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Enhancing Quality of Life in Sedentary Elderly Individuals: The Impact of the Home-Based Full-Body In-Bed Gym Program — A Prospective, Observational, Single-Arm Study

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ABSTRACT

INTRODUCTION. The limitations in mobility frequently encountered by the elderly, often linked to advanced age and concurrent medical conditions, have significant implications for their overall well-being and self-reliance. This decrease in physical activity not only curtails their independence but also elevates the likelihood of prolonged hospitalization and the accompanying complications.

AIM. To assess the impact of a home-based Full-Body in-Bed Gym program, a 10-exercise protocol consisting of three sessions per week for two months, on the quality of life of elderly individuals.

MATERIALS AND METHODS. The study involved participants of both genders aged over 65, who were classified as sedentary, engaging in less than one hour of physical activity per week. Participants with recent orthopedic conditions, severe cardiovascular or oncological diseases, and significant neurological disorders were excluded due to their potential to confound the effects of the Full-Body in-Bed Gym program and impact overall health and quality of life.

RESULTS. A total of 22 subjects, with a median age of 71.90 years, participated in the study.
Elderly individuals engaging in the Full-Body in-Bed Gym program, experienced improvements in their quality of life. These gains were noticeable in the 12-Item Short Form Health Survey (SF-12) Physical Component Summary ($p = 0.07$) and reached statistical significance in the Mental Component Summary ($p = 0.04$).

DISCUSSION. The observed gains in the quality of life among elderly participants engaging in the home-based Full-Body in-Bed Gym program are noteworthy. The positive impact on the mental component of the SF-12 is particularly significant, indicating improvements in mental well-being. This aligns with the broader understanding that physical activity in the elderly is intricately linked to various aspects of their health, including mental health. While the preliminary findings suggest positive outcomes, future research with larger and more diverse cohorts could provide a more robust understanding of the Full-Body in-Bed Gym program's impact.

CONCLUSION. Our findings underscore the potential of a home-based Full-Body in-Bed Gym program to enhance the quality of life in elderly participants, highlighting the need for further exploration of rehabilitation and prevention strategies in this context.

KEYWORDS: frailty, elderly, exercise, quality of life, motor function.

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Улучшение качества жизни у лиц пожилого возраста, ведущих малоподвижный образ жизни: влияние домашней программы «Полноценный тренажерный зал в лежачем положении». Проспективное, обсервационное, неконтролируемое исследование

Маккароне М.К.[1,*], Карраро У.[2,3,4], Карегнато А.[1], Равара Б.[2,3,4], Джуриати В.[2], Каррьеро А.[1], Казеллато Д.[1], Финамони К.[1], Джирилло Р.[1], Ласкова О.[1], Мариго Е.[1], Санчес Д.И.[1], Сено И.[1], Вентурин К.[1], Веронезе Х.[1], Регаццо Д.[1], Масьеро С.[1,5]

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РЕЗЮМЕ

ВВЕДЕНИЕ. Ограничения в мобильности, с которыми часто сталкиваются пожилые люди, часто связанные с преклонным возрастом и сопутствующими заболеваниями, имеют значительные последствия для их общего благополучия и уверенности в себе. Такое снижение физической активности не только ограничивает их независимость, но и повышает вероятность длительной госпитализации и сопутствующих осложнений.

ЦЕЛЬ. Оценить влияние домашней программы тренажерного зала для всего тела в постели, разработанной для смягчения снижения физической активности, на качество жизни пожилых людей. В исследовании приняли участие участники обоих полов в возрасте старше 65 лет, которые были классифицированы как ведущие сидячий образ жизни и занимающиеся физической активностью менее одного часа в неделю. Участники с недавними ортопедическими заболеваниями, тяжелыми сердечно-сосудистыми или онкологическими заболеваниями и значительными неврологическими расстройствами были исключены из-за их потенциальной возможности свести на нет результаты программы тренажерного зала для всего тела в постели и повлиять на общее состояние здоровья и качество жизни.

МАТЕРИАЛЫ И МЕТОДЫ. В исследовании приняли участие в общей сложности 22 испытуемых со средним возрастом 71,90 года. Пожилые люди, занимающиеся по программе тренажерного зала для всего тела в постели, состоящей из трех занятий в неделю в течение двух месяцев, почувствовали улучшение качества своей жизни. Эти улучшения были заметны в кратком опроснике здоровья из 12 пунктов (SF-12) по физическому компоненту ($p = 0,07$) и достигли статистической значимости в кратком обзоре психического компонента ($p = 0,04$).

РЕЗУЛЬТАТЫ. В исследовании приняли участие в общей сложности 22 испытуемых со средним возрастом 71,90 года. Пожилые люди, занимающиеся по программе тренажерного зала для всего тела в постели, почувствовали улучшение качества своей жизни. Эти улучшения были заметны в кратком опроснике здоровья из 12 пунктов (SF-12) по физическому компоненту ($p = 0,07$) и достигли статистической значимости в кратком обзоре психического компонента ($p = 0,04$).

ОБСУЖДЕНИЕ. Заслуживают внимания наблюдаемые улучшения качества жизни среди пожилых участников, занимающихся по домашней программе «Полноценный тренажерный зал в лежачем положении». Положительное влияние SF-12 на психический компонент особенно значительно, что свидетельствует об улучшении психического самочувствия. Это согласуется с более широким пониманием того, что физическая активность пожилых людей неразрывно связана с различными аспектами их здоровья, включая психическое. В то время как предварительные результаты предполагают положительные результаты, будущие исследования с участием более крупных и разнообразных групп могли бы обеспечить более четкое понимание воздействия программы «Полноценный тренажерный зал в лежачем положении».

ЗАКЛЮЧЕНИЕ. Эти результаты подчеркивают потенциал домашней программы тренажерного зала для всего тела в постели для повышения качества жизни пожилых участников, подчеркивая необходимость дальнейшего изучения стратегий реабилитации и профилактики в этом контексте.

КЛЮЧЕВЫЕ СЛОВА: слабость; пожилой возраст; физические упражнения; качество жизни; двигательная функция.

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INTRODUCTION

The challenges associated with physical inactivity in the elderly, often attributed to factors like age and concurrent medical conditions, have far-reaching implications for their well-being and independence. This lack of physical activity not only curtails their autonomy but also increases the risk of extended hospitalization, leading to issues such as neuromuscular weakening, functional limitations, and substantial healthcare expenses [1–4]. Managing these progressive physical inactivity-related impairments demands ongoing attention. While pharmaceutical interventions are currently under consideration, it should be accepted that physical exercise regimens represent a highly promising and multifaceted option. This approach can contribute to global health promotion by enhancing cardiovascular fitness, muscle strength, flexibility, and mental well-being, making it a preventive, low-risk, and cost-effective strategy that can be tailored to individual needs and preferences. Beyond physical benefits, exercise positively impacts mental health and can serve as a complement to pharmaceutical interventions [5]. However, community-based exercise initiatives can face various challenges, including financial constraints, difficulties in accessibility, time limitations, and a shortage of specialized guidance [6, 7]. Hence, advocating for the adoption of home-based physical exercise routines, presents a viable and economically efficient substitute.

AIM

The «Full-Body in-Bed Gym» protocol, designed for home use, can represent a viable option, comprising 10 exercises that can be executed while lying in bed [1, 8–10]. Its primary aim is to alleviate the consequences of physical inactivity and enhance the physical well-being of sedentary individuals, ultimately leading to an improved quality of life. The exercises integrated into this program enhance cardiac, respiratory, and vascular function, as well as fortify limb and trunk muscles, building upon established in-bed cardio-respiratory rehabilitation techniques [9, 10].

Since previous studies had demonstrated the utility of this type of protocol in improving motor function in sedentary elderly patients [1, 11], with this study, we aimed to highlight whether the performance of 10 full-body in-bed gym exercises, repeated three times a week, can indeed contribute to improving the quality of life of sedentary elderly individuals.

MATERIALS AND METHODS

Study Design

This prospective, observational, single-arm study was conducted at the Neurorehabilitation Unit, University of Padua, Padua, Veneto, Italy, between October 2022 and October 2023.

Participants

The study involved individuals of both genders, aged 65 and older, who were classified as sedentary due to their engagement in less than one hour of physical activity per week. To be eligible for participation, individuals were required to have the capacity to maintain both sitting and standing positions. The non-inclusion criteria were set to maintain the homogeneity of the study group and avoid potential confounding factors. Specifically, those under the age of 65 were not considered for inclusion in the study. In addition, we excluded individuals with recent orthopedic

Table 1. Full-Body in-Bed Gym exercise protocol. The protocol includes a variety of upper limb, lower limb, and trunk exercises that can be performed by elderly individuals

Neck and upper limb exercises	1. Arms extension on frontal plane: position the arms with an abduction, flex the elbows, and clench the fists while lying on the bed. Proceed to extend the arms forward while opening the fists, and then return to the initial position. 2. Arms flexion-extension: initiate the exercise by extending the arms along the sides while lying on the bed. Proceed to bend the arms over the head, taking a deep breath as the arms are raised, and exhale while returning to the initial position. 3. Cervical stretching: while sitting on the edge of the bed, flex and extend the head, tilt it, and then rotate it in both directions
Lower limb exercises	1. Ankles flexion-extension: perform ankle flexion and extension while lying in bed. 2. Bed cycling: replicate a pedaling motion by flexing and extending the hips and knees while lying on the bed. Begin by performing the movement with one leg and subsequently progress to using both legs simultaneously. 3. Leg extension: while sitting at the edge of the bed, raise the leg by extending the knee and lifting it off the floor in a leg extension. 4. Stand on tiptoe: while sitting at the edge of the bed, rise onto the tiptoes to stand up and then return to a seated position
Trunk exercises	1. Abdominal exercise: engage the abdominal muscles and raise the upper body while lying on the bed, simultaneously extending the arms. Then, return to the initial position. 2. Pelvis lift: gently raise the pelvis off the bed surface and hold this elevated position for 2 seconds while lying in bed. 3. Trunk lift: While seated at the edge of the bed, use the arms to push against the mattress and lift the upper body in a trunk lift

issues requiring limb immobilization, a history of severe cardiovascular or oncological conditions, and those afflicted by significant neurological disorders, such as limb paralysis, as these conditions could potentially affect their ability to participate in the study or influence the outcomes.

Intervention

The Full-Body in-Bed Gym program was designed to be performed in the comfort of one's home, featuring a set of 10 exercises to be performed three times a week over a span of two months, with sessions on non-consecutive days. These exercises were carefully crafted to target various muscle groups and functional movements, ultimately enhancing overall physical well-being. The set of ten exercises involved a variety of movements: 1) simultaneous ankle flexion and extension with arm movements, 2) frontal arm extension while clenching the fists, 3) replicating a pedaling motion through bed cycling, 4) coordinating arm flexion-extension with deep breathing, 5) performing careful pelvis lifting, 6) engaging in abdominal exercises while extending the arms, 7) stretching the cervical region, 8) lifting the trunk, 9) extending the legs, and 10) standing on tiptoe (Table 1). These exercises are often recommended for individuals who may have physical limitations, are new to exercise, or need to be particularly careful due to medical conditions or previous injuries.

The study's participants received guidance from their Physical Medicine and Rehabilitation physician to manage any minimal exercise-related discomfort or strain. The exercise routine commenced with five repetitions of each exercise and gradually increased in increments of five repetitions over one to two weeks, eventually reaching a maximum of 30 repetitions per exercise per session. Each session could range from approximately 15 minutes to 25–30 minutes. To facilitate participant comprehension and execution of the exercises, instructional materials and video demonstrations were provided (Figure 1). For a dynamic visual representation of the Full-Body in-Bed Gym sessions, a video can be accessed at the following link: https://youtu.be/pcHKmxCLYFs

Fig. 1. An example of bed cycling exercise. The subject is performing a pedaling motion by flexing and extending the hips and knees, replicating a cycling movement while in a supine position

The quality and quantity of exercises were closely monitored through weekly phone calls to ensure participants' safety and compliance with the program.

The study acknowledges the principles outlined in the Helsinki Declaration as revised in 2013 and adheres to the ethical guidelines recommended therein.

Outcomes evaluations

Outcome measurements were assessed at two time points: before the start of the intervention (referred to as T0) and after two months of training (referred to as T1). Each patient's evaluation included parameters such as gender, age, weight, height, and Body Mass Index (BMI). Additionally, a validated Italian version of the 12-Item Short Form Health Survey (SF-12), derived from the larger 36-Item Short Form Health Survey (SF-36), was employed. This survey is frequently used to gauge individuals' perceptions of their psychophysical well-being, particularly in the context of rehabilitation. The SF-12 provides outcomes in two dimensions: the Physical Component Summary (PCS) and the Mental Component Summary (MCS), offering insights into a patient's well-being from both physical and mental perspectives.

Statistical analysis

We performed the statistical analysis using Microsoft Excel software, and the data were presented in medians along with interquartile ranges, taking into account the variable distributions. To evaluate the normality of the data distribution, we applied the Shapiro-Wilk test. The changes between the initial measurement (T0) and the one made after two months of training (T1) were evaluated using paired t-tests for continuous variables that followed a normal distribution, and Wilcoxon signed-rank tests for variables that did not exhibit a normal distribution. A significance level of $p < 0.05$ was used for all statistical analyses.

RESULTS

The study successfully enrolled and assessed a cohort of 22 individuals, all of whom met the inclusion criteria. These participants, with a median age of 71.90 years, represent a diverse age range from 65 to 85 years, reflecting the older adult population's variability. The study also considered the participants' BMI, which ranged from a minimum of 18.75 to a maximum of 39.21.

The gender distribution within the sample was balanced, with 12 female participants and 10 males.

In assessing the quality of life using the SF-12 survey, the study found notable trends in the physical and mental well-being of the participants. The SF-12 PCS demonstrated an improvement, with a median score of 42.41 at T0, ranging from a minimum of 25.26 to a maximum of 59.8. At T1, the median SF-12 PCS score increased to 48.39, with values ranging from a minimum of 31.64 to a maximum of 59.6. While this increase indicated a positive trend towards the improved physical quality of life, the p-value of 0.07 suggested that this improvement did not reach statistical significance within the limited intervention duration.

In contrast, the SF-12 MCS exhibited a notable and statistically significant improvement. The baseline score was measured at a median of 45.28, with a range from a minimum of 22.36 to a maximum of 60.7. At T1, the SF-12 MCS score increased to 50.85, with values ranging from a minimum of 31.8 to a maximum of 60.7, reflecting the participants' enhanced mental well-being and quality of life with a p-value of 0.04.

It is noteworthy that no adverse effects or complications were reported by any of the participants throughout the study.

DISCUSSION

As the global population continues to undergo demographic shifts and the proportion of elderly individuals increases, the close connection between maintaining an active lifestyle and their overall health and quality of life becomes more apparent [12]. These insights are emphasized by the physiological changes inherent in the aging process, often leading to declines in various aspects of health, such as muscle strength, bone density, cardiovascular fitness, and overall functional capacity [13, 14]. Consequently, promoting an active lifestyle should be a central focus of public health efforts [14].

Ensuring a high quality of life for the elderly is of great significance, as it profoundly influences their overall well-being and happiness. The concept of quality of life for elderly subjects encompasses a broad spectrum, including physical, mental, emotional, social, and environmental dimensions, with health and independence serving as its core [13, 14]. Elderly individuals who enjoy good health and well-being can maintain their autonomy, engage in fulfilling activities, and experience fewer health-related limitations [7, 13]. Emotional and mental well-being, including lower levels of stress and mental health issues, can contribute significantly to a higher quality of life [15]. Additionally, being engaged in meaningful activities is integral to achieving and maintaining a high quality of life in the elderly [4, 16].

In this study, we investigated a cohort of elderly patients who participated in a home-based exercise program specifically designed for sedentary individuals challenged by their advanced age and associated health conditions. The exercises in our program were carefully tailored to address the limitations imposed by advanced age and aimed at targeting multiple physiological systems, including cardiovascular, respiratory, and muscular functions. Our assessments documented noticeable improvements in the patients. Participants engaged in the Full-Body in-Bed Gym program for two months showed an overall enhancement in their quality of life. These improvements encompassed both physical and mental well-being, although the increase in physical well-being did not reach statistical significance.

This implementation of the Full-Body in Bed Gym program aligns with the growing understanding that exercise benefits not only physical health but also plays a substantial role in enhancing emotional and mental well-being in elderly individuals [16, 17]. An active lifestyle has been shown to have a profound influence on psychological well-being in the elderly, affecting different emotional aspects, including mood, anxiety, and depression [18–22], with these psychological improvements attributed to a multifaceted range of factors, including neurochemical release and physiological adaptations stemming from exercise [5].

A comprehensive regimen of rhythmic aerobic exercises, such as the Full-Body in-Bed Gym program, aligns with research indicating that aerobic exercises conducted regularly for at least 10 weeks have consistently shown positive effects on psychological well-being in the elderly [18, 23–26]. Moreover, the Full-Body in-Bed Gym program has the potential to boost self-efficacy by fostering a sense of achievement and self-confidence as participants progress, thereby enhancing emotional well-being and overall quality of life in elderly individuals [13, 16].

The absence of reported adverse effects among elderly participants highlights the program's safety and potential for managing age-related inactivity, although further research is needed to establish its effectiveness conclusively, given limitations in sample size, lack of a control group, and short study duration. In our study, we encompassed a diverse group of participants, including both elderly patients aged 65–74 and senile patients aged 75–80, as classified by the World Health Organization (WHO). Additionally, our sample comprised individuals with a range of body weights, from normal weight to obesity. This diversity in terms of age and physical condition introduced variability that may have affected the reliability of our findings regarding the positive effects of the program on physical health. These differences in age and physical condition could have contributed to variations in individual responses to the Full-Body in-Bed Gym program, which may have influenced the outcomes observed. Consequently, future studies with larger sample sizes and more homogeneous groups should be considered to gain a clearer understanding of the program's effects and to refine its suitability for different demographic subgroups.

In summary, this study addresses age-related quality of life issues through the introduction of the home-based Full-Body in-Bed Gym program, which aims to enhance physical and mental well-being in sedentary elderly individuals by involving a series of 10 in-bed exercises. The absence of reported adverse effects underscores its safety and potential for managing age-related inactivity at home. Nevertheless, further research is needed to confirm and build upon these promising findings.

CONCLUSION

Integrating physical activity into the lives of older adults has the potential to enhance their quality of life and independence. Our study suggests that a short series of home-based Full-Body in-Bed Gym exercises can positively impact the overall well-being of sedentary elderly individuals. Although the results are encouraging, more comprehensive research involving larger sample sizes, control groups, and extended follow-up periods should be conducted to gain a more profound insight into the effectiveness of such exercise programs in promoting healthy aging and averting functional decline.

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Results of Audiovisual Stimulation and Psychotherapy in Psychological Correction of Emotional Disorders in Patients in the Late Recovery Period after an Ischaemic Stroke: a Prospective Randomized Study

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ABSTRACT

INTRODUCTION. Emotional and personality disorders that occur in patients after a stroke have a negative impact on the rehabilitation process, reducing its effectiveness, disrupting the motivation for treatment and quality of life. Today, comprehensive rehabilitation programs for patients in the late recovery period after acute cerebrovascular accident, aimed at psychological correction of emotional disorders, are becoming relevant.

AIM. To study the effectiveness of audiovisual stimulation and techniques of rational-emotive and body-oriented psychotherapy on the emotional state of patients in the late recovery period after an ischaemic stroke.

MATERIALS AND METHODS. The study included 40 patients after an acute cerebrovascular accident (ACVA) in the late recovery period (from 6 months to 2 years after ACVA) aged between 45 and 75 years, average age 61.6 [53.95; 68.1]. The patients were randomized into two groups. The main group included patients (n = 20 people, of which 7 men, 13 women, age — 62.09 [53.5; 68.6] years), who underwent a complex basic rehabilitation program, including audiovisual stimulation and psychotherapy techniques; the control group included patients (n = 20, including 6 men, 14 women, age — 61.1 [54.4; 67.5] years) who underwent a basic rehabilitation program. For psychological diagnostics, the Hospital Anxiety and Depression Scale (HADS) and the author's computer program were used to study the current emotional state. The statistical significance of differences before and after the treatment was determined using the nonparametric Wilcoxon test. To assess the statistical comparability of the two groups, the Mann-Whitney test was used ($p > 0.05$).

RESULTS. The use of audiovisual stimulation and techniques of rational-emotive and body-oriented psychotherapy in the psychological correction of emotional disorders in patients in the late recovery period after an ischemic stroke allows us to achieve a statistically significant effect in reducing state and trait anxiety, the level of chronic fatigue, as well as increasing the subjective comfort and quality of life ($p < 0.05$).

DISCUSSION. The study showed that patients in the late recovery period after a stroke before treatment experienced high levels of anxiety and depression and experienced a severe psycho-emotional stress. As a result of audiovisual stimulation and psychotherapy techniques, indicators of the negative emotional state of patients in the late recovery period after an ischemic stroke significantly decreased, mood improved, activity and tolerance to psychological stress increased.

CONCLUSION. A comprehensive rehabilitation of patients in the late recovery period after a stroke, aimed at psychological correction of emotional disorders, significantly improved the emotional background, increased tolerance to psychological stress, and also contributed to increased motivation for restorative treatment and rehabilitation.

KEYWORDS: anxiety, depression, state anxiety, trait anxiety, cognitive sphere, emotional and personal sphere, emotional disorders, psychological correction, ischemic stroke, rational-emotive psychotherapy, body-oriented psychotherapy, audiovisual stimulation.

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Результаты применения аудиовизуальной стимуляции и психотерапии в психологической коррекции эмоциональных нарушений у пациентов в позднем восстановительном периоде ишемического инсульта: проспективное рандомизированное исследование

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РЕЗЮМЕ

ВВЕДЕНИЕ. Эмоциональные расстройства, возникающие у пациентов после инсульта, негативно отражаются на реабилитационном процессе, снижая его эффективность, нарушают мотивацию к лечению и качество жизни. На сегодняшний день становятся актуальными программы комплексной реабилитации пациентов в поздний восстановительный период после острого нарушения мозгового кровообращения, направленные на психологическую коррекцию эмоциональных нарушений.

ЦЕЛЬ. Изучение эффективности применения аудиовизуальной стимуляции и техник рационально-эмотивной и телесно-ориентированной психотерапии на эмоциональное состояние пациентов в позднем восстановительном периоде ишемического инсульта.

