic heart disease are not effective. The history of cardiac shock wave therapy (CSWT) has already numbered 11 years. Although the method has never left the state of marginality. One of the cause of that situation is the absence of clinical trials of the method performed at the level of modern requirements demanded of a clinical trial.

Aim and goals. Aim: To compare the effectiveness of cardiac shock wave therapy of stable angina

with the effectiveness of the optimal medical treatment by the methods of modern clinical experimental analysis at the maximally possible sample.

Aims: to elucidate whether: (1) cardiac shock wave therapy really allows to improve the condition of the patients with stable angina toward which the optimal medical treatment does not result in satisfied effect; (2) cardiac shock wave therapy does not carry any detrimental impact on the myocardium.

Materials and methods. Design: prospective, interventional, treatment, randomized, partially blinded, active control, phase II trial. Two groups of patients, 150 people in each, are created: (1)the group of patients with stable angina receiving the optimal medical treatment (control group), (2) exactly

the same group except additionally undergoing 9 sessions of CSWT 3 times a week every other day each first week of the three consecutive months. The only primary end point of the current clinical trial is the number of a class of angina according to the NYHA Functional classification of angina. The secondary end points: ECG and EchoCG stress-tests, and also a troponin test.

Anticipated results and their discussion. The design of the current clinical trial has been intentionally simplified in order to make the whole trial transparent and purposeful as much as possible, notably, to establish with the highest possible degree of reliability whether: (1) the method CSWT does work, and if so, (2) the method is really safe.

Key words: cardiac shock wave therapy, clinical trial, ischemic heart disease, myocardial revascularization.

MeSH terms: Clinical Trial, Myocardial Ischemia, Myocardial Revascularization.

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Bibliography: 54 items.

CHAPTER 8

Documents which regulate the modern international practice of conduction of the clinical trials of non-pharmacological profile: The current state of the problem. Review of the foreign scientific medical Internet publications

Scherbak S.G., Golota A.S., Lisovets D.G., Popov A.E., Sarana A.M., Tereshin A.E.

The current review brings to light and analyses the range of documents which regulate the current international practice of organization of clinical trials of non-pharmacological profile and publication of their results. The first section considers the general guidelines. The second section focuses attention on the format of protocols and publications. The third section is dedicated to the particular protocol of registration of the current clinical trial of Norwegian investigators with the use of assisting robot *Lokomat*. It is demonstrated that to register and publish the results of clinical trials irrespectively of trial types it is necessary to use already now CONSORT 2010 guidelines. This permits the possibility of publication the results of a trial in prestigious international periodicals. In conclusion, the list of the employed sources is presented.

Key words: clinical trials, guidelines

MeSH terms: Clinical Trial, Practice Guidelines as Topic.

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