МАТЕРИАЛЫ И МЕТОДЫ. В исследование вошли 40 пациентов после острого нарушения мозгового кровообращения (ОНМК) в поздний восстановительный период (срок давности от 6 месяцев до 2 лет) в возрасте от 45 до 75 лет, средний возраст 61,6 [53,95; 68,1] года. Пациенты были рандомизированы на две группы. В основную группу вошли пациенты (n = 20 человек, из них 7 мужчин, 13 женщин, возраст — 62,09 [53,5; 68,6] года), у которых проводился комплекс базовой программы реабилитации, включающий аудиовизуальную стимуляцию и техники психотерапии; в контрольную группу вошли пациенты (n = 20, из них 6 мужчин, 14 женщин, возраст — 61,1 [54,4; 67,5] года), у которых проводилась базовая программа реабилитации. Для психологической диагностики использовались госпитальная шкалы тревоги и депрессии (HADS) и авторская компьютерная программы для исследования актуального эмоционального состояния. Статистический анализ проводили с применением пакета прикладных программ SPSS 23. Статистическую значимость различий до и после лечения определяли с помощью непараметрического критерия Вилкоксона. Для оценки статистической сопоставимости двух групп использовали критерий Манна—Уитни (p > 0,05).

РЕЗУЛЬТАТЫ. Применение аудиовизуальной стимуляции и техник рационально-эмотивной и телесно-ориентированной психотерапии в психологической коррекции эмоциональных нарушений у пациентов в позднем восстановительном периоде ишемического инсульта позволяет получить статистически значимый эффект по снижению ситуативной и личностной тревожности, уровня хронического утомления, а также повышению субъективного комфорта и качества жизни (p < 0,05).

ОБСУЖДЕНИЕ. Проведенное исследование показало, что пациенты в позднем восстановительном периоде после инсульта до лечения переживали тревогу и депрессию высокого уровня, испытывали сильное психоэмоциональное напряжение.

Под влиянием аудиовизуальной стимуляции и техник психотерапии достоверно снизились показатели негативного эмоционального состояния пациентов в позднем восстановительном периоде ишемического инсульта, улучшилось настроение, повысились активность и толерантность к психологическим нагрузкам.

ЗАКЛЮЧЕНИЕ. Комплексная реабилитация пациентов в позднем восстановительном периоде после инсульта, направленная на психологическую коррекцию эмоциональных нарушений, позволила существенно улучшить эмоциональный фон, повысить толерантность к психологическим нагрузкам, а также способствовала повышению мотивации к восстановительному лечению и реабилитации.

КЛЮЧЕВЫЕ СЛОВА: тревога, депрессия, ситуативная тревожность, личностная тревожность, эмоциональные нарушения, психологическая коррекция, ишемический инсульт, рационально-эмотивная психотерапия, телесно-ориентированная психотерапия, аудиовизуальная стимуляция.

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INTRODUCTION

Cerebrovascular diseases remain one of the most socially significant problems of the present-day society. The death rate of the population in the Russian Federation due to cerebrovascular diseases was more than 260 thousand people in 2018. [1]. We can predict an increase in the number of patients with this pathology, as the negative role of the following factors is increasing in the population: atherosclerosis, diabetes mellitus, arterial hypertension, which is confirmed by the data

provided by information bulletins of the WHO. Ischaemic stroke is one of the major causes of mortality, disability and pronounced disadaptation of patients, accounting for about 80 % of all types of acute cerebral circulatory events [2, 3].

For a long time, the main focus of medical rehabilitation of post-stroke patients has been the restorative treatment of motor disorders. At the same time, recent studies suggest the need to correct cognitive, emotional and behavioural disorders after a stroke [4, 5]. Emotional disorders not only have a negative impact on the recovery process after a stroke, reducing the motivation for treatment and the quality of life of patients, but also have a negative impact on death rates, regardless of the age of the patients [5].

Understanding the significance of the problem of emotional and behavioural disorders in patients after a stroke has prompted the introduction of a special section in the current clinical guidelines of many countries, which prescribes psychological diagnosis of these disorders for the timely diagnosis and commencement of treatment [5, 6].

All the above-mentioned causes the relevance of the development of complex rehabilitation programmes for patients in the late recovery period after the ACVA, aimed at psychological correction of emotional and behavioural disorders, increasing the effectiveness of medical rehabilitation, decreasing anxiety and depression, reducing psycho-emotional stress and increasing tolerance to psychological stress, forming a positive motivation for recovery and rehabilitation and improving the subjective comfort and quality of life of patients [7–11].

AIM

To study the effectiveness of audiovisual stimulation and techniques of rational-emotive and body-oriented psychotherapy on the emotional state of patients in the late recovery period after an ischaemic stroke.

MATERIALS AND METHODS

The study included 40 patients after an acute cerebrovascular accident (ACVA) in the late recovery period (from 6 months to 2 years after ACVA) aged between 45 and 75 years, 13 men and 27 women. The patients were treated in a research and clinical center (National Medical Research Center for Rehabilitation and Balneology, Moscow).

The patients were randomized into 2 groups. The control group included patients (n = 20, including 6 men, 14 women, age 61.1 [54.4; 67.5] years) who underwent a basic medical rehabilitation programme.

The basic programme included a special complex of exercise therapy for diseases of the central nervous system and brain, performed in a gym with a physical therapy instructor, No. 10; correction of motor function disorders using computer technologies of the DIEGO 3D system, No. 10; robotic mechanotherapy, No. 10; low-intensity laser radiation, No. 10; magnetic field treatment, No. 10; electrical stimulation, No. 10; therapeutic baths, No. 10; speleological therapy, No. 10; medical massage of the upper and lower extremities, No. 10.

The main group included patients (n = 20, including 7 men, 13 women, age 62.09 [53.5; 68.6] years) who underwent audiovisual stimulation and techniques of rational-emotive and body-oriented psychotherapy against the background of the basic medical rehabilitation programme.

For audiovisual stimulation we used «Hardware-software complex for correction of human psychosomatic state by means of programmed resonance-acoustic oscillations of ECG and/or EEG signals «ECRAN» («AKSMA» LLC, Russia). [10]. The operation mode of the device was adjusted to the programme «Relaxation», according to which the binaural exposure was effected in the mode of smooth readjustment from the state of beta-activity (15 Hz) down to theta-rhythm (7 Hz). The course of treatment included 10 procedures, and the length of one procedure was 22 minutes.

Rational-emotive (REPT) and body-oriented (BOPT) psychotherapy techniques were used to develop emotional response and emotional regulation. The REPT techniques were used for logical, empirical and pragmatic disputation aimed at changing the patient's erroneous beliefs about his/her health and condition. The session length was 30 minutes (10 sessions per course No. 10). Body-oriented psychotherapy techniques, including breathing techniques and relaxation techniques, were aimed at achieving self-regulation and maintenance by the patient of consistent relaxation of muscle groups of the whole body from head to feet. The session length was 30 minutes (10 sessions per course No. 10).

Psychological diagnostic methods included the Hospital Anxiety and Depression Scale (HADS), the author's computer programme for studying the current emotional state, which used the following scales: «State Scale», «State Anxiety Scale», «Trait Anxiety Scale», «Anxiety-Depressive Emotions Scale» and «Degree of Chronic Fatigue» scale [8], the Mini Mental State Examination test (Brief Mental Status Assessment Scale), and the Stroke Specific Quality of Life Scale (SS-QOL).

Statistical analysis was performed using the SPSS 23 software package. The Mann-Whitney test ($p > 0.05$) was used to assess the statistical comparability of the two groups. Statistical significance of differences before and after the treatment was measured using the nonparametric Wilcoxon test (the differences between the groups were considered statistically significant at $p < 0.05$).

RESULTS

When analyzing the indicators of the emotional sphere of 40 patients in the late recovery period after an ischaemic stroke before the rehabilitation measures, the following data were obtained.

According to the HADS (Hospital Anxiety and Depression Scale) test, subclinical anxiety and clinical anxiety were found in 24 (60.0 %) and 6 (15.0 %) patients of the two groups. Subclinical depression and clinical depression were found in 20 (50.0 %) and 8 (20.0 %) patients.

The State-Trait Anxiety Inventory (Spilberger-Khanin) showed a high level of state anxiety in 26 (65.0 %) patients, 5 (12.5 %) patients showed a borderline level of state anxiety, in which the patient could not cope with a

stressful situation and needed medication to correct the emotional state, 3 (8.0 %) patients showed a low level of state anxiety, indicating disorders in the motivational sphere. A trait anxiety according to the State-Trait Anxiety Inventory was observed in 27 (67.5 %) patients, in 12 (30.0 %) a borderline level was found, at which emotional and neurotic breakdowns are possible.

In the emotion profile, 34 (85.0 %) the patients in the two groups showed anxious and depressive emotions.

The quality of life according to the SS-QOL scale was reduced in 26 (65.0 %) and low in 4 (10.0 %) patients. One of the main factors reducing the patients' quality of life was negative psycho-emotional background found in 28 (70 %) patients.

According to the Mini Mental State Examination test, cognitive impairments were found in 22 (55.0 %) patients of the two groups.

Thus, the initial diagnostic indicators suggest pronounced disorders in the emotional, personal and cognitive spheres in patients in the late recovery period after an ischaemic stroke and the need to carry out psychological correction.

Assessment of the emotional state in the groups after the treatment demonstrated improvement in both the main group and the control group, but of different degrees of manifestation.

Thus, anxiety and depression scores on the HADS scale were significantly reduced in both the main group and the control group ($p < 0.05$). At the same time, a significant decrease in state and trait anxiety on the Spilberger-Khanin scale (State-Trait Anxiety Inventory) and anxiety-depressive emotions on the emotion scale was achieved only in the main group ($p < 0.05$) (Table 1).

After the treatment, there was a statistically significant increase in the subjective comfort score on the state scale in the patients of the main group. A high level of the subjective comfort was found in 13 (65.0 %) patients, and an acceptable level of the subjective comfort was found in 7 (35.0 %) patients, indicating an improvement in well-being, increased activity, and interest in rehabilitation and restorative treatment in all patients in the main group ($p < 0.05$); while in patients in the control group, a high level of the subjective comfort was found in 4 (20.0 %) patients, and a low level of the subjective comfort was found in 16 (80 %) patients, which suggests an increase in the subjective comfort in individual patients in the control group, while in the group as a whole the subjective comfort indicator remained at the level of a low subjective comfort.

The level of chronic fatigue on the fatigue scale after the treatment significantly decreased in relation to the initial indicator also in the main group: 16 (80.0 %) patients of the main group had no signs of chronic fatigue, 4 (20.0 %) patients showed only initial signs of chronic fatigue ($p < 0.05$). In the control group, there was no significant decrease in the chronic fatigue indicator: 4

Table 1. Dynamic pattern of emotional state indicators (in points) in post-stroke patients when exposed to audiovisual stimulation and techniques of rational-emotive and body-oriented psychotherapy (Me [Q_1; Q_3])

Indicators	Group I (main), *n* = 20		Group II (control), *n* = 20	
	Before	After	Before	After
Anxiety and depression on the HADS scale				
Anxiety	9.0 [7.5; 10.0]	3.5 [2.0; 6.5]*	8.5 [7.5; 10.0]	3.0 [1.5; 5.0]*
Depression	8.0 [7.0; 9.5]	3.0 [2.0; 6.5]**	8.5 [7.5; 10.0]	8.0 [7.5; 9.5]#
State and trait anxiety on the Spilberger-Khanin scale				
State anxiety	47.5 [43.0; 58.0]	36.0 [34.5; 40.5]**	49.0 [45.0; 53.0]	34.0 [23.0; 38.0]##
Trait anxiety	49.5 [47.0; 65.5]	44.0 [34.5; 44.5]**	52.0 [47.0; 58.0]	45.0 [45.0; 50.0]##
Anxious-depressive emotions on the emotion scale				
Anxious and depressive emotions	23.0 [21.0; 27.0]	12.0 [12.0; 14.5]*	23.0 [21.0; 26.5]	21.0 [19.0; 24.5]#

Note. *Differences were analyzed using the Wilcoxon test; * statistically significant difference before and after the treatment, $p < 0.05$; ** — $p < 0.001$; the significance of differences between the groups after the treatment was established by the Mann-Whitney test: # — $p < 0.05$; ## — $p < 0.001$.*

Table 2. Dynamic pattern of indicators of the subjective comfort, level of chronic fatigue, quality of life, cognitive functions (in points) in post-stroke patients when exposed to audiovisual stimulation and techniques of rational-emotive and body-oriented psychotherapy (Me [Q_1; Q_3])

Indicators	Group I (main), *n* = 20		Group II (control), *n* = 20	
	Before	After	Before	After
Subjective comfort on the state scale				
Subjective comfort	34.0 [28.5; 39.0]	52.5 [49.0; 58.0]**	34.5 [30.5; 37.5]	41.0 [34.0; 48.5]*#
Level of chronic fatigue on the fatigue scale				
Chronic fatigue level	39.0 [32.5; 46.5]	16.5 [12.5; 18. 0]*	38.0 [34.0; 43.5]	23.0 [18.0; 28.5]#
Quality of life on the SS-QOL scale				
The quality of life	193.0 [175.0; 211.0]	218.0 [207.0; 234.5]*	187.5 [175.3; 223.5]	185.5 [179.0; 226.5]#
Cognitive functions on the MMSE scale				
Cognitive functions	27.0 [24.0; 29.0]	28.0 [25.3; 28.0]	27.0 [26.0; 28.8]	28.5 [28.5; 29.8]

Note. *Differences were analyzed using the Wilcoxon test; * — statistically significant difference before and after the treatment, $p < 0.05$; ** — $p < 0.001$. The significance of differences between the groups after the treatment was established by the Mann-Whitney test: # — $p < 0.05$; ## — $p < 0.001$.*

(20 %) patients had no signs of chronic fatigue, 8 (40.0 %) patients showed initial signs of chronic fatigue and 8 (40.0 %) patients showed signs of pronounced chronic fatigue, when patients find it difficult to do anything; they feel tired all the time.

The quality of life indicator on the SS-QOL scale after the treatment changed in relation to the initial indicator also in the main group ($p < 0.05$), while no significant change in this indicator was found in the control group.

Assessment of the changes of the cognitive functions indicator on the MMSE scale in the groups after the treatment showed an improvement of the indicator in both the main group and the control group, but no statistically significant improvement of cognitive functions was achieved (Table 2).

The comparative analysis changes of the emotional state indicators in two groups when exposed to audiovisual influence and techniques of rational-emotive and body-oriented psychotherapy showed a significant decrease in high indicators of state and trait anxiety, a high level of chronic fatigue and increase in the subjective comfort in the patients of the main group ($p < 0,05$) (see Table 2).

DISCUSSION

The study showed that the patients during the late recovery period after a stroke were experiencing a high level of anxiety and depression before the treatment, and were experiencing a severe psycho-emotional stress. This partly confirms the conclusions made by other researchers that anxiety, depression, impaired cognitive functions, mood, and mental state are among the most common problems of these patients [6, 7, 9, 11].

The results of the conducted study of the effect of a complex rehabilitation programme with the inclusion of audiovisual stimulation and techniques of rational-emotive and body-oriented psychotherapy on the emotional state of patients in the late recovery period after an ischaemic stroke indicate a significantly substantial decrease in anxiety and depression, a decrease in state and trait anxiety, and an increase in the subjective comfort. This confirms the findings of other researchers about the reduction of negative emotional state indicators after clinical application of audiovisual impact [12, 13], increases the possibilities of correction of anxiety-depressive disorders in patients in the late recovery period after a stroke by means of psychotherapy techniques.

It is important to emphasize that post-stroke patients during the late recovery period when exposed to audiovisual stimulation and techniques of rational-emotive and body-oriented psychotherapy improved mood, decreased psycho-emotional stress, increased activity and tolerance to psychological stress.

At the same time, under the influence of psychotherapy, the patients learnt adaptive coping-strategies that allowed them to avoid the recurrence of neurotic manifestations and promoted active inclusion of patients in the rehabilitation process [14, 15].

CONCLUSION

Psychological diagnostics of initial indicators of emotional state and cognitive functions, carried out in patients during the late recovery period after an ischaemic stroke, showed pronounced emotional disorders in 65.0 % of patients and the need for psychological correction of high indicators of anxiety and depression, high level of state and trait anxiety, a high level of chronic fatigue and low indicators of the subjective comfort.

1. Psychological correction of emotional disorders in post-stroke patients during the late recovery period, included in the complex programme of medical rehabilitation, contributed to the normalization of emotional state in 70.0 % of patients.
2. The use of audiovisual stimulation and techniques of rational-emotive and body-oriented psychotherapy enabled to significantly reduce state and trait anxiety, chronic fatigue, and increase the subjective comfort ($p < 0.05$) in patients during the late recovery period after a stroke.
3. A comprehensive rehabilitation programme with the inclusion of audiovisual stimulation, rational-emotive and body-oriented psychotherapy techniques contributed to a significant decrease in anxiety-depressive emotions and improved the quality of life of patients in the late recovery period after an ischemic stroke ($p < 0.05$).
4. The findings serve as a basis for the inclusion of audiovisual stimulation methods and psychotherapy techniques in the programmes of the complex medical rehabilitation of post-stroke patients.

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Ethics Approval. The authors declare that all procedures used in this article are in accordance with the ethical standards of the institutions that conducted the study and are consistent with the 2013 Declaration of Helsinki. The study was approved by the decision of the Local Ethics Committee of the National Medical Research Center for Rehabilitation and Balneology (Protocol No. 10, 11.28.2022).
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Effectiveness and Safety of Robotic Mechanotherapy with FES and VR in Restoring Gait and Balance in the Acute and Early Rehabilitation Period of Ischemic Stroke: Prospective Randomized Comparative Study

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ABSTRACT

INTRODUCTION. Impaired gait and balance after a stroke significantly affect patients' daily activities and quality of life. Robotic mechanotherapy and virtual reality technologies are actively studied and used to restore lower limb muscle strength, balance and gait pattern.

AIM. To assess the effectiveness and safety of rehabilitation using robotic mechanotherapy (exoskeleton) with functional electrical stimulation (FES) and virtual reality (VR) technology with plantar stimulation in the restoration of gait and balance disorders in patients in acute and early recovery periods of ischemic stroke.

MATERIAL AND METHODS. Men and women aged 39 to 75 with ischemic stroke in acute and early recovery periods with gait impairment and lower limb paresis from 0 to 4 MRC scores. The patients were randomized using the envelope method into 4 groups: Group 1 (33 people) — exoskeleton with FES, Group 2 (32 people) — combined application of robotic mechanotherapy with FES and VR with plantar stimulation, Group 3 (35 people) — VR with plantar stimulation, Control group (30 people) — conventional training.

RESULTS. Group 2 and 3 had significantly greater increases in muscle strength in the hip extensors, tibia flexors and flexors of the foot compared to the control group. Patients in the main groups also had a significant improvement in Tinetti Walking and balance Scale at follow-up. The analysis of the stabilometry results on the first and last day of the study revealed a decrease in the area of the statokinesiogram in the main groups both in the intragroup comparison and in the comparison with the control group.

DISCUSSION AND CONCLUSION. Exoskeleton gait training with FES and exercises on a VR with plantar stimulation, as well as combined use of these techniques allowed to achieve better recovery of lower limb muscle strength, walking functions and balance in patients in acute and early rehabilitation periods of stroke. This is probably due to the large number of steps or their imitation performed by the patient during rehabilitation sessions, which leads to activation of neuroplasticity and better recovery. The study demonstrated the safety and efficacy of an exoskeleton interval training system that prevents the development of orthostatic hypotension in patients in the acute period of ischemic stroke.

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KEYWORDS: robotic mechanotherapy, functional electrical stimulation, virtual reality, medical rehabilitation, neurorehabilitation, stroke, gait rehabilitation, balance rehabilitation.

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Опыт применения технологий роботизированной механотерапии с функциональной электростимуляцией и виртуальной реальности в восстановлении ходьбы и равновесия в остром и раннем реабилитационном периоде ишемического инсульта

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РЕЗЮМЕ

ВВЕДЕНИЕ. Нарушение ходьбы и равновесия после перенесенного инсульта в значительной степени влияют на повседневную активность и качество жизни больных. Роботизированная механотерапия и технологии виртуальной реальности активно изучаются и используются для восстановления силы мышц нижних конечностей, баланса и паттерна ходьбы.

ЦЕЛЬ. Исследование эффективности и безопасности реабилитационных программ с применением технологии роботизированной механотерапии (экзоскелет) с функциональной электростимуляцией (ФЭС) и технологии виртуальной реальности (ВР) с подошвенной стимуляцией в восстановлении нарушений ходьбы и у пациентов в остром и раннем восстановительном периодах ишемического инсульта.

МАТЕРИАЛЫ И МЕТОДЫ. В исследование были включены мужчины и женщины в возрасте от 35 до 75 лет с впервые возникшим ишемическим инсультом в остром и раннем восстановительном периоде. Выраженность пареза нижних конечностей составляла от 0 до 4 баллов по MRC. Пациенты были распределены случайным порядком в 4 группы: группа 1 (33 пациента) — применение экзоскелета с ФЭС, группа 2 (32 пациента) — комбинированное применение экзоскелета с ФЭС и ВР с подошвенной стимуляцией, группа 3 (35 пациентов) — применение ВР с подошвенной стимуляцией, контрольная группа (30 больных).

ОБСУЖДЕНИЕ И ЗАКЛЮЧЕНИЕ. Восстановление ходьбы в экзоскелете с ФЭС и занятия на тренажере ВР с подошвенной стимуляцией, а также комбинированное применение этих методик позволили добиться лучшего восстановления силы мышц нижних конечностей, функций ходьбы и равновесия у пациентов в остром и раннем восстановительном периодах ишемического инсульта.

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INTRODUCTION

According to WHO, stroke is recognized as the second leading cause of death among cardiovascular diseases after myocardial infarction [1,2]. In adults, stroke is the main factor causing long-term disability. The result of the population aging and an increase in the efficiency of medical care was an annual increase in the number of patients with the consequences of a stroke, especially hemiplegia [3]. Gait disorder is considered the most common in the strength decrease in lower extremities. Up to 80 % of patients with ischemic stroke have an altered walking pattern and 70 % have episodes of falling during the first year after disease onset [4]. The main statolocomotor disorders are gait asymmetry, increased muscle tone of the lower extremities and balance disorders [3]. In the acute stroke, spasticity and imbalance contribute most to the restriction of daily activity [1]. It is known that there are processes of self-recovery of muscle strength, which can be completed in 2–3 months. However, the pathological walking pattern (impairment of the neural mechanism of movement control, occurrence of pathological synergies, leading to improper muscle activation in movement and at rest, incomplete hip extension, circumferential leg movement, improper transfer of the center of gravity) [5] can become anchored, therefore, early rehabilitation

with the formation of correct movement stereotypes is crucial for optimizing human functioning after a stroke [6]. Correction of the resulting neurological deficit occurs in the first months after a stroke, but some functions can be actively restored during the first year [7,8].

In the last 15 years, robotic mechanotherapy (RM), in particular exoskeletons, has become actively studied and introduced into clinical practice, presenting an alternative to classical conventional rehabilitation [9,10]. There is evidence that the use of an exoskeleton allows not only muscle strength recovery, but also contributes to the improvement of cognitive functions in stroke patients [11,12]. This phenomenon is explained by the active production of myokines during walking, which, penetrating through the blood-brain barrier, activate the processes of neuroplasticity and neurogenesis. One of the latest trends is the combination of functional electrostimulation (FES) with robotic orthoses, which allows achieving greater efficiency in the reconstruction of walking pattern [13,14].

The use of virtual reality (VR) technology is another recognized method for restoring muscle strength after a stroke [7,15]. However, most of the data in the clinical guidelines focus on upper limb paresis. According to one systematic review on the role of virtual reality in post-stroke rehabilitation, this technique slightly improves walking speed (by 0.09 m/s) [16]. There are also sporadic data on the combined and combined application of these techniques, but this direction needs further study.

AIM

The main purpose of this clinical trial was to study the effect of RM with FES and VR with plantar stimulation on gait and balance recovery in patients in the acute and early rehabilitation period of ischemic stroke. The main objectives were to prove the safety and effectiveness of the use of innovative technologies, as well as to create a program of motor rehabilitation using these methods.

MATERIALS AND METHODS

The clinical protocol of the study was approved by the local ethical committee of Moscow Centre for Research and Practice in Medical Rehabilitation, Restorative and Sports Medicine of Moscow Healthcare Department, protocol 1 date 17.03.2022 and registered at ClinicalTrails.gov ID: NCT05423626. Before starting the study, all patients received detailed information about the rehabilitation technologies applied and signed informed agreement. The inclusion criteria were as follows: men and women aged 18 to 75 years with established diagnosis of ischemic stroke in acute (up to 3 weeks) and early recovery (up to 6 months) periods with walking impairment, lower limb paresis from 0 to 4 MRC scores. An important criterion was the preservation of cognitive functions (at least 27 points on the MoCA) and a Rankin scale score of 3 to 4, the weight of the patients was no more than 100 kg, and the height varied from 160 to 190 cm, this was due to the technical characteristics of the exoskeleton. The exclusion criteria were as follows: significant muscle spasticity (more than 3 score MAS), bone and joint diseases or serious diseases affecting organ function, expressed vegetative dysreflexia, uncontrolled arterial hypertension visual or hearing disorders, unable to cooperate with the study. All patients underwent physical and neurological examination on admission and discharge. The degree of lower limb paresis was assessed according to the five-point MRC scale, National Institutes of Health Scale (NIHSS). Spasticity was determined using the modified Ashworth scale (MAS). Functional independence was examined using the modified Rankin Scale (mRS) and the Rivermead Mobility Index. Gait and balance impairment were assessed using the Tinetti Scale. Diagnostic stabilometry was also performed on admission and at discharge. The patients were randomized using the envelope method into 4 groups:

- Group 1 (robotic mechanotherapy with FES) — in addition to basic therapy, patients received 10 procedures of walking in ExoAtlet I exoskeleton with FES, 5 times a week, the duration of medical rehabilitation course — 12–14 days. The duration of the procedure was 30 minutes.
- Group 2 (combined application of robotic mechanotherapy with FES and VR with plantar stimulation) — besides basic therapy, the patients received 10 procedures on Virtual reality simulator with sole stimulation (ReviVR), the duration of one procedure was 30 minutes, 5 times a week, followed by training in ExoAtlet I exoskeleton with FES after 90 minutes. Duration of motor activity during one session was 30 minutes, 5 times a week, duration of medical rehabilitation course was 12–14 days.
- Group 3 (VR technologies with plantar stimulation) — besides basic therapy patients received 10 procedures on ReviVR simulator, 5 times a week, the duration of medical rehabilitation course was 12–14 days. The duration of one procedure was 30 minutes.
- Control group — restoration of walking and balance was carried out with the help of conventional training (individual or group therapeutic exercise classes), 5 times a week, the duration of the medical rehabilitation course — 12–14 days.

Exoskeleton training duration, according to the patient's condition, up to 1 hour (taking into account the time for exoskeleton readjustment and patient positioning). Measurement of pulse, pressure and saturation in the preparatory, main and final parts. The length of time in the upright position depends on the patient's condition. In patients in the acute period of stroke, a pause for rest in a sitting position is made every 10 minutes of training. Transition to the formation of subsequent skills is recommended after mastering the skills of the previous procedure. Starting from the 4th session, patients are switched to continuous walking. The total duration of the VR procedure is 30 minutes. Before the procedure, BP and HR are measured and the size of pneumatic cuffs on the feet is selected. After briefing the patient and selecting the virtual environment and optimal speed of movement in VR, VR glasses are fitted. Next, rehabilitation exercises are performed for 15 minutes. The patient moves in the virtual environment, receiving visual, auditory and tactile cues that form the correct walking pattern. At the end of the exercise, the VR goggles are disassembled. Then BP and HR are measured and information about the feeling and sensations during

Table 1. Characteristics of groups on admission

Feature	Group 1, *n* = 33	Group 2, *n* = 32	Group 3, *n* = 35	Control group, *n* = 30	*p*
Age (years)	62.5 ± 7.7	57.4 ± 8.2	60.6 ± 7	62 ± 6.5	> 0.05
Stroke onset time (days)	15 [12; 2 4]	21 [13; 91]	15 [12; 67]	17.5 [12; 67.5]	> 0.05
BMI	26 [23.9; 29.9]	28 [25.7; 29.4]	27.7 [24; 30.4]	27.5 [25; 29.3]	> 0.05
Systolic BP	130 [120; 132.5]	130 [122; 139]	130 [120; 140]	130 [120; 130]	> 0.05
MRC int.	3.66 [2.5; 4]	3.44 [2.38; 4]	3 [2.66; 4]	3.5 [2.9; 4]	> 0.05
MAS int.	0 [0; 1]	0.33 [0; 1]	0 [0; 1]	0 [0; 1]	> 0.05
mRS	3 [3; 4]	3 [3; 3]	3 [3; 4]	3 [3; 4]	> 0.05
Rivermead Mobility Index	7 [5; 8]	7 [7; 9.75]	7 [7; 9]	7 [7; 7]	> 0.05
Tinetti Scale balance	6 [4; 9]	8 [5.25; 9]	7 [4; 9]	6 [3.75; 9]	> 0.05
Tinetti Scale walking	4 [2; 5.5]	5 [4; 6]	4 [3; 6]	5 [2; 7]	> 0.05
MoCA	28 [27; 28]	28 [28; 28]	28 [27; 28]	27.7 [27; 28]	> 0.05

Note: *MRC int. — integral index of strength in all studied muscles; MAS int. — integral index of muscle tone in all studied muscles.*

the procedure is recorded. Basic therapy included laser therapy, magnetic therapy, and therapeutic massage of the lower extremities. The control group additionally used electrical stimulation of the affected limb. All basic therapy was performed according to protocols from the National Physical Therapy Manual [17]. A system of interval training was developed for groups using RM with FES, which consisted in dividing the exercise into 10-minute intervals with mandatory 5-minute breaks, which the patient spent in a sitting position. This approach allowed the patients to adapt faster to physical activity and achieve a distance of 1500–1800 steps per exercise, as well as to avoid orthostatic reactions during the exercise.

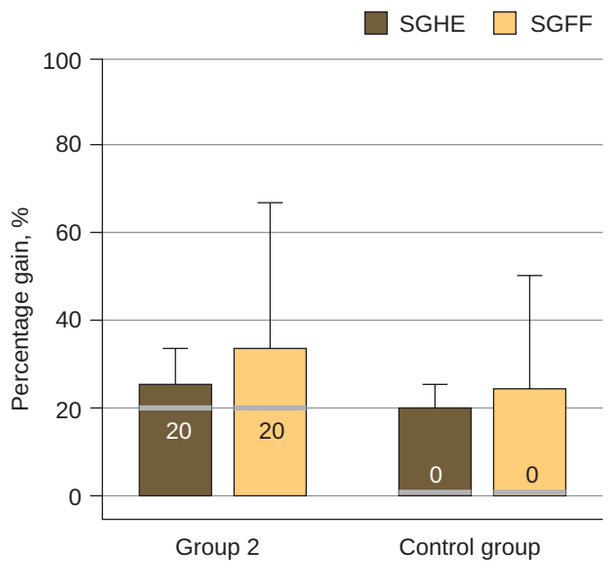

Fig. 1. Comparison of strength gains in the hip extensors and foot flexors in groups 2 and 4
Note: *SGHE — strength gain in hip extensors; SGFF — strength gain in the foot flexors.*

Statistical analysis

Statistical analysis to assess the effectiveness of rehabilitation in different groups was performed by comparing initial and final data, as well as changes in the main and additional neurological scales before and after the rehabilitation course. Nonparametric tests (Wilcoxon test, Mann-Whitney test, Kruskal-Wallis test) were used to reveal statistically significant changes. The data were checked for normality using the Kolmogorov-Smirnov test. Spearman correlation analysis was used to determine the mutual influence of the variables. Results are presented as mean values with standard deviation, medians with the 25th and 75th percentiles.

RESULTS

The study included 130 patients (38 women and 92 men), mean age was 60.6 ± 7.6 years. Patients were divided into a main (group 1 — 33 patients, group 2 — 32 patients, group 3 — 35 patients) and a control group (30 patients). The comparative characteristics of the groups are shown in Table 1.

On admission, the groups were comparable for all parameters. On examination after the course of treatment, patients in all groups had comparable values of absolute strength indices for all muscle groups. Group 2 had significantly greater increases in muscle strength in the hip extensors and flexors of the foot compared to the control group (Figure 1).

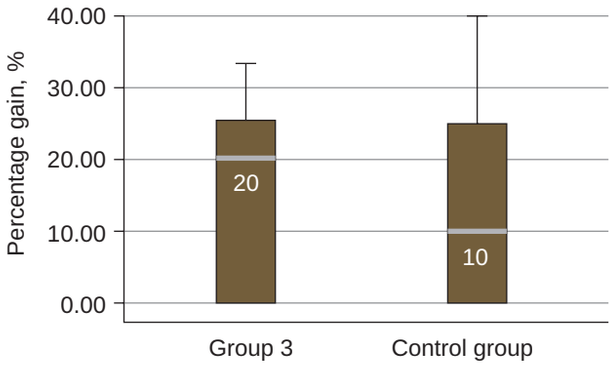

Fig. 2. Comparison of hip extensor strength gains in groups 3 and 4

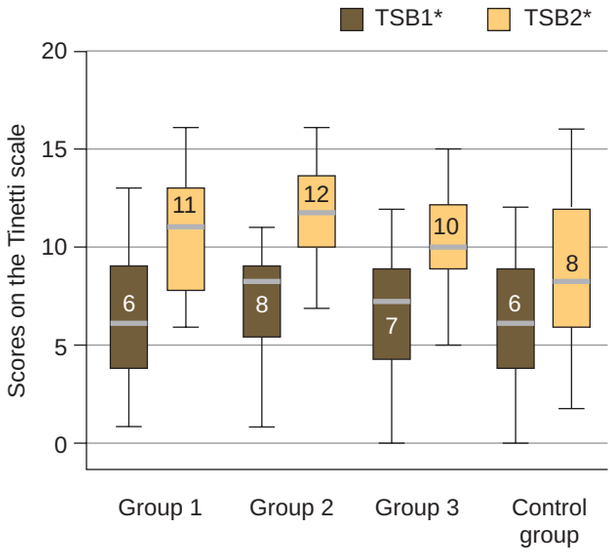

Fig. 3. Comparison of balance values on the Tinetti scale at admission and discharge in the main and control groups

Note: *TSB1* — Tinetti scale balance value at admission; TSB2* — Tinetti Scale balance value at discharge.*

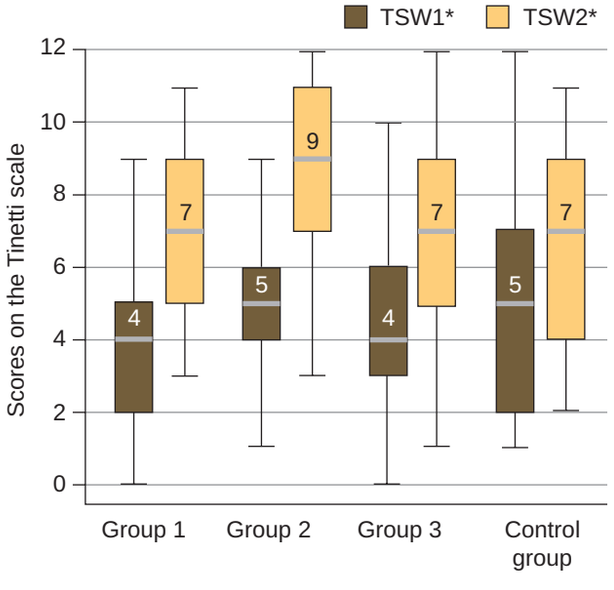

Fig. 4. Comparison of Tinetti Walking Scale values on admission and discharge in the main and control groups

Note: *TSW1 — Tinetti Walking Scale value at admission; TSW2 — Tinetti Walking Scale value at discharge.*

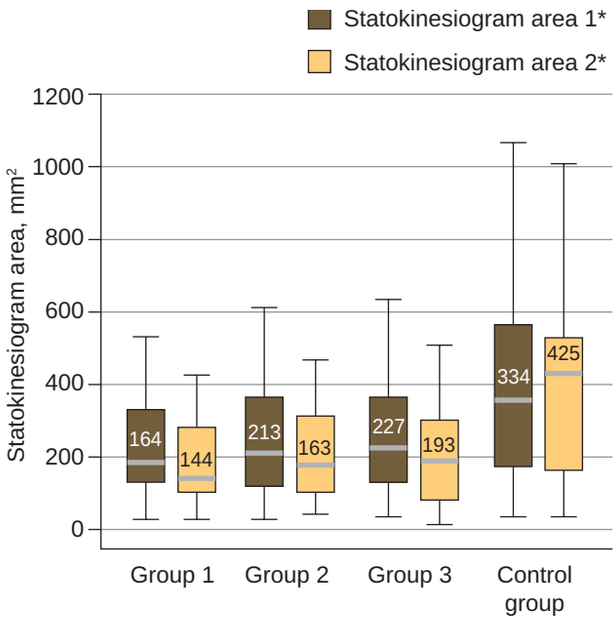

Fig. 5. Comparison of the dynamics of statokinesiogram area in the main groups and the control group on the first and the last day of the study

Note: *Statokinesiogram area 1* is the area of the statokinesiogram on admission; statokinesiogram area 2* — statokinesiogram area at discharge.*

There was significantly more growth in the tibia flexors in the VR technology group compared to the control group (Figure 2).

Patients in the main groups also had a significant improvement in balance on the Tinetti Scale (Kruskal-Wallis test, $p = 0.606$ vs 0.007) at follow-up (Figure 3). However, no difference was found when comparing between the main groups.

In the Tinetti Walking Scale assessment, patients in the combined VR and RM with FES group achieved better results both when compared to the control group (Kruskal-Wallis test, $p = 0.314$ vs 0.023) (Figure 4), and to the main groups (Mann-Whitney test, group 2 vs group 1 $p = 0{,}028$, group 2 vs group 3 $p = 0{,}048$, group 2 vs control group $p = 0{,}001$).

The analysis of the stabilometry results on the first and last day of the study revealed a decrease in the area of the statokinesiogram in the main groups both in the intragroup comparison and in the comparison with the control group. In the control group, there was an increase in the values of this index (Figure 5).

DISCUSSION AND CONCLUSION

VR technologies and robotic mechanotherapy have been used in motor rehabilitation after stroke for the past 15 years. National guidelines around the world mention these approaches to the restoration of walking and balance in one way or another, but there are no clear criteria for the severity of neurological symptoms and the timing of the application of these technologies [18]. At present, there is a lack of sufficient data proving the superiority of RM or VR over conventional (traditional) methods of gait and balance restoration [18]. The main advantage of training in an exoskeleton is considered to be the possibility of achieving a large number of

correct walking cycles. On the one hand, these trainings help to restore the physiological gait pattern — the correct weight distribution and hip extension of the affected limb. On the other hand, the patient performs about 1500–1800 steps per workout, it contributes to myokine production and increases afferent innervation from the lower extremities, which leads to activation of neuroplasticity [19]. When using the ReviVR, walking is induced by plantar stimulation combined with the projection of movement in a virtual reality helmet. During these trainings proprioceptive stimulation is significantly increased in combination with simulation of movement in the virtual environment without the risk of falling.

According to the results of the study, the use of VR technology and RM with FES demonstrated its effectiveness and safety in restoring muscle strength of the lower extremities. The VR group and the combined technology group showed a significantly better increase in lower limb muscle strength compared to the control group. Moreover, Group 2 achieved statistically significant strength gains in the hip extensors and foot flexors, the main muscles involved in the step cycle. Patients in all main groups achieved a significant improvement in balance according to stabilometry data. Improvement of support function was directly related to recovery of gait and general stability, which was confirmed by the results of the motor performance evaluation scale (Tinetti Scale). After the course of rehabilitation, the patients in Group 2 were able to walk at a faster pace and walk a greater distance compared to the other groups.

An important achievement was the creation and testing of a system of interval training in an exoskeleton with FES, which demonstrated its safety and effectiveness in reducing the risks of orthostatic reactions, as there were no adverse events during the entire study. Also, patients reached the required distance of 1500–1800 steps in 3–4 training sessions. When comparing with the results of other studies on the effect of robotic mechanotherapy on gait recovery after a stroke [20–26], the small number of patients both in the main groups and the practical absence of control groups is immediately noted. Masafumi M. [20] — 10 patients in the main group, no control group; Tan C.K. [21] — 8 patients in the main group, absent of control group; Molteni F. [22] — 12 patients in acute stroke group and 8 patients with consequences of cerebral circulation disorder, no control group; in Murray S.A. [23] and Lifang Li [24] 3 patients each without control groups, in the study of Hassan M. [25] included 5 patients. Only in the study of Jayaraman A. [26] study, 27 patients were included in the main and control groups. Also, the vast majority of studies included patients with both ischemic and hemorrhagic stroke [20–26]. Practically all researchers note high efficiency of RM use in gait recovery, except Hassan M., in whose study patients had increased asymmetry and desynchrony of step after HAL use. This can be explained by the presence of a robotic orthosis only on the affected side and the absence of FES, which has proven to be an effective method to restore synchronous contraction of the lower limb muscles. In the Jayaraman A. study, patients in the main group showed an increase in muscle strength in the lower extremities, and the authors attribute this to the greater number of steps walked during the day, including per exoskeleton training, compared with the control group (4,100 vs 3,000 steps per day). It is worth noting that heterogeneity in the etiology and localization of stroke, can greatly affect the rehabilitation process. For example, a patient with a subarachnoid hemorrhage differs from a patient with a hemispheric ischemic stroke, including the amount and intensity of physical activity they are able to perform. Similarly, stem stroke differs from hemispheric in the presence of more pronounced coordinator and ataxic abnormalities. Homogeneity and sample size is a significant strength of our study. Also, there are practically no studies comparing effectiveness of RM and VR technologies with traditional methods of walking and balance restoration in patients with ischemic stroke, as well as their cross-sectional comparison and comparison with the group of combined application.

Thus, combining robotic mechanotherapy with FES and VR technology with plantar stimulation during rehabilitation allows to achieve a significant improvement in gait and balance, as well as restoration of lower limb muscle strength. Further studies are required to investigate the long-term results of these technologies. It is likely that an increase in the number of procedures, as well as repeated rehabilitation cycles will contribute to the improvement of motor functions. It is possible that the results achieved will trigger the activation of neuroplasticity and contribute to a fuller recovery of patients in the future.

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Data Access Statement. Data supporting the findings of this study are publicly available. Registration: ClinicalTrails.gov identifier: NCT05423626. Registered June 14, 2022.

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Expiratory Muscle Training Versus Functional Electrical Stimulation on Pulmonary and Swallowing Functions in Acute Stroke Patients

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ABSTRACT

INTRODUCTION. Post-stroke dysphagia is reported in 30–50 % of stroke population. It increases mortality rate and leads to serious complications such as expiratory muscle affection which is a major cause of defective swallowing and ineffective airway protection. Expiratory muscle strength training (EMST) and functional electrical stimulation (FES) are recommended techniques to improve expiratory muscles performance.

AIM. To compare the effect of EMST to that of FES on pulmonary and swallowing functions in acute stroke patients.

MATERIAL AND METHODS. Seventy-two patients with post-stroke dysphagia were divided into two groups. Both groups received traditional dysphagia treatment. In addition, the first group received EMST and the second received neck and abdominal FES. Pulmonary functions were measured before and after in form of forced vital capacity (FVC), forced expiratory volume in one second (FEV1), FEV1/FVC ratio and peak expiratory flow (PEF), and arterial blood gases (ABG) while the Gugging Swallowing Scale (GUSS) was used as an indicator of swallowing function results of both groups were compared after one month of treatment.

RESULTS. The post-treatment GUSS, FVC, FEV1 and PEF of the EMST group showed more significant increase compared to the FES group ($p < 0.05$) with no significant differences in FEV1/FVC ($p > 0.05$). Regarding ABG, there was more significant decrease in $PaCO_2$ and HCO3 of EMST group compared to FES group ($p < 0.01$).

CONCLUSION. EMST was more effective than FES when it comes to improving expiratory and swallowing functions in patients with post-stroke dysphagia.

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KEYWORDS: humans, deglutition, deglutition disorders, forced expiratory volume, vital capacity, electric stimulation.

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Тренировка экспираторных мышц в сравнении с функциональной электростимуляцией для улучшения легочной и глотательной функций у пациентов после острого инсульта

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РЕЗЮМЕ

ВВЕДЕНИЕ. Постинсультная дисфагия отмечается у 30-50 % пациентов, перенесших инсульт. Она повышает смертность и приводит к таким серьезным осложнениям, как поражение экспираторной мускулатуры, являющееся основной причиной нарушения глотания и неэффективной защиты дыхательных путей. Тренировка силы экспираторных мышц и функциональная электростимуляция являются рекомендуемыми методами для улучшения работы дыхательных мышц.

ЦЕЛЬ. Сравнить влияние тренировки силы экспираторных мышц и функциональной электростимуляции на легочную и глотательную функции у пациентов после острого инсульта.

МАТЕРИАЛ И МЕТОДЫ. Семьдесят два пациента с постинсультной дисфагией были разделены на две группы. Обе группы получали традиционное лечение дисфагии. Кроме того, в первой группе проводилась тренировка экспираторной мускулатуры, а во второй — функциональная электростимуляция шеи и брюшной полости. Легочные функции измерялись до и после лечения в виде форсированной жизненной емкости (FVC), форсированного экспираторного объема за одну секунду (FEV1), соотношения FEV1/FVC и пикового экспираторного потока (PEF), газов артериальной крови (ABG), в то время как тест Gugging Swallowing Scale (GUSS) использовался как показатель функции глотания. Результаты обеих групп сравнивались после одного месяца лечения.

РЕЗУЛЬТАТЫ. После лечения GUSS, FVC, FEV1 и PEF в группе тренировки силы экспираторных мышц достоверно увеличились по сравнению с группой функциональной электростимуляции ($p < 0,05$) при отсутствии значимых различий по показателям FEV1/FVC ($p > 0,05$). Что касается (ABG) газов артериальной крови, то в группе тренировки силы экспираторных мышц (EMST) наблюдалось более значительное снижение $PaCO_2$ и HCO3 по сравнению с группой функциональной электростимуляции (FES) ($p < 0,01$).

ЗАКЛЮЧЕНИЕ. Тренировка силы экспираторных мышц оказалась более эффективной, чем функциональная электростимуляция, в отношении улучшения экспираторной и глотательной функций у пациентов с постинсультной дисфагией.

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КЛЮЧЕВЫЕ СЛОВА: люди, заглатывание, нарушения заглатывания, объем форсированного выдоха, жизненная емкость, электростимуляция.

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INTRODUCTION

Stroke is considered a primary cause of mortality and residual disability all over the globe, it also leads to a variety of complications that prolong hospitalization and place a significant burden on the healthcare system [1]. In Egypt, the annual incidence of stroke is approximately 150,000–210,000 and stroke accounts for 6.4 % of all deaths and ranks third after cardiovascular and gastrointestinal diseases [2, 3]. One of the most affected systems by stroke is the respiratory system; it goes through detrimental changes including weak respiratory muscles, ineffective airway clearance, reduced chest wall compliance and abnormal respiratory patterns which in turn lead to poor airway protection and weak cough reflex [4]. Cough plays a vital role in airway protection as it is a strong defense mechanism that prevents foreign body aspiration. For cough to be effective, critically-ill patients in general and stroke patients in particular must demonstrate expiratory muscles of sufficient strength [5]. Affection of expiratory muscles in conjunction with impaired swallowing is reported in as high as 30–50 % of stroke survivors [6]. Post-stroke swallowing disorder further increases the mortality risk in this patient group because it makes them more prone to aspiration pneumonia, malnutrition, and dehydration [7]. In terms of prognosis of post-stroke dysphagia, spontaneous recovery within the first seven days was reported in 50 % of patients. The remaining percentage who did not demonstrate

spontaneous recovery in the early stages may fully or partially recover with the help of dysphagia treatment. [8] therefore, proper diagnosis and appropriate treatments are important [9].

Expiratory muscle strength training (EMST) is a therapeutic approach used to indirectly improve swallowing functions by performing resisted expiration through the mouth [9] overloading the expiratory muscles triggers new fiber formation, muscle hypertrophy, and better adaptability to increased ventilatory demands. It also contributes to better pharyngeal and laryngeal muscle control involved in speech production and swallowing [10]. Strengthening the expiratory muscles leads to significant improvement in peak flow and swallowing functions, when assessed by swallowing ability, food intake and penetration/aspiration [11]. Moreover, it results in more efficient clearance of supraglottic and tracheal secretions or aspirated food and water which subsequently reduces risk of aspiration and aspiration-related complications such as pneumonia and malnutrition. Additionally, improved PEF may reduce the risk of death, as it has recently been considered a good predictor of the survival rate in the older population [11].

Electrical stimulation (FES) is an intervention that improves the respiratory function, increases respiratory muscles' strength, endurance, and speed of contraction, diaphragmatic thickness, as well as lung volumes and flows [12]. When FES was applied on the abdominal muscles, a measurable increase was witnessed in vital capacity (VC), forced vital capacity (FVC), and peak expiratory flow (PEF) in comparison with the initial measurements. Improvement of these values led to a significant improvement in the peak flow of cough [13,14] FES was further used in dysphagia treatment to increase patients' swallowing mechanism by achieving stronger swallowing muscles and promoting the recovery of the cortical control of swallowing [7]. Using muscular electrical stimulation along with traditional exercises yields promising therapeutic benefits, especially for patients with post-stroke dysphagia [7]. Although, there are several proven methods used to treat dysphagia in acute stroke survivors, there is lack of publications comparing the effect of EMST and FES for abdomen and neck in these patients.

AIM

To compare EMST and FES in order to determine the most effective technique for improving patients' ability to swallow and reduce their risk of aspiration and pneumonia during the early stage when the chances of recovery are potentially higher. In our hypothesis, we suggested that EMST and FES are effective techniques for improving swallowing and pulmonary function in acute stroke patients.

MATERIALS AND METHODS

This controlled parallel randomized research adopted the latest CONSORT Statement [15] and was carried out in compliance with the Helsinki Declaration. Prior to the active enrollment of the participants, a written informed consent was obtained from each participant or their surrogate after a detailed explanation of the study's objectives and procedures. The study began in October 2021 after getting the institutional ethics board approval (P.T.REC/012/003420), and registered with Pan-African Clinical Trials Registry (PACTR202205908494752).

Study Participants

Patients who were considered fit to participate were of both genders, aged between 55 and 65 years, body mass indices (BMI) ranged between 25 and 29.9 kg/m2, diagnosed with acute ischemic stroke with dysphagia confirmed by computed tomography or Magnetic resonance imaging (MRI), hemodynamically and medically stable and in good cognition that enabled them to comprehend the study requirements. Included patients' spirometric measures fell within the following features [5] forced expiratory volume in one second (FEV1) and FVC: 60–69 %, FEV1/FVC: < 80 % and PEF: 50–80 %, they must have demonstrated moderate to severe dysphagia based on the GUSS score 0–14 [7] with evident presence of arterial blood gases abnormalities upon intensive care unit (ICU) admission.

On the other hand, patients were considered ineligible for participation in the study if they showed evidence of hemorrhagic stroke, showed signs of cognitive and psychiatric disorders or impairment (i.e., Glasgow coma scale < 11), found unable to follow instructions (e.g., in case of sensory aphasia, blindness, dementia, and deafness), showed paralysis or affection of facial muscles upon examination, showed or developed uncontrolled metabolic and cardiovascular conditions or complications, had one or more contraindications to abdominal electrical stimulation (e.g., cardiac pace maker, acute abdominal surgery, acute neck surgery, tracheostomy and skin diseases) or had been previously diagnosed with orthopedic, neurological, or chest disorders that affected trunk muscles control or caused respiratory disorders as chronic obstructive pulmonary disease (COPD).

Data Collection

Patient data were obtained from admission notes, progress notes, ICU flow sheets, laboratory results, demographics (age, gender, and body mass index (BMI)), the physician's diagnosis based on physical examination and radiological findings in addition to physical therapy assessment. The presence of exclusion factors was assessed within the first 24 hours after inclusion. The respiratory function was measured via forced vital capacity (FVC), forced expiratory volume in 1 s (FEV1), peak expiratory flow (PEF), as soon as possible after the participant was able to breathe independently and follow instructions. When possible, each measurement was repeated until three reproducible results within 5 % were registered, and the greatest value used for analysis.

Participants' Eligibility

All consecutive admissions ($n = 127$) between October 2021 and December 2022 were assessed for eligibility, 72 patients were randomized, 55 patients were omitted because they did not match the inclusion criteria, through the evaluation, 12 participants were drop out from the study (5 withdrew, 3 developed cardiovascular complications not related to the intervention, 2 had cognitive deterioration, 2 did not commit to completing the sessions after ICU discharge) as demonstrated in Figure 1. Finally, 60 participants completed the intervention and the analysis, and only they were included in the data analysis.

Randomization and blinding

Participants were randomly assigned to EMST group and FES group which were labeled initially as Group A and B respectively. A statistician (not a member of the research team) performed a masked centralized randomized method

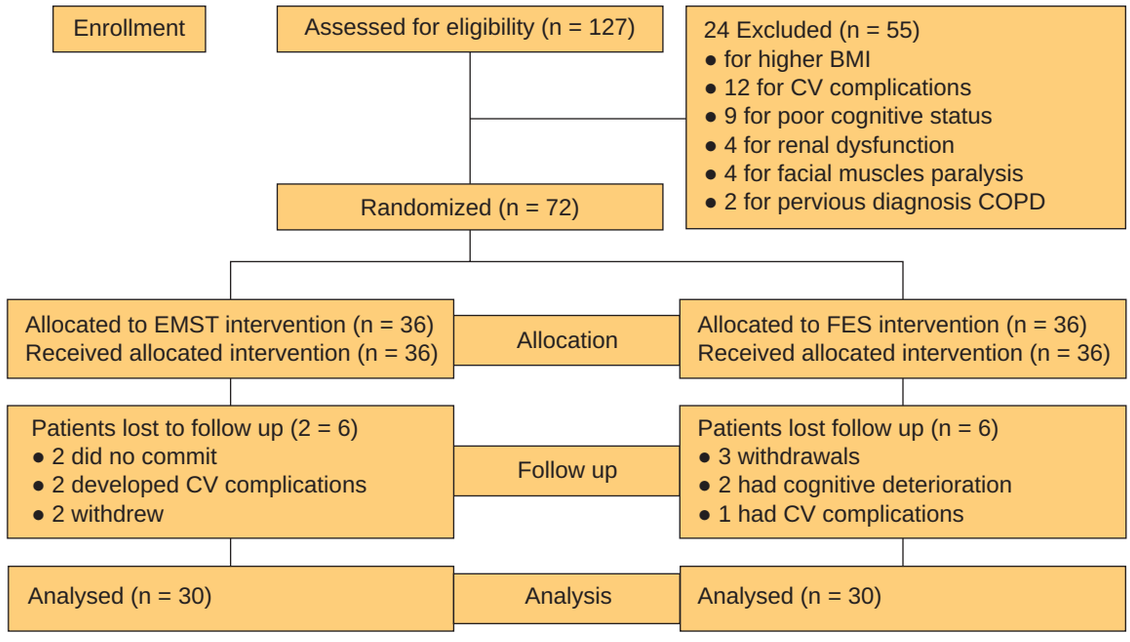

Fig. 1. Flowchart demonstrating patient who were assessed and enrolled and those who completed the study

with allocation concealment in which the participants and research team members (except the physiotherapists involved in the intervention) were unaware of the assignment. The randomization sequence was created with R Software (version 2.11) and segregated by gender, age (60–75 years), and BMI. To keep an even number of participants in each group, block sizes were varied at random between four and eight. Furthermore, the participants in each group received their exercise in private to keep all participants blinded.

Intervention

After initial screening, pre-treatment assessment and randomization, participants were treated according to the group they are enrolled in as follows:

Expiratory Muscle Strength Training (EMST) Group

This group included 36 (30 completed and 6 dropped out) acute stroke patients with dysphagia. They received expiratory muscle strength training using (EMST 150) device (Aspire Products LLC., USA) in addition to the traditional dysphagia exercises.

EMST Progression

On day 1, the participants who were enrolled in this group underwent the initial assessment of the pulmonary function (FEV1, FVC, FEV1/FVC and PEF), ABG, SPO2 and the swallowing function (GUSS) within 24 hours of enrolment. All initial data was recorded for documentation and comparison. EMST treatment was also started within 24 hours of enrolment and after initial assessment was completed. The training lasted for a total of 30 minutes of EMST including rest periods. The frequency of treatment was 1 session/day, 5 days/week for a total of 4 weeks [6]. In each session, EMST was performed in form of sets of 5 breaths with 15–30 sec rest in between breaths and a 1-minute rest between sets. The Intensity was started at the first tolerated resistance and was progressed by ¼ knob turn for every week of training as directed in the device manual. [16] After completing 4 weeks of training final assessment was conducted to resemble the initial assessment: the pulmonary function (FEV1, FVC, FEV1/FVC and PEF), ABG, SPO2 and the swallowing function (GUSS).

Functional Electrical Stimulation (FES) Group

This group included 36 (30 completed and 6 dropped out) acute stroke patients with dysphagia. They received electrical stimulation on the neck and abdomen using (Ev-906,4CH Digital TENS/EMS, Taiwan) device in addition to the traditional dysphagia exercises. Electric stimulation was applied to the anterior neck and laryngeal elevator muscles of the larynx above and below the hyoid bone using four surface electrodes and applied for the abdomen to stimulate rectus abdominis and external oblique muscles bilaterally using two stimulation channels.

FES Application and Progression

On day 1, the participants who were enrolled in this group underwent the initial assessment of the pulmonary function (FEV1, FVC, FEV1/FVC and PEF), ABG, SPO2 and the swallowing function (GUSS) within 24 hours of their enrolment. All initial data was recorded for documentation and comparison. FES treatment was started within 24 hours of enrolment and after initial assessment was completed. Abdominal and neck muscle FES were conducted for a total of 30 minutes each in separate times of the day with at least 30 minutes of rest in between both applications [14, 17]. The treatment was continued for the duration of the study (i.e., a total of 4 weeks). Stimulation parameters were different for neck and abdominal muscles as stated in table 1. Patients were encouraged to swallow during the neck FES and were encouraged to forcefully but slowly exhale, huff and cough during abdominal FES. After completing 4 weeks of training, a final assessment was conducted to resemble the initial assessment: the pulmonary function (FEV1, FVC, FEV1/FVC and PEF), ABG, SPO2 and the swallowing function (GUSS).

Table 1. Parameters of neck and abdomen FES

Parameter	Neck FES	Abdominal FES
Frequency, Hz	30–50	Up to 80
Amplitude, mA	25–400	0–25
Pulse Width, μs	25–400	25–400
Progression limit	Up to the reported feeling of deep tension and limited by patient tolerance	Up to palpable contraction and limited by patient tolerance
Imitating functions	Patients were encouraged to swallow repeatedly as they feel the tension in their neck	Patients were encouraged to forcefully but slowly exhale, huff and cough along with the muscle contraction

Traditional Dysphagia Therapy

Both groups received conventional dysphagia treatment including (volume and texture modifications, strategies such as chin tuck, head tilt, head turn, effortful swallow, supraglottic swallow, super-supraglottic swallow, Mendelsohn maneuver and exercises such as the Shaker exercise and Masako (tongue hold) maneuver in addition to chest physiotherapy if needed.

Outcomes

Initially, all patients were assessed for primary and secondary outcomes on the first day of inclusion and re-assessed by the same blinded physiotherapist after 4 weeks of treatment. The assessment included:

Primary Measured Outcomes

These measurements included pulmonary function parameters in form of FVC, FEV1, FEV1/FVC and PEF, using Hand held lung function spirometry (CONTECTM Model:CMS501, Made in China) as well as swallowing function represented by Gugging Swallowing Scale (GUSS). These measurements were used to correlate the improvement in the expiratory muscle strength and the improvement in the swallowing function.

Secondary Measured Outcomes

Including Oxygen Saturation (SPO2) and Arterial Blood Gases (ABG) in form of PaO2, PCO2, PH and HCO3 using Arterial blood gases analyser (Abbott Laboratories Pharmaceutical Company, Singapore)

Statistical Analysis

Sample size calculation was performed using G*POWER statistical software (version 3.1.9.2; Franz Faul, Universitat Kiel, Germany) based on data of FEV1 derived from pilot study conducted on 5 subjects in each group; and revealed that the required sample size required for this study was 30 subjects in each group. Calculation is made with α=0.05, power = 80 % and effect size = 0.54 a maximum drop-out percentage of 17 % was allowed in each group.

Unpaired t-test was implemented to compare the results between the two groups. Chi squared test was conducted for comparison of sex distribution between the groups. The Shapiro-Wilk test was used to check the normal distribution of the data. The homogeneity of variances was checked using Levene's test for homogeneity of variances. Mixed MANOVA was conducted to measure the effect the treatment had on GUSS, pulmonary function and atrial blood gases. Post-hoc tests using the Bonferroni correction were carried out for subsequent multiple comparison. The level of significance for all statistical tests used in this study was set at $p < 0.05$. All statistical analysis was conducted through the statistical package for social studies (SPSS) version 25 for windows (IBM SPSS, Chicago, IL, USA).

RESULTS

Table 2 shows the subject characteristics of EMST and FES groups respectively. There was no significant difference between the two groups in terms of weight, age, heigh, BMI and sex distribution ($p > 0.05$).

Table 2. Comparison of subject characteristics between the EMST and FES Groups

Parameter	EMST Group	FES Group	MD	t-value	*p*-value
	Mean ±SD	Mean ±SD			
Age, years	60.53 ± 3.18	59.7 ± 3.56	0.83	0.95	0.34
Weight, kg	72.86 ± 6.63	73.03 ± 5.95	−0.17	−0.1	0.91
Height, cm	164.2 ± 6.67	163.6 ± 6.42	0.6	0.35	0.72
BMI, kg/m²	26.97 ± 1.01	27.25 ± 1.03	−0.28	−1.06	0.29
Sex, n (%)					
Females	16 (53 %)	14 (47 %)		χ^2= 0.26	0.61
Males	14 (47 %)	16 (53 %)			

Note: *SD — Standard deviation; MD — Mean difference; χ^2 — Chi-squared test; BMI — body mass index.*

Table 3. Comparison of the primary outcomes in EMST and FES groups

	Pre-treatment	Post-treatment			
	Mean ± SD	**Mean ± SD**	**MD**	**% of change**	***p* value**
GUSS					
EMST Group	7.8 ± 1.95	12.8 ± 1.24	−5	64.10	0.001
FES Group	8.07 ± 1.36	10.86 ± 1.71	−2.79	34.57	0.001
MD	−0.27	1.94			
	***p* = 0.54**	***p* = 0.001**			
FVC (L)					
EMST Group	2.32 ± 0.27	2.94 ± 0.31	−0.62	26.72	0.001
FES Group	2.34 ± 0.32	2.73 ± 0.36	−0.39	16.67	0.001
MD	−0.02	0.21			
	***p* = 0.81**	***p* = 0.02**			
FEV1 (L)					
EMST Group	1.78 ± 0.25	2.39 ± 0.24	−0.61	34.27	0.001
FES Group	1.79 ± 0.22	2.18 ± 0.25	−0.39	21.79	0.001
MD	−0.01	0.21			
	***p* = 0.88**	***p* = 0.001**			
FEV1/FVC (%)					
EMST Group	76.57 ± 5.74	81.7 ± 8.55	−5.13	6.70	0.001
FES Group	76.46 ± 3.31	79.83 ± 3.95	−3.37	4.41	0.01
MD	0.11	1.87			
	***p* = 0.92**	***p* = 0.28**			
PEF (L/min)					
EMST Group	402.76 ± 100.16	528.93 ± 92.37	−126.17	31.33	0.001
FES Group	394.49 ± 98.76	448.14 ± 81.11	−53.65	13.60	0.006
MD	8.27	80.79			
	***p* = 0.74**	***p* = 0.001**			

Note: *SD — Standard deviation; MD — Mean difference; GUSS — The Gugging Swallowing Screen; EMST — Expiratory Muscle Strength Training; FES — Functional Electrical Stimulation; FEV1 — Forced Expiratory Volume in 1st Second; FVC — Forced Vital Capacity; PEF — Peak Expiratory Flow.*

1. Effect of treatment vs. time on GUSS, PF and ABG

Using Mixed MANOVA a clinically significant interaction effect of treatment and time was measured (F = 4.03, p = 0.001). There was a significant main effect of treatment (F = 2.71, p = 0.01). There was a significant main effect time (F = 70.7, p = 0.001).

2. Within-Group Comparison

Both groups showed significant increases in all primary measurements after the treatment compared with the pre-treatment measurements ($p > 0.01$). (Table 3). Regarding secondary measurements, both groups showed a significant increase in PaO2, SPO2 and pH and a significant decrease in PaCO2 and HCO3 post-treatment compared with the pre-treatment values ($p < 0.01$) (Table 4).

3. Between-Group Comparison

When both groups were compared, EMST group showed more significant increase in main outcomes compared FES group ($p < 0.05$) except FEV1/FVC that revealed no significant difference ($p > 0.05$) (see Table 3). For secondary measurements, there was a significant decrease in PaCO2 and HCO3 of the EMST group compared with that of the FES group ($p < 0.01$), while there was no significant difference in PaO2, SPO2 and pH ($p > 0.05$) (see Table 4).

Adverse Events of Applied Intervention

Over the course of this study, no adverse events from EMST application or FES were reported, as documented in weekly

interviews to record any adverse events experienced by the participants.

DISCUSSION

Even though physiotherapy modalities play an important role in restoring normal swallowing function, there is lack of comparative studies to determine the most effective modalities to be implemented in the rehabilitation program of acute stroke patients. This study aimed at comparing the effects of EMST and FES on the pulmonary and swallowing functions in these patients. After completion of this study, the results revealed the following:

In EMST group, EMST significantly improved patients' spirometric parameters (i.e., FVC, FEV1, FEV1/FVC and PEF). These parameters increased by 26.72 %, 34.27 % 6.7 % and 31.33 % respectively after receiving EMST for one month. Regarding swallowing function, the GUSS score in EMST group improved by 7.40 %. These percentages indicate that EMST strengthens expiratory muscles and leads to better breathing outcomes that can positively affect patients' swallowing and airway protection mechanisms. The results obtained come in agreement with those of Laciuga et al. [18] who included 24 selected articles in their narrative review regarding the effect of EMST on different measures including, but not limited to, the respiratory function, in form of: speech, voice, swallowing and coughing in patients affected by neurological diseases like Parkinson's disease,

Table 4. Comparison of the secondary outcomes in EMST and FES Groups

	Pre-treatment	Post-treatment			
	Mean ± SD	**Mean ± SD**	**MD**	**% of change**	***p* value**
PaO_2 (mmHg)					
EMST Group	88.36 ± 7.77	94.9 ± 8.71	−6.54	7.40	0.001
FES Group	87.13 ± 9.08	91.46 ± 7.4	−4.33	4.97	0.01
MD	1.23	3.44			
	***p* = 0.57**	***p* = 0.11**			
$PaCO_2$ (mmHg)					
EMST Group	48.7 ± 4.42	39.16 ± 2.15	9.54	19.59	0.001
FES Group	47.03 ± 6.41	41.17 ± 2.37	5.86	12.46	0.001
MD	1.67	−2.01			
	***p* = 0.24**	***p* = 0.001**			
SPO_2 (%)					
EMST Group	97.13 ± 1.43	98.53 ± 1.11	−1.4	1.44	0.001
FES Group	97.33 ± 1.39	98.16 ± 1.51	−0.83	0.85	0.002
MD	−0.2	0.37			
	***p* = 0.58**	***p* = 0.28**			
pH					
EMST Group	7.374 ± 0.029	7.402 ± 0.015	−0.028	0.38	0.001
FES Group	7.379 ± 0.033	7.398 ± 0.016	−0.019	0.26	0.002
MD	−0.005	0.004			
	***p* = 0.48**	***p* = 0.33**			
HCO_3 (mEq/L)					
EMST Group	27.46 ± 2.55	23.66 ± 1.34	3.8	13.84	0.001
FES Group	27.16 ± 3.07	24.46 ± 0.97	2.7	9.94	0.001
MD	0.3	−0.8			
	***p* = 0.68**	***p* = 0.01**			

Note: *SD — Standard deviation; MD — Mean difference; EMST — Expiratory Muscle Strength Training; FES — Functional Electrical Stimulation; PaO_2 — Partial Pressure of Oxygen in Arterial Blood; $PaCO_2$ — Partial Pressure of Carbon Dioxide in Arterial Blood; SpO_2 — Oxygen Saturation; pH — Potential of Hydrogen; HCO_3 — Bicarbonate.*

multiple sclerosis (MS), and Lance-Adams syndrome. The majority of the studies included in this systematic review revealed promising outcomes of EMST as a training for airway protection in patients with neuromuscular-induced dysphagia [18]. Another research by Lee et al. [19] revealed concomitant results after investigating the effects of EMST on pulmonary function (PF) and other functional parameters in chronic stroke survivors. They reported more significant improvements in PF in the study group participants than in controls and concluded that EMST significantly improves pulmonary function in stroke survivors [19]. A similar study by Park et al. [20] assessed the effects of EMST on the activity of suprahyoid muscles, risk of aspiration and dietary stages. They confirmed that EMST is an effective therapeutic method to facilitate the suprahyoid muscle and reported improvements in aspiration and penetration outcomes in patients with post-stroke dysphagia [20].

Conflicting results were reported in a systematic review by Templeman et al. [21] who included nine RTCs assessing the effect of EMST on Maximal expiratory pressure (MEP), PF and/or cough function in a variety of population including healthy adults, MS, COPD, acute stroke, and spinal cord injury. They reported an overall improvement in MEP following EMST but also reported no significant improvement in cough flow, FVC or FEV1 [21]. Another systematic review Mancopes et al. [22] included 11 relative articles assessing the effect of EMST on swallowing functions in different patient population. They reported no clinical significance in the swallowing function following the application of EMST. However, the included studies were limited by differences in the severity and aetiology of dysphagia in studied populations [22].

In the FES group, FES on the neck and abdomen led to statistically significant improvement in spirometric parameters (i.e., FVC, FEV1, FEV1/FVC and PEF) when pre and post treatment measurements were compared. These parameters increased by 16.67 %, 21.79 % 4.41 % and 13.60 % respectively. The percentages of improvement indicate that FES leads to better breathing outcomes and can positively affect patients' swallowing and airway protection mechanisms. The current results agree with those of McCaughey et. al. [17] who conducted a narrative review on FES in spinal cord injury patients. They concluded that FES of the abdominal muscles has a direct effect on the coughing of quadriplegic patients. After repeating FES for 6 weeks, improvement in unassisted respiratory function was observed, in addition to a decrease in ventilator duration, tracheostomy rate and cannulation time [17]. On the contrary, McLachlan et. al. [14] used functional electrical stimulation (FES) in patients with quadriplegic spinal cord injury who had low vital capacity and no observable abdominal movement. They revealed an immediate increase in FVC, FEV1 and PEF during training. However, they reported no significant change in the outcome measurements after 3 weeks of training [14].

Moreover, in 2019, McCaughey et al. [23] investigated the effect of abdominal FES on critically ill mechanically ventilated patients. They feasibility of FES in these patients and hypothesized that it can be an effective method to decrease mechanical ventilation and ICU stay. However, in their results, there were no differences in abdominal muscle or diaphragm thickness after FES McCaughey et al. [23] reported several limitations of their studies including the inability to directly measure the effect of FES on PF parameters due to the nature of the studied population, they also did not take into consideration the effects of ICU-acquired muscle weakness and the ventilator-associated muscle dysfunction in the studied parameters.

According to literature, ischemic stroke affects the respiratory system in many ways depending on the nature, site and extent of the lesion. The most common ABG presentation in acute stroke patients is respiratory acidosis. However, there are some reported cases who presented with respiratory alkalosis that are both often corrected by the metabolic component as a part of the body's physiological response. [5] This is concurrent with the findings of the present study that revealed respiratory acidosis in all of our included patients upon admission with different levels of physiological and iatrogenic compensation. The overall goal of the treatment was to observe the changes in ABG after treatment, if any. At the end of the study, there was a significant increase in pH, PaO_2, and Oxygen saturation post-treatment compared to pre-treatment values, with no significant differences between the two groups. Moreover, there was a significant decrease in $PaCO_2$ and HCO_3 to normal levels post-treatment compared to pre-treatment in both groups with EMST group values showing more significant decrease compared to those of FES group. These results indicate that both EMST and FES can positively affect the ABG values in post-stroke patients. However, this study did not consider the speed of ABG normalization in each group, which could have been another indicative factor of effectiveness. It is recommended to conduct further studies in this area while closely monitoring ABG changes in a shorter time window.

In the present study, although FES led to significant increase in all measured spirometry parameters and GUSS scores, when the effects of EMST and FES were compared together, it was evident that EMST led to more significant increase in FVC, FEV1, PEF and GUSS scores compared to FES. Which provides more evidence that active involvement of muscles in rehabilitation yields better improvement in muscle outcomes. This indicates that for future treatment plans, both EMST and FES can be used in combination or independent from one another. However, the present study does not favour one modality over another; EMST may be favourable for conscious, cooperative patients who have no health and physical problems preventing them from using an EMST device. Yet, FES can be the ideal for use in unconscious, uncooperative patients who will not be able to actively participate in the treatment session or for those who cannot effectively use EMST devices (e.g., facial nerve palsy) and can also be started earlier in the rehabilitation plan than EMST.

Limitations

Due to ethical considerations, there was no control group to compare the treatment-induced changes to a no-intervention group. As there is plenty of research proving the effectiveness of both modalities, using one of the modalities was necessary for all patients to improve the recovery outcomes. In addition to that, time factor was also considered a limitation in this study when it comes to the secondary measured outcomes; according to mixed MANOVA statistical analysis, the time factor interfered with the treatment plan due to the expected physiological buffering of blood pH values. In other words, the study lasted for one month and pre- and post-treatment

evaluations were carried out with a one-month-gap. During this time, physiological compensation was normally expected to occur provided that patients with renal problems were already excluded from the study. Moreover, there are other external factors that were not taken into consideration in this study; for instance, the type of respiratory failure and the external correction measures that might have been taken prior to study inclusion in emergency settings or during ICU stay, such as mechanical ventilation and intravenous corrections which requires further research in the future.

CONCLUSION

EMST was more effective than FES in improving patients' expiratory functions and patients' swallowing functions in a post-stroke dysphagia. However, both techniques can be effectively and safely implemented in the treatment of dysphagia.

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Efficacy and Safety of Remote Physical Rehabilitation in Patients with Hip or Knee Replacement: a Prospective Randomized Comparative Study

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ABSTRACT

INTRODUCTION. An urgent problem of medical rehabilitation is the loss of results that were achieved at various stages due to the interruption of the recovery process and the absence of patients' classes at home after discharge from a medical institution. In this regard, at the third stage of medical rehabilitation, the remote (telemedicine) form of rehabilitation assistance is of particular importance, which has broad prospects for development due to the emergence of new information technologies that allow for active communication between a medical professional and a patient. Nevertheless, the issues of the effectiveness and safety of remote physical rehabilitation remain insufficiently studied, and therefore it is necessary to conduct randomized comparative trials with the analysis of long-term results.

AIM. Evaluation of the effectiveness and safety of the remote physical rehabilitation (RPR) model for a group of patients who have undergone hip (HR) or knee (KR) replacement, the study of patient adherence, as well as the selection of the most informative evaluation tools.

MATERIALS AND METHODS. The study included 30 patients aged 30 to 75 years who underwent HR or KR. The study participants were distributed by the envelope method into groups for remote rehabilitation in addition to routine clinical practice of providing medical rehabilitation (RPR group) or conducting only routine medical rehabilitation (comparison group), including daily independent physical exercises at home, mastered during inpatient medical rehabilitation, lifestyle modification, taking nonsteroidal anti-inflammatory drugs with the development of pain syndrome. An assessment of the effectiveness and safety of rehabilitation measures was carried out, including an analysis of physical examination data, vital signs, as well as data from various scales, tests and questionnaires (the 10-point visual-analog scale (VAS), the Timed 25-Foot Walk (T25-FW), the "Timed Up and Go Test", the Berg Balance Scale (BBS), the Western Ontario and McMaster University Osteoarthritis Index (WOMAC)).

RESULTS AND DISCUSSION. 14 patients were randomized to the remote physical rehabilitation group (49.6 ± 12.4 years) and 16 to the comparison group (57.8 ± 11.2 years). Participation in the study was completed by 10 patients from the RPR group and all 16 patients in the comparison group. Comparing the results of rehabilitation between the groups 1 month after the inclusion of participants in the study revealed a more pronounced statistically significant improvement in the functional profile of the patient on the T25-FW ($p < 0.0001$), the "Timed Up and Go Test" ($p = 0.0064$), the Berg Balance Scale ($p = 0.0008$) and WOMAC ($p < 0.0001$) in group of RPR. The "Timed Up and Go Test", the visual analog scale and the WOMAC were selected based on the results obtained for further practical work. The most significant predictors of premature termination of RPR were older age (χ^2 16.75, $p < 0.0001$), pensioner status (χ^2 11.75, $p = 0.0006$) and residence in the region (χ^2 11.75, $p = 0.0006$). The analysis of adverse events showed that 4 patients in the RPR group and 6 in the comparison group had a periodic increase in pain syndrome in the operated limb.

CONCLUSION. The results obtained demonstrate that of patients who have undergone hip or knee replacement is safe and effective in restoring functional mobility, reducing the risk of falls and the severity of pain syndrome, and increases adherence to physical exercises. The main limitations in the practical use of remote physical rehabilitation are related to the availability of high-speed Internet and the skills of using Internet portals.

KEYWORDS: telemedicine, remote physical rehabilitation, total joint replacement, hip joint, knee joint.

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Эффективность и безопасность дистанционной физической реабилитации у пациентов с эндопротезированием тазобедренного или коленного сустава: проспективное рандомизированное сравнительное исследование

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РЕЗЮМЕ

ВВЕДЕНИЕ. Прерывание восстановительного процесса и отсутствие занятий пациентов в домашних условиях после выписки из лечебного учреждения приводит к потере результатов, достигнутых на различных этапах медицинской реабилитации. В связи с этим особое значение приобретает дистанционная (телемедицинская) форма оказания реабилитационной помощи, имеющая широкие перспективы развития в связи появлением новых информационных технологий, позволяющих реализовывать активную коммуникацию между медицинским работником и пациентом. Тем не менее, вопросы эффективности и безопасности дистанционной реабилитации остаются недостаточно изученными, в связи с чем необходимо проведение рандомизированных сравнительных исследований с использованием наиболее информативных оценочных инструментов.

ЦЕЛЬ. Оценка эффективности и безопасности модели дистанционной физической реабилитации (ДФР) для группы пациентов, перенесших эндопротезирование (ЭП) тазобедренного (ТБС) или коленного (КС) сустава, изучение приверженности пациентов, а также отбор наиболее информативных оценочных инструментов.

МАТЕРИАЛЫ И МЕТОДЫ. В исследование включено 30 пациентов от 30 до 75 лет, перенесших эндопротезирование тазобедренного или коленного сустава. Участники исследования распределялись методом конвертов в группы для проведения ДФР в дополнение к рутинной клинической практике оказания медицинской реабилитации (группа ДФР) или проведения только рутинной медицинской реабилитации (группа сравнения), включающей ежедневные самостоятельные занятия физическими упражнениями в домашних условиях, освоенные во время стационарной медицинской реабилитации, модификацию образа жизни, прием нестероидных противовоспалительных препаратов при развитии болевого синдрома. Выполнена оценка эффективности и безопасности реабилитационных мероприятий, включающая анализ данных физикального обследования, показателей жизнедеятельности, а также данных различных шкал, тестов и опросников (10-балльная визуально-аналоговая шкала (ВАШ), тест времени прохождения 7,62 м (Timed 25-Foot Walk, T25-FW), тест «встань и иди», шкала равновесия Берга (Berg Balance Scale, BBS), функциональный индекс оценки остеоартроза коленного и/или тазобедренного сустава (Western Ontario and McMaster University Osteoarthritis Index, WOMAC)).

РЕЗУЛЬТАТЫ И ОБСУЖДЕНИЕ. 14 пациентов рандомизированы в группу ДФР (49,6 ± 12,4 года) и 16 в группу сравнения (57,8 ± 11,2 года). Участие в исследовании завершили 10 пациентов из группы ДФР и все 16 пациентов в группе сравнения. При сравнении результатов реабилитации между группами спустя 1 месяц после включения участников в исследование выявлено более выраженное статистически значимое улучшение функционального профиля пациента по T25-FW ($p < 0,0001$), тесту «встань и иди» ($p = 0,0064$), шкале Берга ($p = 0,0008$) и WOMAC ($p < 0,0001$) в группе ДФР. На основании полученных результатов для дальнейшей практической работы были отобраны тест «встань и иди», визуально-аналоговая шкала и WOMAC. Наиболее значимыми предикторами преждевременного прерывания ДФР являлись более старший возраст ($\chi2$ 16,75, $p < 0,0001$), статус пенсионера ($\chi2$ 11,75, $p = 0,0006$) и проживание в области ($\chi2$ 11,75, $p = 0,0006$). Анализ нежелательных явлений показал, что у 4 пациентов в группе ДФР и 6 в группе сравнения отмечалось периодическое усиление болевого синдрома в оперированной конечности.

ЗАКЛЮЧЕНИЕ. Полученные результаты демонстрируют, что дистанционная физическая реабилитация пациентов, перенесших эндопротезирование тазобедренного или коленного сустава, безопасна и эффективна в отношении восстановления функциональной мобильности, снижения риска падений и выраженности болевого синдрома, позволяет повысить приверженность к занятиям физическими упражнениями. Основные ограничения при практическом использовании дистанционной физической реабилитации связаны с доступностью высокоскоростного интернета и навыками использования интернет-порталов.

КЛЮЧЕВЫЕ СЛОВА: телемедицина, дистанционная физическая реабилитация, эндопротезирование, тазобедренный сустав, коленный сустав, медицинская реабилитации.

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INTRODUCTION

In the last decade, great changes have been taking place in the system of organization of medical rehabilitation (MR) in Russia: a new specialty «doctor of physical and rehabilitation medicine» has appeared, a clear three-stage system of routing of rehabilitation patients has been established, and the corresponding regulatory and legal framework has been developed [1, 2]. However, one of the problems is the loss of the results achieved at different stages of MR due to the patients' discontinuation of home-based activities after discharge from the treatment facility [3]. This problem is associated with a significant burden on the rehabilitation care system due to the large number of people in need of MR in Russia (more than 6 million people) and staff shortages [1, 2]. The availability of rehabilitation care at home may also be reduced due to geographical peculiarities (long distances and low population density) of some regions of our country [4].

In this regard, the remote form of organizing rehabilitation at the third stage of rehabilitation care is of particular importance, which has prospects for development due to the emergence of new information technologies that enable the implementation of active communication between the healthcare worker and the patient [5]. Remote MR is one of the areas of telemedicine and is a system of interactive rehabilitation process with the use of information and telecommunication technologies that help to restore health, functional state and working capacity of patients [1, 6]. In both developed and developing countries, there are still obstacles to the introduction of telemedicine, which unnecessarily slows down its spread. In the Russian Federation, remote rehabilitation currently exists only in some rehabilitation institutions; there are no unified approaches to its organization [7, 8]. In addition, the efficacy and safety of remote rehabilitation remain poorly studied, and therefore randomized comparative studies with analysis of long-term outcomes are needed.

Since February 2023 the Institute of traumatology and orthopaedics of the University Clinic of FSBEI HE «Privolzhsky Research Medical University» of the Ministry of Health of Russia (Nizhny Novgorod) has been implementing the project «Development of a model of remote rehabilitation care for persons with motor disorders within the third stage of the MR using a digital rehabilitation platform» within the frames of Privolzhsky Research Medical University «Priority-2030» Development programme. The aim of the project is to create a model of remote physical rehabilitation (RPR) for persons with motor impairments due to a hip or a knee joint replacement and to introduce this model into the practice of rehabilitation institutions of the Russian Federation. The choice of the DFR model is not accidental: on the one hand, kinesiotherapy is the basis for rehabilitation of patients who have undergone a hip or a knee joint replacement, on the other hand, the number of physical rehabilitation specialists is still insufficient to meet the demand for full-time rehabilitation of patients with this profile at stage III. The relevance of this project is particularly emphasized by the fact that approximately 500,000 hip and knee replacements are performed worldwide each year and the need for these operations is constantly increasing [9–12]. According to the report of «National Medical Research Centre for Traumatology and Orthopaedics named after N. N. Priorov», 76,849 knee replacements and 54,720 knee replacements were performed in Russia in 2019, the increase in the number of endoprosthetic surgeries during 2017–2019 was 16.2 % [9, 13]. Among 85 regions of the Russian Federation, Nizhny Novgorod region ranks the 7th in the number of primary hip replacements (7.4 per 10,000 population) and the 16th in the number of knee replacements (3.3 per 10,000 people) [9, 13]. The growing number of hip and knee replacements increases the relevance of remote approaches to medical rehabilitation of this category of patients [14].

When planning the work, it was decided to use the existing portal of remote rehabilitation «Steps Reabil» («Digital Technologies Centre» Ltd.), having created a separate block for it regarding DPR of patients with hip or knee replacements. The «Steps Reabil» Internet platform combines the best practices of other similar Internet resources and is already being actively used in leading medical institutions of the Russian Federation, such as the Pirogov National Medical and Surgical Centre, Federal State Autonomous Institution «National Medical Research and Development Centre «Treatment and Rehabilitation Centre» of the Ministry of Health of Russia, FSBI Federal Centre for Brain and Neurotechnology of FMBA of Russia and others. This interactive platform contains more than 150,000 combinations of exercises for motor, speech and psychological rehabilitation, with a video library of exercises and software placed in a «cloud» storage. Access to personal programmes (video files) is provided through the web-interface of any device: computer, laptop, tablet, smartphone, virtual reality headset and smart TV (TV set with integrated internet and interactive functions). The functionality of the platform provides for the doctor's ability to create a rehabilitation plan and exercise schedule, maintain feedback with the patient via e-mail, chat and video, and evaluate the effectiveness of MR using tests and questionnaires. It is also possible to integrate the DPR platform into the medical information system of the institution. Connecting participants to the platform and conducting remote training on the platform is possible within a day [5, 8, 15].

Under the agreement between FSBEI HE «Privolzhsky Research Medical University» of the Ministry of Health of Russia and «Digital Technologies Centre» LLC on the basis of «STEPS REABIL» platform a block/module «Orthopaedics» (https://pimunn.stepsreabil.com/) was created, which contains 522 video clips with demonstration of physical exercises used at different stages of MR of patients after hip or knee replacement, as well as a set of evaluation tools to monitor the effectiveness of MR. The posted videos were filmed and edited by specialists of «Privolzhsky Research Medical University», who have many years of experience in physical rehabilitation of patients who have undergone hip or knee replacement. The physical exercises presented in the video library have different levels of difficulty and are aimed at restoring muscle strength of key muscles, balance training, prevention of contractures, restoration of normal walking pattern, improvement of functional mobility of patients. Video clips were «tagged», i.e. each video clip with demonstration of a particular physical exercise was assigned keywords, according to which the specialist selects exercises for a particular patient. The video library is tagged by the position in which the exercise is performed (on the back, stomach, on the side, palm-knee, etc.), by the body part involved (hip, knee, buttock, leg, etc.), by the training focus (coordination, walking, motor skills, etc.), by the level of difficulty and aspect, and by the gymnastic equipment used (block, wand, elastic strap, ball, Swedish wall, etc.) (Figure 1). When creating a set of videos for a particular patient, the «Steps Reabil» portal allows you to specify the number of repetitions, the duration of the exercise and the purpose of the exercise.

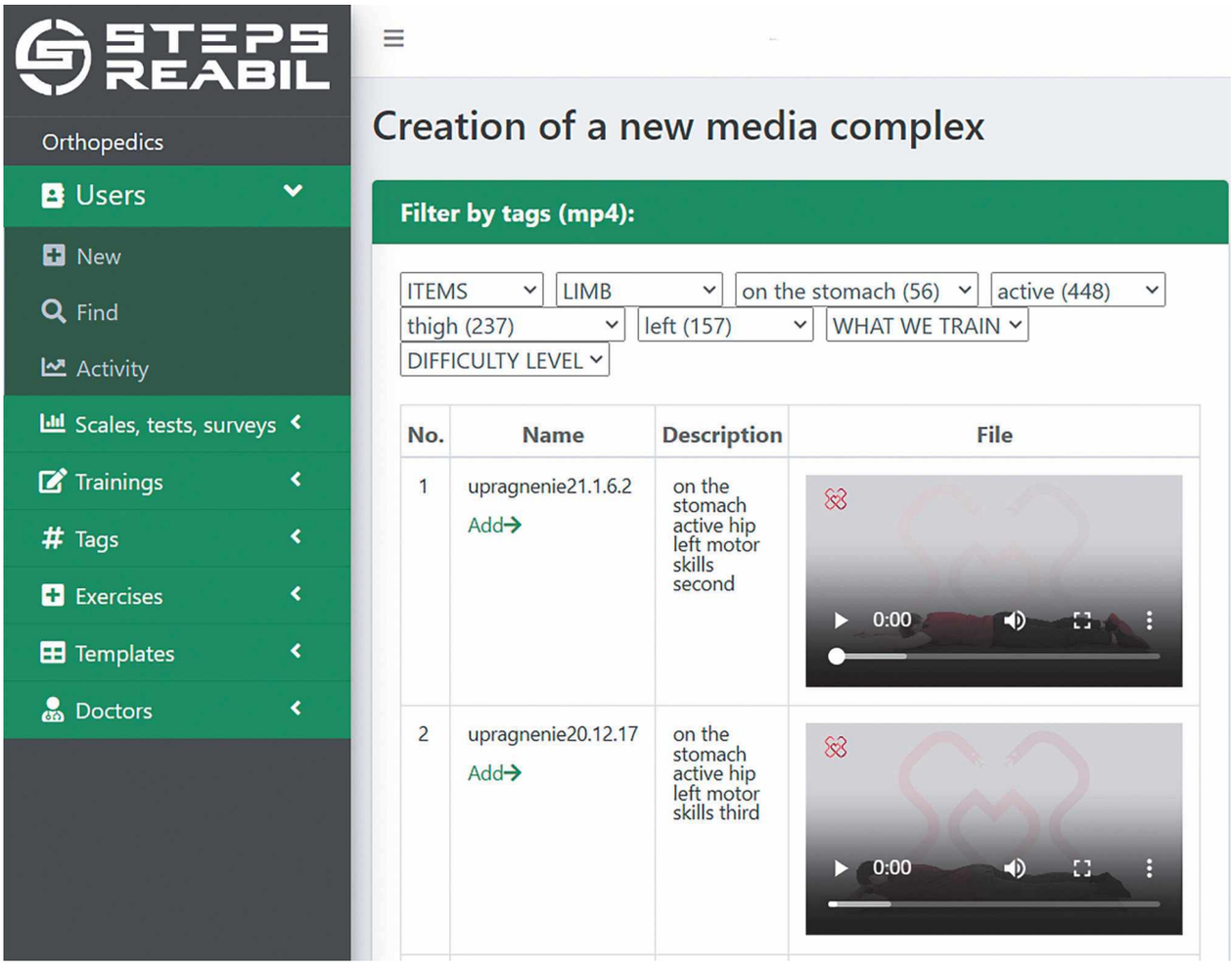

Fig. 1. The interface of the «Ortopediya» block of Privolzhsky Research Medical University on the portal of remote rehabilitation «Steps Reabil» in the mode of selecting a set of videos by tags

The set of assessment tools was formed in accordance with clinical guidelines for the management of patients with coxarthrosis and gonarthrosis and includes various tests, scales and questionnaires to assess the severity of pain syndrome, functional mobility and risk of falls [11, 12]. In the future, as the collection of video library with exercises designed for rehabilitation of patients with injuries and diseases of the spine, hand, foot, shoulder, elbow, wrist joints and other orthopaedic pathologies grows, it is planned to add appropriate tests and questionnaires to assess the effectiveness of rehabilitation. The portal also offers an opportunity to place information materials that contain useful information for patients regarding MR.

AIM

To assess the effectiveness and safety of the DFR model for a cohort of patients who have had a hip or a knee replacement, to study patient adherence, and to select the most informative assessment tools.

MATERIALS AND METHODS

We have developed and received approval in the local ethical committee of FSBEI HE «Privolzhsky Research Medical University» of the Ministry of Health of Russia (extract from minutes No. 04 of 17 March 2023) the protocol of a prospective randomized comparative study in a group of patients who underwent a hip or a knee replacement, using the «Orthopaedics» block of the digital rehabilitation platform for adults and children «Steps Reabil». The duration of participation in the study is 2 months per participant, with 4 face-to-face visits to a physical and rehabilitation medicine or physical therapy physician (screening, randomization, visit 4 and 8 weeks after randomization). The total estimated duration of the study, which is planned to include 80 patients, will be 15 months. At the screening visit, the patient is invited to participate in the study and provided with all relevant information. During this visit, inclusion/exclusion criteria will be assessed, informed consent will be signed, demographic and medical history will be collected, physical examination will be performed, and baseline vital signs will be measured. Randomization is done by the closed-envelope method within 30 days after the screening visit and includes reassessment of inclusion/exclusion criteria, physical examination, measurement of vital signs, assessment of pain severity, functional mobility and risk of falls using various tests, scales and questionnaires, followed by the closed-envelope method placement of patients into one of the groups.

Inclusion Criteria

Informed consent signed by the participant before any procedures related to the study; participant's age from 30 to 75 years inclusive; a scheduled hip or knee replacement; documentation of the first and second stages of MR after endoprosthetics; absence of complications during surgery and in the postoperative period; the patient's fluency in Russian; the patient's ability to access the Internet from a personal computer, laptop, tablet, smartphone.

Exclusion Criteria

Current or past significant co-morbidities in the opinion of the investigator that may adversely affect participation in this study; persistent chronic or active recurrent infection with a need for antibiotic, antiviral or antifungal treatment; any malignancy within 5 years prior to the screening visit; serious mental disorder e.g. bipolar disorder, dementia; short life expectancy due to pre-existing condition(s), in the opinion of the treating physician (rehabilitation physician).

The study participants, according to the protocol, were placed in groups at the third stage of rehabilitation in a 1:1 ratio to receive DPR in addition to routine clinical practice of MR (DPR group) or routine MR alone (comparison group). Routine MR includes daily independent physical exercises at home, learnt during inpatient treatment in the second stage of MR, lifestyle modification, taking non-steroidal anti-inflammatory drugs in case of pain syndrome development. The patients in the DPR group are advised that there is no need to do any physical activities at home other than those presented on the DPR portal. Patients in the comparison group enter the date, start and end times of exercise and adverse events in the diary for self-monitoring and further compliance analysis. In the DPR group, information about the fact and duration of exercise can be automatically accessed by the physician in the "Activity" section of the DPR portal.

The patients randomized to the DPR group are provided with instructions on how to use the «Orthopaedics» block of the «Steps Reabil» portal and a personal account and the peculiarities of DPR are explained. A link is then sent to the study participant from the DPR group by e-mail, which the patient uses to access the personal account to undergo DPR within 1 month. The DPR programme, which includes a set of videos with exercise demonstrations, is formed for each individual patient individually, taking into account his or her individual functional capabilities and comorbid background. During the randomization visit, the physician explains to the patient the substance of the exercises, their duration and frequency, as well as the necessary conditions for their performance. Subsequently, a physical rehabilitation specialist interacts with the patient for the duration of DPR, who can make changes to the distance rehabilitation programme. The patient performs DPR exercises independently for 1 month daily for an average of 20–40 minutes. 2 times a day. The duration and frequency of exercises are strictly individual, and may be modified by the physical rehabilitation specialist depending on the patient's well-being and recovery progress. According to the protocol, absences due to patient's ill health or family circumstances are allowed, but not more than 5 consecutive days or more than 15 days per month in total. All the patient's activity on the «Steps Reabil» portal (videos watched, tests, scales and questionnaires completed) is monitored in real time by the physical rehabilitation specialist and adjustments can be made. If necessary, the patient can contact the physical rehabilitation specialist via chat on the DPR portal or bya phone call.

Clinical Assessment of the Effectiveness of Rehabilitation Measures

According to the protocol, clinical assessment of the rehabilitation effectiveness in both groups is carried out during face-to-face visits (randomization, completion and follow-up visits) and includes analysis of physical examination data, vital signs, and data from various scales, tests and questionnaires. Within the frames of the approbation we used a 10-point visual analogue scale (VAS), the Timed 25-Foot Walk (T25-FW), the «Timed Up and Go» test, the Berg Balance Scale (BBS), the Western Ontario and McMaster University Osteoarthritis Index

Table 1. Clinical and demographic data of subjects

Characteristics	RPR Group, *n* = 14	Comparison Group, *n* = 16	*p*
Age, years	49.6 ± 12.4	57.8 ± 11.2	0.0677*
Gender, male	6 (43 %)	8 (50 %)	0.7005 χ^2 Pearson's chi-squared test 0.73 Fisher's exact test
Operated joint, HJ/KJ	11(79 %)/3(21 %)	11(69 %)/5(31 %)	0.5507 χ^2 Pearson's chi-squared test 0.6887 Fisher's exact test
BMI, kg/m²	28.5 [25.5; 32.5]	27.2 [25.8; 31.9]	0.6177**
Obesity	5(36 %)	4(25 %)	0.5299 χ^2 Pearson's chi-squared test 0.6943 Fisher's exact test
Education level, secondary/ higher	6(43 %)/8(57 %)	8(50 %)/8(50 %)	0.7005 χ^2 Pearson's chi-squared test 0.7300 Fisher's exact test
Social status, working/not working	9(64 %)/5(36 %)	8(50 %)/8(50 %)	0.4386 χ^2 Pearson's chi-squared test 0.4837 Fisher's exact test
Type 2 diabetes mellitus	2(14 %)	6(38 %)	0.1584 χ^2 Pearson's chi-squared test 0.2255 Fisher's exact test
Hypertension	7(50 %)	9(56 %)	0.7364 χ^2 Pearson's chi-squared test 1.0 Fisher's exact test

Note: *RPR — remote physical rehabilitation; HJ — hip joint, KJ — knee joint; BMI — body mass index; * — Independent samples t-test; ** — Mann-Whitney test.*

(WOMAC). Based on the results of the platform approbation, the most informative and non-duplicative tests were selected.

Statistical processing

Of the findings was performed using MedCalc Statistical Software and Microsoft Office Excel, 2021. The normality of distribution of quantitative characteristics is checked using the Shapiro-Wilk test. Quantitative data are presented in the form of arithmetic mean and standard deviation in case of normal distribution of indicators or in the form of medians and borders of interquartile range in case of distribution of indicators different from normal; qualitative indicators — in the form of absolute values and percentages; n — volume of the analyzed group, p — value of statistical significance of differences. Statistical comparison of mean values in the group is performed using methods of parametric and nonparametric statistics: paired Student's t-test and Wilcoxon's test, respectively (for related samples), Student's test and Mann-Whitney's test, respectively (for unrelated samples). The Pearson χ2 test for contingency tables is used to test the hypothesis of the relationship between qualitative and ordinal characteristics. If there is a risk of bias in the results obtained using Pearson's χ2 test for contingency tables, Fisher's exact test is used to test the null hypothesis by pairwise comparison of the data of the analyzed groups in four-field tables. Analysis of the relationship (correlation) between two quantitative characteristics is carried out by the Spearman rank correlation method (r). The critical value of the significance level is assumed to be 5 % ($p \leq 0.05$).

RESULTS AND DISCUSSION

From May 2023, 30 patients who had undergone hip or knee replacement were included in the study. Of these, 14 were randomized to the DPR group and 16 to the comparison group. There were no differences in the main clinical and demographic characteristics of the patients at the time of inclusion into the study (Table 1). The patients in the comparison group were independently engaged in gymnastics at home, using physical exercises learnt at the inpatient stage of DPR. 7 patients in the DPR group and 6 in the comparison group took periodically non-steroidal anti-inflammatory drugs for pain. 2 patients from the DPR group used a magnetic therapy device at home, 1 patient from the comparison group performed kinesiotaping of the knee joint in a private clinic, and 2 other patients from the comparison group occasionally used an Orthosis on the knee joint of the operated limb for pain.

When comparing baseline scores of tests, scales and questionnaires (T25-FW, «Timed Up and Go» test, VAS, BBS and WOMAC) between groups at the time of inclusion of participants in the study, no statistically significant deviations were found.

Ten patients in the DPR group and all 16 patients in the comparison group completed the study according to the protocol. 4 patients in the DPR group terminated their participation early due to absenteeism or refusal to participate. In the DPR group (n = 10), the mean number of days per month that a patient engaged in physical activity using the portal was 23.7 ± 3 days and the duration per session was 33.2 ± 5.3 minutes. In the comparison group, the mean number of exercise sessions that participants performed at home independently during the month was 17.7 ± 3.6 days and the duration was 25.1 ± 6.1 minutes, which was statistically significantly less (p = 0.0002, p = 0.0023, respectively) than in the DPR group.

Comparison of results in the DPR group (n = 10) 1 month after DPR sessions revealed statistically significant improvement in T25-FW (p = 0.0487), "Timed Up and Go" test (p = 0.0132), VAS (p = 0.0090), WOMAC (p = 0.0003) and BBS (p = 0.0455), confirming improvement in the patient's functional profile and reduction in pain severity. The comparison group also showed improvement after 1 month of routine MR as part of the third phase, but only in VAS (p = 0.0458) and WOMAC (p = 0.0415); no statistically significant improvements were found in other

Table 2. Comparison of indicators of questionnaires/scales inside the groups

Scale / test / questionnaire	The average value of the indicator			
	RPR Group		Comparison Group	
	Initial indicators, n = 14	Indicators after 1 month, n = 10	Initial indicators, n = 16	Indicators after 1 month, n = 16
T25-FW, sec	7 ± 1.2	6.1 ± 0.5	7.6 ± 1.0	7.6 ± 0.8
p	**0.0487***		0.6795*	
«Timed up and go» test, sec	8.5 ± 2	7 ± 0.9	8.8 ± 1.5	8.6 ± 1.5
p	**0.0132***		0.2419*	
VAS, score	5 [4; 5]	2 [1; 2]	3 [1.5; 4]	2 [1.5; 3]
	0.0090**		**0.0458****	
BBS, score	43 ± 6.5	47.5 ± 3.7	42.3 ± 4.9	41.1 ± 4.3
p	**0.0455***		0.0983*	
WOMAC, score	36.4 ± 6.2	18.9 ± 7.6	34.8 ± 5.9	32.9 ± 4.7
p	**0.0003***		**0.0415***	

Note: *RPR — remote physical rehabilitation; BBS — Berg Balance Scale; WOMAC — Western Ontario and McMaster University Osteoarthritis Index; * — Paired samples t-test; ** — Wilcoxon test.*

tests, scales and questionnaires (T25-FW, the «Timed Up and Go» test and BBS) (Table 2).

Furthermore, when comparing rehabilitation outcomes between groups 1 month after inclusion of participants in the study, a greater statistically significant improvement in T25-FW ($p < 0.0001$), «Timed Up and Go» test ($p = 0.0064$), BBS ($p = 0.0008$) and WOMAC ($p < 0.0001$) scales was found in the DPR group, suggesting greater effectiveness of DPR in addition to routine MR compared to routine MR rehabilitation care alone as part of the third phase of the MR program.

Correlation analyses of the results of examinations performed 1 month after the inclusion of participants in both groups in the study showed a positive correlation between the «Timed Up and Go» and T25-FW tests ($r = 0.501$, $p = 0.0482$), both of which assess functional mobility [16, 17], and the «Timed Up and Go» and BBS tests ($r = 0.623$, $p = 0.0100$), which assess the risk of falls [16, 18]. These results indicate that it is acceptable to use only the «Timed Up and Go» test to assess the risk of falls and functional mobility. Based on these results, the «Timed Up and Go» test, VAS and WOMAC were selected for further practical work.

Special attention was paid to the problems encountered during DPR, namely compliance issues of DPR patients. The main problem was the availability and speed of the Internet. Some participants ($n = 5$) living in the districts of Nizhny Novgorod region noted that despite their desire to perform the exercises, they could not do so due to temporary interruptions in the operation of their Internet provider, i.e. the company providing the client's access to the Internet. Four patients missed more than 5 consecutive days or refused to complete the DPR due to technical reasons related to the internet. The likely factors influencing the refusal or inability to use DPR on a regular basis were analyzed. The factors analyzed included the participant's education level (primary/secondary/higher education), social status (working/not working), age, and place of residence (city/region). Univariate regression analysis showed that older age (χ^2 16.75, $p < 0.0001$), pensioner status (χ^2 11.75, $p = 0.0006$) and residence in the region (χ^2 11.75, $p = 0.0006$) were more significant predictors of premature DPR interruption, which is probably related to low skills in modern mobile and communication devices, as well as low internet speed and internet provider outages.

The analysis of adverse events showed that 4 patients in the DPR group and 6 in the comparison group had periodic increase of pain syndrome in the operated limb during the first days of physical rehabilitation. After changing the intensity of the exercises, the pain syndrome regressed or the pain severity significantly decreased. No other adverse events related to the study were detected.

Limitations of the study and recommendations for further studies

The presented findings are preliminary, as they were obtained using a small sampling. Continuation of the study with the inclusion of a larger number of participants will allow obtaining more accurate data necessary to draw correct conclusions.

CONCLUSION

The remote form of rehabilitation organization has great prospects for development due to the emergence of new information technologies that allow for active communication between a healthcare professional and a patient. We have developed a model of remote physical rehabilitation of patients, which is based on the principle of continuity and consistency of rehabilitation care. The model involves remote provision of individualized exercise complexes to the patient, presented in the form of video clips, as well as the possibility of online control over the progress of the patient's condition. The approbation involving 30 patients who underwent replacement of large joints of the lower limb demonstrated that the remote form of physical rehabilitation in this category of patients is safe and effective in restoring functional mobility, reducing the risk of falls and the severity of pain syndrome, and helps to increase adherence to physical exercise. The main limitations in the practical use of remote physical rehabilitation are related to the availability of high-speed internet and skills in using internet portals. It is planned to continue this study with the inclusion of more participants and evaluation of long-term results, which will provide the accurate findings needed to draw correct conclusions.

Further development of the portal of remote medical rehabilitation for this category of patients, in addition to improving the shortcomings identified in the process of approbation, provides for the implementation of a multidisciplinary approach (including sessions with an occupational therapist and a medical psychologist).

ADDITIONAL INFORMATION

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Ethics Approval. The authors declare that all procedures used in this article are in accordance with the ethical standards of the institutions that conducted the study and are consistent with the 2013 Declaration of Helsinki. The study was approved by the local Ethics committee of Privolzhsky Research Medical University Protocol No. 04 dated March 17, 2023.

Data Access Statement. The data that support the findings of this study are available on reasonable request from the corresponding author.

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Effect of Stabilization Exercises on Craniovertebral Angle and Cervical Range of Motion among Visual Display Users with Forward Head Posture

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ABSTRACT

INTRODUCTION. VDT (video display terminal or visual display terminal) is used, especially in ergonomic studies, for the computer display. When using a VDT, static posture raises muscle tension, which causes a variety of neuromuscular symptoms, most frequently in the upper body, including discomfort, numbness, loss of function, and other symptoms. The advent of the technological revolution has rendered modern computing and communication tools indispensable for both professional and recreational purposes. The companies have extended its market reach by introducing their computing products, specifically Video Display Terminals (VDTs), beyond the confines of traditional business settings to include personal laptops used in residential spaces such as bedrooms.

AIM. The study aimed to compare the effects of stabilization exercises vs traditional exercise on cervical range of motion and the Craniovertebral angle in VDT users with a forward head posture.

MATERIALS AND METHODS. Comparative study design with 26 participants, comprising both genders with forward head posture between the ages of 20 and 35. Following selection, subjects were randomly divided into two groups: Group A, which received stabilization exercises, consist of 12 subjects; Group B, with 14 subjects; the main outcome measures were cervical range of motion and Craniovertebral angle.

RESULTS. Group A shows statistically substantial improvement in all the outcomes. Group B also shows statistically significant improvement in selected cervical range of motion; however, the group did not improve the Craniovertebral angle and cervical rotations substantially.

CONCLUSION. The results of the current study showed that stabilizing exercises are superior to conventional training in reducing the craniovertebral angle and increasing cervical range of motion in visual display terminal users with a forward head posture.

KEYWORDS: visual display terminal users, forward head posture, swiss ball, stabilization exercise.

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Влияние стабилизирующих упражнений на краниовертебральный угол и диапазон движения шейного отдела позвоночника у пользователей визуальных дисплеев с положением головы вперед

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РЕЗЮМЕ

ВВЕДЕНИЕ. ВДТ (видеодисплейный терминал или визуальный дисплейный терминал) используется, особенно в эргономических исследованиях для отображения информации на экране компьютера. При использовании ВДТ статическая поза вызывает напряжение мышц, что приводит к различным нервно-мышечным симптомам, чаще всего в верхней части тела, включая дискомфорт, онемение, потерю функции и другие симптомы. Наступление технологической революции сделало современные компьютерные и коммуникационные средства незаменимыми как для профессиональных, так и для развлекательных целей. Компании расширили сферу своего влияния на рынок, выведя свои вычислительные продукты, в частности ВДТ, за рамки традиционной деловой среды и распространив их на персональные ноутбуки, используемые в жилых помещениях, например, в спальнях.

ЦЕЛЬ. Сравнить влияние стабилизирующих упражнений и традиционных упражнений на диапазон движения шейного отдела позвоночника и краниовертебральный угол у пользователей ВДТ с наклоном головы вперед.

МАТЕРИАЛЫ И МЕТОДЫ. В сравнительном исследовании приняли участие 26 человек обоих полов с прямой позой головы в возрасте от 20 до 35 лет. После отбора испытуемые были случайным образом разделены на две группы: Группа А, получавшая стабилизирующие упражнения, состояла из 12 человек; Группа В — из 14 человек; основными показателями были диапазон движения шейного отдела позвоночника и краниовертебральный угол.

РЕЗУЛЬТАТЫ. Группа А показала статистически значимое улучшение по всем показателям. Группа В также показала статистически значимое улучшение в выбранном диапазоне движения шейного отдела; однако группа не улучшила краниовертебральный угол и ротацию шейного отдела.

ЗАКЛЮЧЕНИЕ. Результаты данного исследования показали, что стабилизирующие упражнения превосходят обычные тренировки в уменьшении краниовертебрального угла и увеличении диапазона движения шейного отдела позвоночника у пользователей визуальных терминалов с положением головы вперед.

КЛЮЧЕВЫЕ СЛОВА: пользователи терминалов с визуальным дисплеем, положение головы вперед, швейцарский мяч, стабилизирующие упражнения.

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INTRODUCTION

In technologically advanced eras, computer users have grown to be the most important group for keeping up with time and progress. To enable and speed up data flow and information, banks, government agencies, corporate organizations, autonomous institutions, and nearly every organization are becoming computerized. Modern computing and communication tools are now necessary for both work and play due to the arrival of the technology revolution. They have expanded their presence with their computing devices VDT from the fixed desktop of an office environment to a user's laptop in the bedroom [1–2].

Conferring to National Statistical Office reports that as more individuals own computers and have access to larger internet networks, the amount of time per week that each individual spends using a computer has substantially increased, rising from 5.9 hours in 1997 to 14.6 hours in 2003. Additionally, 56.2 % of computer users log on for 10 hours or more per week. Computers boost productivity and effectiveness at work, but prolonged use can cause VDT syndrome, which can cause headaches, visual disturbances, musculoskeletal pain, and other symptoms. Of these concerns, musculoskeletal issues are the most prevalent [3–6].

The characteristics of the task determine the effects on head and neck posture. VDT work typically entails staying in a fixed position for an extended period. Szeto et al. [7] discovered that during VDT work, People tend to hunch their heads forward more often, which is comparable to a protracted portion of the cervical spine where the lower cervical vertebrae are flexed in a forward glide and the upper cervical vertebrae are extended [8]. This forward head posture involves an excessive anterior part of the head regarding the theoretical plumb line perpendicular to the body's center of gravity.

Although the link between forward head posture and neck pain has not been established, a tool for developing neck pain from habitual postures has been demonstrated [9] According to research on the effects of sustained forces, a single stance should not be held for more than 60 minutes. McGill and Brown have demonstrated that 20 minutes of persistent stress can cause soft tissue creep, with recovery requiring up to 40 minutes [10].

The normal cervical lordosis is a curve in the cervical spine, which houses the neck vertebrae. This curve is perfectly standard

and even desirable because it aids in the stabilization of the head and spine. The cervical lordosis in a healthy spine resembles an extensive C, with the C pointing towards the back of the neck. The load affects cervical postural changes. Prolonged static postures are more common, and both non-neutral and neutral neck postures have been linked to cervical discomfort [11].

The studies found that subjects with head, neck, and shoulder discomfort are more likely to have a smaller craniovertebral angle, which indicates a forward head posture, than asymptomatic subjects. Neck posture is significantly associated with musculoskeletal neck disorders in occupational settings [12]. FHP and rounded shoulders are both characterized by head and shoulder protrusion in the sagittal plane. These changes in the cervical region may lead to musculoskeletal discomfort, such as "upper crossed syndrome," as a result of keeping a bad head position for an extended period of time (upper cervical extension and flexion of the lower cervical spine). Additionally, neck and shoulder pain are prominent complaints among FHP patients [13].

The CV angle is the angle formed by a horizontal line passing through C7 and a line extending from the tragus of the ear to C7, which is significantly reduced in subjects with FHP [14] CV angle, has an average range of 42–54. The CV angle is a reliable way to assess forward head posture (ICC-0.95) [15]. Restoring normal neck flexion and extension range of motion should be the aim of treatment for poor cervical posture. Enhancing cervical mobility to manage CV angle assisted in lowering the FHP for neck stabilization [16].

Workers in VDU now place proper posture of the cervical spine in relation to the shoulders. There isn't much that defines stance based on measurements, and a few other postural detriments have been linked with quantitative measures; furthermore, working for lengthy periods of time causes atypical postures due to the stress that builds up during the workday.

Previously, different ergonomic measures were discussed in computer users, and the role of stabilizing exercises has become vital in daily life to avoid future illness development and improve quality of life further to it age specific protocols can be developed.

AIM

Hence the aim of the training is intended to find out the effect of stabilization exercises on craniovertebral angle and cervical range of motion among Visual display users with forward head posture.

MATERIALS AND METHODS

Participants

The data is collected from Kritiprakashan pvt LTD and Cognizant technology solutions Bangalore with forward head posture with total sample size of 26 by simple random sampling technique. Randomization — Allocation concealment mechanism:

$$n = \frac{(Z_{1-\alpha/2}+Z_{1-\beta})^2 \times S^2 \times 2}{d^2}$$

The group is transcribed on paper and preserved in a solid closed envelope using the sequentially numbered, solid, closed envelope (SNOSE) technique. A serial number is inscribed on the label of the envelope, subsequently attaining the subjects consent; the researcher opens the sealed envelope and designates the therapy group as necessary.

Inclusion criteria

1. Neck pain for more than three months.
2. Desktop or laptop usage for more than 2 hours/day.
3. Both male and female subjects.
4. Age group: 19–35 years.
5. Subjects with forward head posture.

Exclusion criteria

1. Patients with cervical discal pathology (Radiographic evaluation was done to evaluate for degenerative pathology to rule out osteophytes).
2. Infectious pathology in or around the spinal column.
3. Previous history of cervical surgery.
4. Patients with temporomandibular joint disturbances.
5. Patients with vestibular imbalance.

The study has been approved by the ethical committee vide of Padmashree Institute of Physiotherapy, Ref: PIP/EC/15-10/03-18 dated 15.03.2018. The subjects were divided into two groups.

Out of 26 subjects 12 were in Group A received stabilization exercises and 14 were in Group B who received isometric exercises. The back ground variables of age and gender are homogenous in both the groups with mean and SD of age and frequency and percentage of the gender (Table 1).

Table 1. Description of Background Variables

Sl. No	Variables	Group A (n = 12)	Group B (n = 14)	p-value
		Mean ± SD	Mean ± SD	
1	Age	29.00 ± 2.32	29.00 ± 3.43	p = 1.00
2	Gender	9 (75.0)/3 (25.0)	8 (57.1)/6 (42.9)	p = 0.340

Note: Not significant ($p > 0.05$).

Group A (n = 12) (Experimental Group): This group performed stabilization exercises on the Swiss ball. Stabilization exercises performed strengthening of deep cervical neck flexors and scapular retractors.

Exercises for strengthening neck flexors

The subjects lay supine with head up and chin tuck both the hands are placed on abdomen [17]. For strengthening of scapular retractors: the subjects were positioned prone with shoulders at 90°–120° abduction, then extended their spine by externally rotating their arms while maintaining the chin-tuck.

The subjects performed these exercises twice a week for four weeks, with ten repetitions and 10 seconds hold in the first two weeks and 15 seconds hold in the following two weeks [18].

Group B (n = 14): 10–15 repetitions of isometric exercises were carried out while lying on the back with the chin resting against a towel roll under the neck for 10 seconds at a time, with 15-second pauses in between holds. Then, in the seated position, isometric workouts were carried out with maximum effort by resisting cervical flexion, extension, lateral flexion, and rotation with one's own hand for the same number of repetitions and duration as in the supine position.

Table 2. Comparison of Pre Intervention outcome variables

Sl. No	Variables	Group A (*n* = 12)	Group B (*n* = 14)	*p*-value
		Mean ± SD	Mean ± SD	
1	CV angle	56.50 ± 3.89	58.14 ± 3.65	*p* = 0.279
2	Flexion	26.75 ± 5.27	27.21 ± 3.63	*p* = 0.795
3	Extension	34.75 ± 7.96	30.93 ± 3.56	*p* = 0.118
4	Flexion LT side	38.75 ± 7.99	36.50 ± 7.73	*p* = 0.473
5	Flexion RT side	43.08 ± 8.78	42.57 ± 8.34	*p* = 0.880
6	Left Rotation	53.42 ± 15.5	51.21 ± 13.4	*p* = 0.703
7	Right Rotation	63.25 ± 6.93	61.71 ± 8.54	*p* = 0.623

Note: *Not significant (p > 0.05).*

The stabilization exercise group has performed two sets of exercise and the isometric group has performed only one set of exercises hence there is a variation in the frequency of sessions in the groups.

Outcome Measures

Universal Goniometer for the assessment of cervical ROM [19] Cervical X-Rays for the evaluation of CV angle [20–23].

A body marker is used to identify the ear tragus and the spinous process of C7. Draw a horizontal line that intersects C7 and forms a right angle with the vertical. Two lateral pictures of the person in a relaxed seated position without back support are taken in order to estimate the craniovertebral angle

Statistical Analysis

The data was carefully elicited on the outcome measures, and demographic characteristics of the forward head posture subjects were evaluated by SPSS software (version 20.0). The level of significance was set at 5 % (i.e., α = 0.05). The frequency and percentage analysis described the demographic data of the subjects. Baseline variables and primary variables have been computed using Mean and standard deviation.

The significant difference between pre- and post-test results was examined using the paired t-test. The significant difference between the experimental and control groups was examined using an unpaired t-test.

The significance of the difference in gender proportion across groups was examined using the chi-square test. The Shapiro-Wilk test is used to determine whether the data for quantitative outcomes are normal. The graphs and tables were created using MS-Excel and MS-Word.

RESULTS

The outcome measures of CV angle and cervical range of motion (Flexion, Extension, Left side Flexion, Rt side flexion, left and right rotation were compared and given in the above table before the intervention the mean and SD of outcome measures pre interventionally more or less similar individually in both the groups. The Unpaired t test was shown to be non-significant for all the variables (Table 2).

Table 3 presents the pre and posttest comparison of the outcome measures individually for Group A and Group B the CV angle, and cervical range of motion Flexion, Extension, left side flexion and Right side flexion were found to be significant in both the groups but the outcome measures of left rotation and right rotation were found to be statistically significant while comparing pre and post test scores individually in both the groups.

The post-intervention assessment of outcome variables revealed that Group A (Stabilization Exercises) showed significantly greater improvement in flexion and extension range of motion

Table 3. Comparison of Pre and Post Intervention outcome variables

Sl.No	Variables	Group A (*n* = 12)	*p*-value	Group B (*n* = 14)	*p*-value	
		Mean ± SD		Mean ± SD		
1	CV angle	Pre test	56.50 ± 3.89	0.000	58.14 ± 3.65	*p* = 0.000
		Post test	63.42 ± 4.20		60.64 ± 3.60	
2	Flexion	Pre test	26.75 ± 5.27	0.000	27.21 ± 3.63	*p* = 0.000
		Post test	38.50 ± 4.94		29.43 ± 3.45	
3	Extension	Pre test	34.75 ± 7.96	0.000	30.93 ± 3.56	*p* = 0.000
		Post test	52.17 ± 10.1		32.71 ± 3.26	
4	Flexion LT side	Pre test	38.75 ± 7.99	0.015	36.50 ± 7.73	*p* = 0.000
		Post test	44.08 ± 7.45		39.00 ± 7.01	
5	Flexion RT side	Pre test	43.08 ± 8.78	0.000	42.57 ± 8.34	*p* = 0.000
		Post test	49.75 ± 9.32		43.93 ± 8.30	
6	Left Rotation	Pre test	53.42 ± 15.5	0.079	51.21 ± 13.4	*p* = 0.207
		Post test	59.75 ± 14.5		53.21 ± 13.2	
7	Right Rotation	Pre test	63.25 ± 6.93	0.063	61.71 ± 8.54	*p* = 0.752
		Post test	68.58 ± 11.4		62.93 ± 8.10	

Note: *Not significant (p > 0.05), significant (p < 0.05).*

Table 4. Comparison of Post Intervention outcome variables

Sl. No	Variables	Group A (*n* = 12)	Group B (*n* = 14)	*p*-value
		Mean ± SD	Mean ± SD	
1	CV angle	63.42 ± 4.20	60.64 ± 3.60	$p = 0.083$
2	Flexion	38.50 ± 4.94	29.43 ± 3.45	$p = 0.000$
3	Extension	52.17 ± 10.1	32.71 ± 3.26	$p = 0.000$
4	Flexion LT side	44.08 ± 7.45	39.00 ± 7.01	$p = 0.086$
5	Flexion RT side	49.75 ± 9.32	43.93 ± 8.30	$p = 0.105$
6	Left Rotation	59.75 ± 14.5	53.21 ± 13.2	$p = 0.242$
7	Right Rotation	68.58 ± 11.4	62.93 ± 8.10	$p = 0.156$

Note: *Not significant ($p > 0.05$); significant ($p < 0.05$).*

compared to Group B, which was treated with isometric exercises (Table 4). The post-test scores of other outcomes did not show any statistically significant differences between the groups. The0data suggests that the intervention applied in Group A is much more efficacious than in Group B, whereas the other outcome measures showed no significant differences. The post-test scores in Group A exhibited higher mean and standard deviation compared to the post-test scores in Group B.

DISCUSSION

The study aimed to determine the effect of stabilization exercises on the CV angle and cervical ROM among visual display terminal users with forward head posture.

There is a slight variation between groups based on gender, and it was found to be not f = 1) at the 5 % level, i.e., ($p > 0.05$). The baseline characteristics of age were similar in both groups.

Group A improved significantly the within-group results in the CV angle post stabilization exercises on a swiss ball in the existing study, with the post-test mean and SD of 63.42 ± 4.20 indicating statistically significant improvement (i.e., t = 14.778 and $p < 0.001$). These findings are consistent with the results of a study conducted by Boyoung I'm et al. through his findings the effects of scapular stabilization exercise on neck posture and muscle activation in people with neck pain and forward head posture. The finding suggests that, it can concentrate on muscle activation patterns during different scapular movements, are that scapular stabilization exercise helps to improve head posture and pain in patients with neck pain and forward head posture [22].

In the present study, there was a significant statistical improvement (i.e., $p < 0.001$) in the cervical ROM post stabilization exercise, and the findings were comparable to the effects of the study done by Arins GA et al., who explained in their research that when the individual does not move through a comprehensive range of motion, the muscles regularly shorten, which causes adaptive variations in muscle length as a result, both regular and pain-affected individuals' cervical range of motion will be affected by their head posture [24].

In the present study, there was a statistically significant improvement (t = 6.813, $p < 0.05$) in the extension range and left lateral flexion (t = 10.142, $p < 0.05$) in the stabilization group. The current study's findings are corroborated by Won Gyu Yoo et al. They observed a correlation between the alterations in the cervical spine that occur after the usage of VDT (Visual Display Terminal) and the range of motion in the neck. During their training, they highlighted a negative association between the craniocervical angle and neck extension. The negative correlation can be explained by the association between changes in the craniocervical angle and the shortening of the scalenus muscles, resulting in a limited range of motion in neck extension [25]. They also claimed that there was a negative correlation between left lateral flexion and the cervicothoracic angle because the people used their right hands to operate a work station and it's probable that this repetitive use shortens muscles like the upper trapezius. The study demonstrated that a stabilizing exercise led to an enhancement in left lateral flexion, along with an improvement in muscle control.

In comparison to Group B, Group A's performance significantly improved statistically ($p < 0.001$), according to the data. The results of a study by Hye-Young Cho and colleagues on the impact of swiss ball stabilization exercise on the deep and superficial cervical muscles and pain in patients with chronic neck pain, where he came to the conclusion that the results showed that continuous swiss ball stabilization exercise, at specific timings plays a crucial role.

According to Kim D. et al. [16], neck pain with a forward-facing head posture is linked to a variety of illnesses, including an excessive workload, postural issues, psychiatric conditions, bad postures, and structural disorders. They also showed how treating these conditions can reduce pain and enhance quality of life in patients with forward head posture.

Limitations

1. The exercise program involved in this study lasted just four weeks, the findings could not be used to assess the exercise's long-term benefits.
2. It was challenging to extrapolate the benefits of scapular stabilizing exercise due to the small sample size.
3. People who had neck pain found it difficult to focus for extended amounts of time and were certainly under fatigue.
4. The sessions and exercise intensity has been varied as the concept of exercise intensity is a multifaceted construct that pertains to the metabolic expenditure associated with a certain activity session.

CONCLUSION

Subjects with a forward head posture tend to have neck pain that is correlated with pain intensity. In patients with a forward head posture, the stabilization exercises showed a significant improvement in cervical range of motion and craniovertebral angle. Stabilization exercises significantly affect Craniovertebral angle and cervical range of motion in Visual display unit users with forward head posture. Hence this type of exercise can be incorporated as an ergonomic measure to handle the postural deviations in different rehabilitation setups.

Recommendations

More research is required to evaluate synchronously acquired 3-D motion and electromyography data of the neck and shoulder from several VDT workers as well as to comprehend the nature of motor control issues in deep muscles in patients with work-related musculoskeletal diseases (WRMD).

ADDITIONAL INFORMATION

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Author Contributions. All authors confirm their authorship according to the international ICMJE criteria (all authors contributed significantly to the conception, study design and preparation of the article, read and approved the final version before publication). Special contributions: Shyama S. — conceptualization, investigations, methodology, resources, Visualization; Nagaraj S. — conceptualization, data curation, project administration, review and editing.

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Ethics Approval. The authors declare that all procedures used in this article are in accordance with the ethical standards of the institutions that conducted the study and are consistent with the 2013 Declaration of Helsinki. The study has been approved by the ethical committee vide of Padmashree Institute of Physiotherapy, Ref: PIP/EC/15-10/03-18 dated 15.03.2018.

Data Access Statement. The data that support the findings of this study are available on reasonable request from the corresponding author.

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Meteorological Parameters and Hypertensive Crisis Risk: a Longitudinal Study for Prediction Model Developing

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ABSTRACT

INTRODUCTION. Integrating climatotherapy into health resort therapy for arterial hypertension in diverse landscapes has the potential to yield positive effects, if used in target groups and preventing the occurrence of meteopathic reactions, including a hypertensive crisis (HC). While the impact of natural healing factors on the human body has been previously studied, the utilization of modern mathematical approaches in developing HC models has enabled accurate predictions and timely prevention of HC during adverse weather periods.

AIM. To analyze publicly available meteorological data time series to construct a mathematical model for predicting high-risk situations of HC based on the influence of climatic factors on patients with arterial hypertension. This model would identify unfavorable periods for hypertensive patients staying in health resorts throughout the year, allowing for timely therapeutic and preventive measures to prevent HC during these periods.

MATERIALS AND METHODS. The study was conducted over a 22-month period, from January 1, 2019 to October 31, 2020, in Gelendzhik and Novorossiysk, renowned resort destinations located on the Black Sea coast of the Caucasus. These regions have a dry and subtropical climate. Meteorological data were obtained from Gelendzhik and Novorossiysk weather stations, and ambulance calls data were collected from Gelendzhik (12,268 calls) and Novorossiysk (12,226 calls), resulting in a total of 24,494 ambulance calls.

The model was calculated using the maximum likelihood method through nonlinear logit regression. Key factors for the model included the main indicators of climate[1] and geomagnetic conditions[2]. The logistic regression method exhibited a sensitivity of 56.0 % and a specificity of 77.3 %, with an overall accuracy of 76.0 %.

RESULTS. According to the developed predictive model, the winter season has no more than 75.0 % of days associated with a low risk of hypertension, decreasing to 59.0 % in spring. However, the proportion increases to 89.0 % in summer and reaches 77.0 % in autumn. Model adequacy checks indicated a high degree of relevance, with Q (model quality) ranging between +0.64 and –0.117, and $p > 0.3$.

CONCLUSION. The developed logistic regression models provide more accurate calculations of individual risks for developing complications of hypertension and offer the opportunity to formulate individual strategies for patients. These models contribute to the field of climatotherapy and enhance the understanding of the impact of climatic factors on hypertensive patients, facilitating targeted interventions and improved management of hypertensive crises.

KEYWORDS: seasons, likelihood functions, climatotherapy, logistic models, weather, hypertension, prognosis, spa treatment, meteorological factors.

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[1] *Source of meteorological factors data. Available at: www.gismeteo.ru or http://www.kubanmeteo.ru/index.php/podrazdeleniya/set-meteostantsij (accessed: 02.07.2023)*
[2] *Geomagnetic activity data source: http://spaceweather.izmiran.ru*

Метеорологические параметры и риск развития гипертонического криза: лонгитюдное исследование для разработки модели прогнозирования

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РЕЗЮМЕ

ВВЕДЕНИЕ. Включение климатотерапии в состав санаторно-курортного лечения артериальной гипертензии (АГ) в различных местностях, обладающих характеристиками природного лечебного ресурса, может дать положительный эффект в целевых группах при условии предотвращении возникновения метеопатических реакций, в том числе гипертонического криза (ГК). Влияние природных лечебных факторов на организм человека изучалось и ранее, но использование современных цифровых технологий построения моделей риска возникновения ГК позволяет точно прогнозировать и своевременно предотвращать ГК в неблагоприятные погодные периоды.

ЦЕЛЬ. На основе анализа временных рядов общедоступных метеорологических данных построить математическую модель для прогнозирования периодов высокого риска ГК на основе влияния климатических факторов на пациентов с АГ. Данная модель позволит выявить неблагоприятные периоды пребывания пациентов с АГ в санаторно-курортных учреждениях в течение года, что позволит своевременно проводить лечебно-профилактические мероприятия по предупреждению ГК в эти периоды.

МАТЕРИАЛ И МЕТОДЫ. Лонгитюдное следование проводилось в течение 22 месяцев, с 1 января 2019 г. по 31 октября 2020 г., в Геленджике и Новороссийске — городах, расположенных на Черноморском побережье Северного Кавказа. В этих регионах преобладает сухой субтропический климат. Метеорологические данные были получены с метеостанций городов Геленджик и Новороссийск. Данные о вызовах скорой помощи также были собраны в Геленджике (12 268 вызовов) и Новороссийске (12 226 вызовов), в результате чего суммарно было изучено 24 494 вызова скорой помощи. Математическая модель была построена с использованием метода максимального правдоподобия посредством нелинейной логит-регрессии. Ключевыми факторами для модели стали основные показатели климата и геомагнитной обстановки. Метод логистической регрессии показал чувствительность 56,0 % и специфичность 77,3 % с общей точностью 76,0 %.

РЕЗУЛЬТАТЫ. На основании разработанной прогностической модели в зимний сезон приходится не более 75,0 % дней, связанных с низким риском ГК, число которых снижается до 59,0 % в весенний период. Однако доля увеличивается до 89,0 % летом и достигает 77,0 % осенью. Проверки адекватности модели показали высокую степень релевантности с K (качество модели) в диапазоне от +0,64 до –0,117 и $p > 0,3$.

ЗАКЛЮЧЕНИЕ. Разработанные модели логистической регрессии обеспечивают более точные расчеты индивидуальных рисков развития осложнений АГ и дают возможность сформулировать индивидуальные стратегии для пациентов. Эти модели вносят свой вклад в область климатотерапии и улучшают понимание влияния климатических факторов на пациентов с АГ, облегчая целенаправленные вмешательства и улучшая лечение ГК.

КЛЮЧЕВЫЕ СЛОВА: сезонность, функция максимального правдоподобия, климатотерапия, логистические модели, погода, артериальная гипертония, прогноз, санаторно-курортное лечение, метеорологические факторы.

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1. INTRODUCTION

Arterial hypertension is a leading cause of high mortality from cardiovascular diseases [1–4]. Today, medical professionals consider approximately 14 risk factors for arterial hypertension when making a diagnosis [4, 5]. It is important to note that there are other factors, including psychological, genetic, and climatic factors, that impact the course of the disease. However, these factors are not widely utilized in medical practice due to their high cost, the complexity of performing diagnostic procedures, or the challenge of calculating an integral indicator that can provide an unequivocal and sufficiently accurate diagnostic outcome [5]. Nevertheless, these factors still hold significant importance and contribute to the development and progression of the disease.

According to estimates from the World Health Organization (WHO), the adverse effects of climate factors are currently responsible for approximately 150,000 premature deaths worldwide and 55 million person-years of disability per year on average. These figures account for approximately 0.3 % and 0.4 % of the global rates of mortality and disability, respectively. Furthermore, climate factors have a significant impact on

cardiovascular diseases, particularly arterial hypertension, as well as other health conditions [6–8].

Previous studies have identified the main weather conditions that induce meteopathic reactions in Moscow region [9]. These reactions are influenced by both terrestrial and space weather factors, including atmospheric pressure, atmospheric air temperature, atmospheric air humidity, atmospheric electric field strength, and magnetic storms [10]. Meteopathic reactions can manifest through various symptoms, such as a decline in general well-being, significant fluctuations in blood pressure leading to a hypertensive crisis (HC), headache, myalgia and arthralgia, heart pain, acute coronary syndrome, angina pectoris, changes in partial oxygen tension in the inhaled air (PO2 atm), variations in atmospheric electrical activity, and extreme weather events like floods, droughts, hurricanes, among others. Additionally, environmental pollution resulting from the transformation of substances due to insolation, high temperature, forest fires, as well as the impact of physical factors like noise and vibration, also play a role in meteopathic reactions [8, 10, 11].

The clinical guidelines for physicians regarding the treatment of arterial hypertension emphasize the importance of lifestyle interventions for all patients, regardless of the stage, degree of the disease, or whether they are receiving pharmacological therapy or not [5]. In line with a personalized approach to treatment and prevention, non-drug methods should be incorporated, and comprehensive rehabilitation treatment should be carried out in sanatoria and spas [9, 11].

Currently, there is a significant demand for personalized forecasting methods for meteopathic reactions, which can worsen the course of hypertensive disease and increase the risk of complications during spa treatment [10, 12]. While we cannot control weather conditions, we can predict periods with a higher risk of HC. Patients from northern and eastern regions are particularly susceptible to this risk [1]. With this in mind, our study aims to construct a mathematical model by analyzing time series of publicly available meteorological data. This model would allow us to predict high-risk situations of HC related to the impact of climatic factors on the patient's body. By identifying unfavorable periods for patients with arterial hypertension staying in health resorts throughout the year, we can implement timely therapeutic and preventive measures to prevent the development of HC during these periods.

The digitalization of spa medicine, in general, would enable us to address these objectives at a new level, significantly enhancing the effectiveness of spa treatment in the country and establishing a competitive position for spa facilities in the global market.

2. AIM

To analyze publicly available meteorological data time series to construct a mathematical model for predicting high-risk situations of HC based on the influence of climatic factors on patients with arterial hypertension.

3. MATERIAL AND METHODS

3.1. Study design

The study was conducted from January 01, 2019 until October 31, 2020, in Gelendzhik (44° 36'N 38° 08'E) and Novorossiysk (44°43'N 37°46'E). The study utilized data from the website www.gismeteo.ru. The number of medical care requests for the specific condition under study amounted to 24,494, with 64.6 % of the patients being women and 35.4 % being men. Among the patients, 84.4 % were over the age of 65, with an average age of 59.9 years (± 10.2 years). The race of the patients was reported as white, and their ethnicity was noted as non-Caucasian.

Seasonal dependence of emergency care attendance for HC was studied.

The study was supported by the Independent Local Ethics Committee of the Federal State Budgetary Institution "National Medical Research Centre for Rehabilitation and Balneology" of the Ministry of Health of the Russian Federation (Minutes No. 4, dated April 16, 2017). The study protocol adhered to the principles outlined in the Declaration of Helsinki. The researchers obtained a de-identified primary dataset from the emergency room staff in response to a written request. The reports contained information about the reasons for seeking emergency care.

The information used in the study was collected from the daily reports of all ambulance sub-stations that provided medical services to patients residing in the study area. These reports allowed for the identification of patients within the city and region. Additionally, patients were categorized according to the length of their residence in the region, which could be established by the name and tariff code of the insurance company. The dataset included data on patients aged 18 and older, with further categorization based on age (over or under 65), sex (male or female), race, and length of residence (0–5 years or more than 5 years) in the study area. The researchers also had the opportunity to identify patients who were permanent residents of other territories, but were in the region for seasonal work or tourism, based on payment rate codes provided by insurance companies.

3.2. Climatological data and geographical area

The meteorological data used in the study were obtained from the website gismeteo.ru and from meteorological stations located in Gelendzhik and «Vulan» sanatorium and resort complex (44°36' north latitude, 38°53' east longitude). The emergency medical data was collected from Gelendzhik and Novorossiysk (44°36' north latitude, 38°08' east longitude; 44°43' north latitude, 37°46' east longitude). These cities are situated in a lowland area within a dry subtropical zone. The altitude ranges from 10 to 60 meters above sea level. The region experiences 2416 hours of sunshine per year. The weather patterns are variable in winter and stable in summer. Summers are warm, with an average monthly temperature of 22.9 °C in July. Sunny weather predominates during summers (70–80 %), while rainy weather accounts for approximately 5 % and hot and humid weather comprises about 10 % of the period. The relative humidity in the area is generally low, ranging from 55 % to 70 %. Winters are moderately mild, with temperatures around -3.9 °C in January. Weather with temperature transitions through 0 °C occurs in about 40–45 % of cases, and moderately frosty weather accounts for approximately 10–20 % of the period. Figure 1 displays the annual heliomagnetic temperatures.

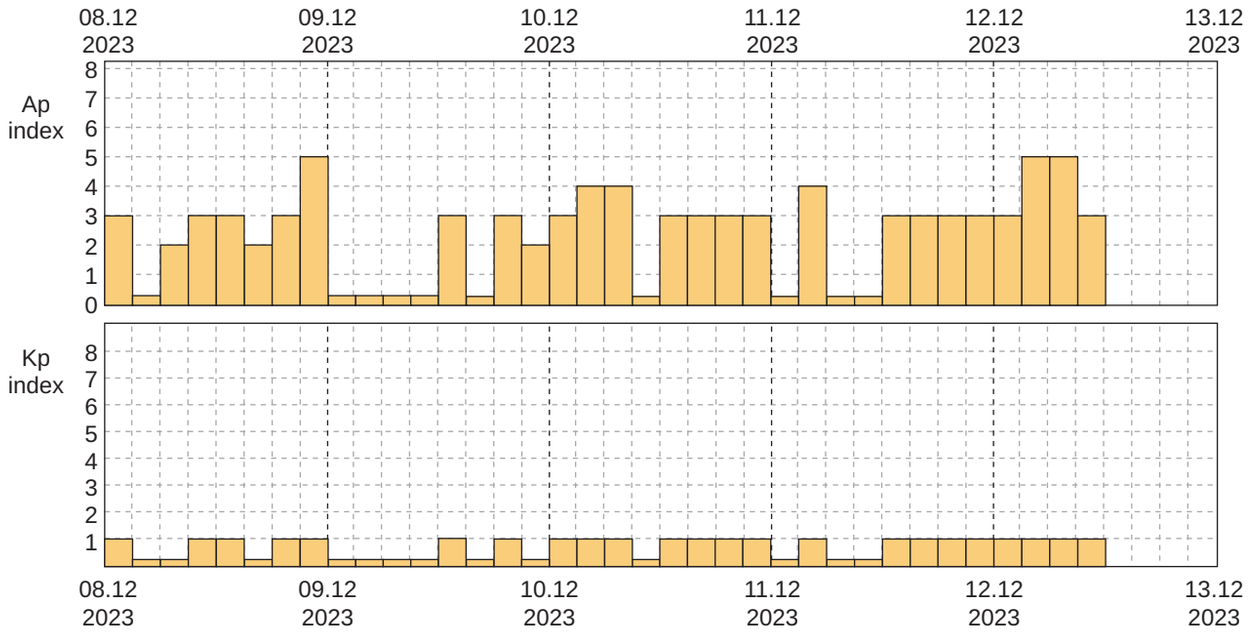

Fig. 1. Map of geomagnetic activity for the period October 16–21, 2022 (The upper diagram displays the Ap-index, the lower diagram — the Kp-index) (source: http://spaceweather.izmiran.ru)

According to data from Rosstat (Federal State Statistics Service) in 2017, Krasnodar Territory, which encompasses Gelendzhik and Novorossiysk, had a total of 5,483,567 patients. Among them, 46.4 % were men, and 79.6 % belonged to the urban population. The regional mortality rate was recorded as 1,253.1 per 100,000 populations, with mortality from circulatory diseases reaching 536.6 cases per 100,000 individuals. The gross regional product in Krasnodar Territory was reported as 301,436 RUB, while the average per capita income was 28,788 RUB per person. These income figures are close to the averages for the Russian Federation[1].

According to the Federal State Statistics Service (Rosstat), in 2021 Gelendzhik had a population of 75,504 people, while Novorossiysk had a population of 340,800. The Southern Federal District, which includes the region, experiences a high level of migration. In 2021, there were approximately 143,919 people migrating within the district annually. Additionally, there were more than 250,000 people migrating from the Southern Federal District to other regions of the Russian Federation each year. The region also sees a significant level of international migration[2].

3.3 Inclusion criteria

- Such patients are to be 18 years of age or older at the time of seeking medical care;
- Such patients are required to have lived in Gelendzhik or Novorossiysk continuously for at least 5 years;
- Such patients should be diagnosed with «Hypertensive crisis» in accordance with the recommendations of the Russian Society of Cardiology[3] [5].

3.4 Exclusion criteria

- Patients under the age of 18 at the time of seeking medical care.
- Patients who refused to participate in the study.
- Patients whose diagnosis of «Hypertensive crisis» was associated with the consumption of cocaine, amphetamines, an overdose of ephedrine, and/or norepinephrine.
- Patients with pre-eclampsia during pregnancy.

3.5 Statistical analysis and data processing

To construct the risk models, we employed a nonlinear logit regression model with a stepwise variable inclusion using the maximum likelihood method, as described in the previous studies [13–15]. It is important to note that the model was based on anonymized data, and therefore adjustments for different calendar events (such as public, church, and family holidays, vacations, etc.) were not applied. The risk of disease occurrence was quantitatively assessed using the odds ratio (OR) in the presence or absence of the disease under investigation [13–15]. To construct risk models, we implemented a nonlinear logit regression with a stepwise inclusion of variables using the maximum likelihood method [13–15].

If the probability p was less than 0.5, we assumed that the event would not occur; otherwise, the event was not expected [16]. The χ^2-test was used to assess the significance of the risk of pathology, and a 95 % confidence interval was calculated for the odds ratio [17, 18].

[1] *Federal state statistics service (2017) Russian statistical Yearbook. Moscow. Available at: https://rosstat.gov.ru/bgd/regl/b17_13/Main.htm (In Russ.)*
[2] *Federal state statistics service (2021) Russian statistical Yearbook. Moscow. Available at: https://eng.rosstat.gov.ru/storage/mediabank/Ejegodnik_2021(1).pdf (In Russ.)*
[3] *Arterial hypertension in adults. Clinical guidelines (2020) Russian Journal of Cardiology 25(3):3786. (In Russ.) http://dx.doi.org/10.15829/1560-4071-2020-3-3786*

When the regression coefficient is positive, it indicates that the odds ratio (OR) is greater than one, suggesting an increase in the chances of the disease with an increase in the predictor level. Conversely, a negative regression coefficient signifies an odds ratio (OR) less than one, indicating a decrease in the risk of disease with an increase in the predictor level [19, 20]. The exponential coefficient of the regression equation (bx) shows how many times the chances of the predicted disease (e.g., hypertensive crisis) will change when the factor level increases by one [21, 22].

Preliminary processing and analysis of the time series data were conducted using the ARIMA (Autoregressive Integrated Moving Average) method. A short-term model (7 days) for the development of HC was built using the ARIMA prediction method [23, 24]. The short-term forecasting (7 days) was conducted with the Almon distributed lag method [23, 24].

The significance of the differences was considered at $p < 0.05$ [25]. The research results were processed using software such as Statistica for Windows, v. 8.0 (StatSoft Inc., USA) and Microsoft Excel (Microsoft, USA).

4. RESULTS

It was found that reliance on emergency medical aid in the case of hypertensive crisis (HC) is associated with weather factors. However, only weak correlations between the onset of HC and weather factors were found, such as atmospheric pressure, daytime air temperature, and K-index. The long-term observation data recording the parameters used to build the model are provided above. The variables that were found ruled out the possibility of constructing reliable predictive models. This situation can be explained by the non-linear response of the human organism to weather factors, the presence of several adaptation phases, the absence of a clearly leading factor, and the superposition and accumulation of changes throughout the year.

In addition, we analyzed the frequency of ambulance calls in Gelendzhik during 2019 and the first 10 months of 2020. It was observed that in summer, there was a lower incidence of HC compared with spring and autumn, with an accuracy rate of 33.0 %. Seasonal statistics on weather factors and ambulance calls are presented in Figures 2–4. Since the geoclimatic characteristics of Novorossiysk and Gelendzhik are similar, identical results were obtained.

Drawing on these findings, we developed a logistic regression model using the main indicators of climate and geomagnetic conditions as factors to predict an increase in the risk of developing HC in the studied population. Table 1 presents the indicators included in the calculation along with their corresponding symbols: (1) daytime air temperature (T); (2) atmospheric pressure (Atm); (3) relative humidity (Hum); (4) K-index (K-ind). The model was constructed using daily mean temperatures and their standard deviations, calculated from the baseline data measured every 3 hours (from 9:00 to 18:00).

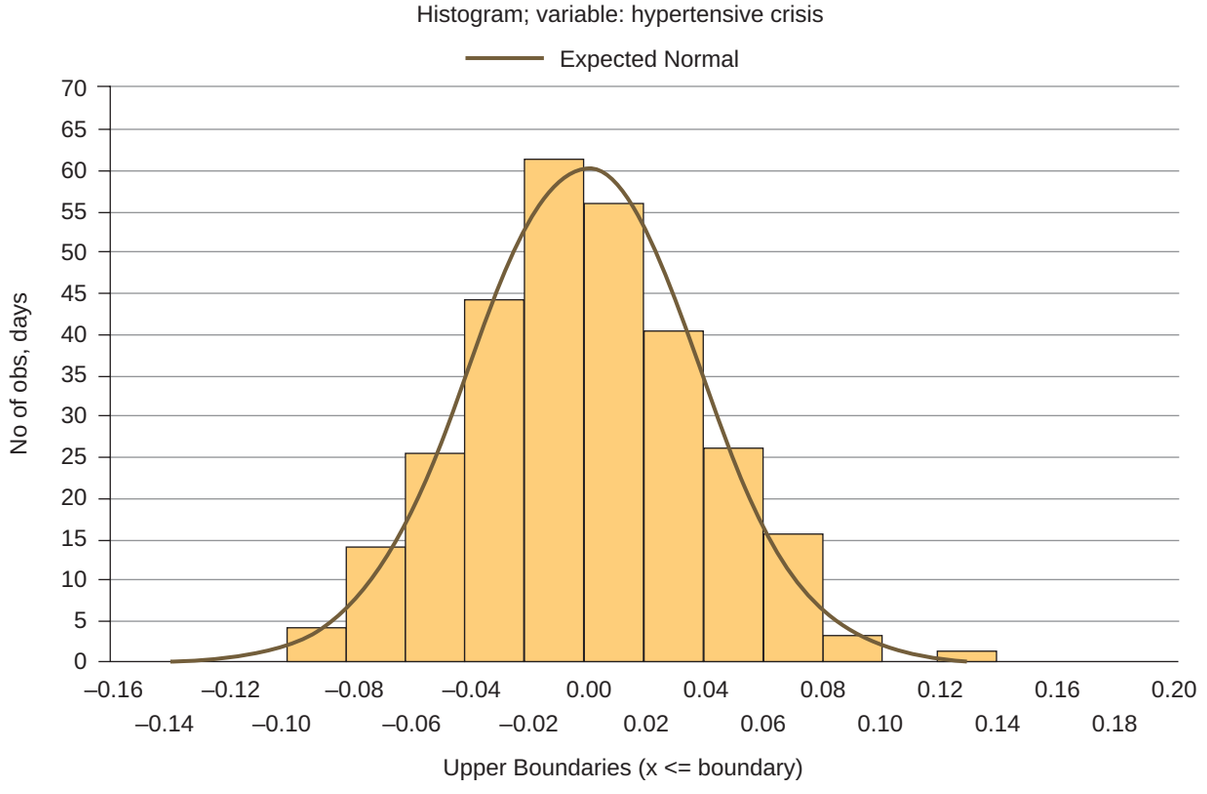

Fig. 2. Days with high risk of (below the red line) hypertensive crisis development in Gelendzhik, calculated using the logistic regression ($n = 604$)

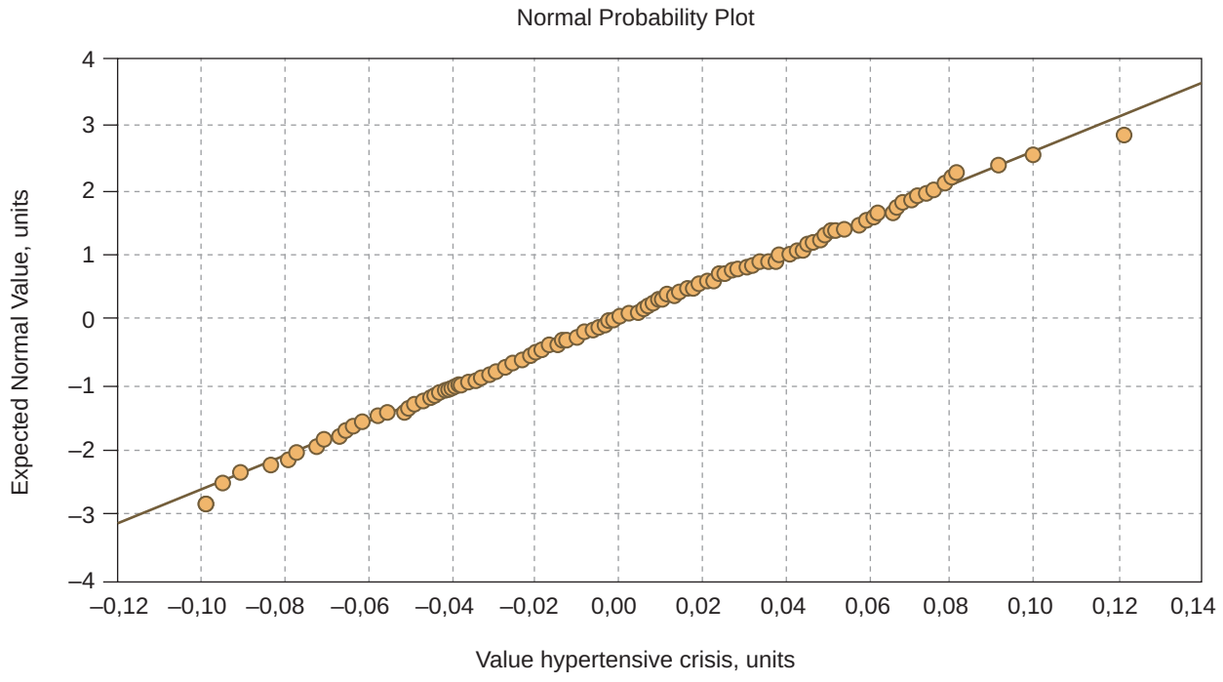

Fig. 3. Histogram of the residuals of the ARIMA model: hypertensive crisis

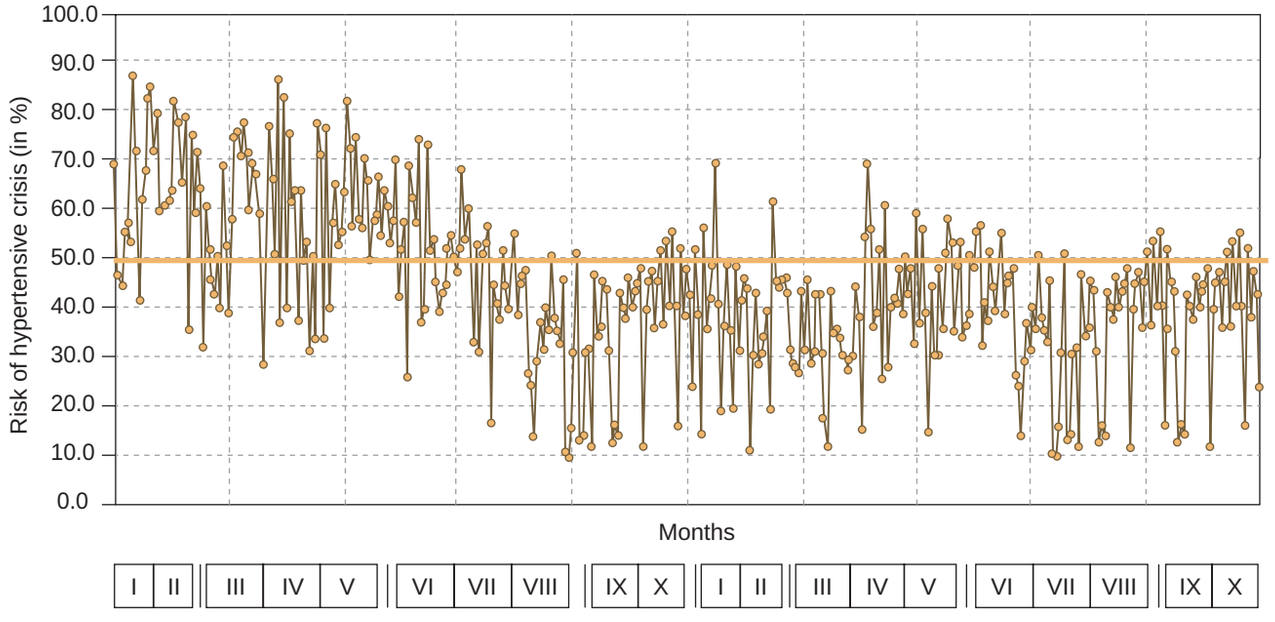

Fig. 4. Normal probability plot of ARIMA model residuals: hypertensive crisis

Table 1. Model of logistic regression analysis of the risk of developing a hypertensive crisis

Indicators	E ± SE	OR (e^b)	Used coefficient	*p*
Free term of logistic regression (B0)	19.4 ± 10.2	–	–	0.03
T, °C	–0.07 ± 0.002	1.07	0.07	0.001
Atmospheric pressure, mmHg	–0.02 ± 0.03	1.02	0.02	0.03
Relative humidity, %	–0.01 ± 0.001	1.01	0.01	0.03
K-index	0.02 ± 0.001	1.02	0.02	0.03

Note: *χ^2 = 13,3; p = 0,0001; OR — Odds ratio (range); E — Estimate; SE — Standard Error.*

When comparing the calculated results with the actual data on the presence of HC, a strong correlation was obtained: $\chi^2 = 9.8$; $p = 0.002$; OR = 4.25; 95 % CI — 1.6–11.2. The overall accuracy of the predictive model was 76.0 % (Table 2).

Table 2. Correspondence of the calculated results obtained using the logistic regression equation with the actual data on the risk of a hypertensive crisis in the subjects

Actual results		Calculated results: hypertensive crisis positive (*n* = 286)	Calculated results: hypertensive crisis negative (*n* = 18)
Hypertensive crisis	Negative (*n* = 229)	221 (14.5 %)	8 (33.7 %)
	Positive (*n* = 75)	65 (9.6 %)	10 (42.2 %)

Note: *$\chi^2 = 9.8$; $p = 0.002$.*

When the air temperature increment changes during the daytime from 1 (OR: 1.07, CI: –4.07–6.04) to 5 (OR: 1.35, CI: –3.65–6.35) degrees, the chances of a hypertensive crisis increase by 26.0 %. When the increment of atmospheric pressure increased from 1 (OR: 1.02, CI: 1.01–1.05) to 5 (OR: 1.10, CI: 1.07–1.13) mmHg, the chances of a HC increased by 55.0 %. Similarly, a change in the step of the K-index value from 3 (OR: 1.06 CI: 1.04–1.08) to 4 (OR: 1.08 CI: 1.06–1.10) points led to a 55.0 % increase in the chances of a HC.

Statistical analysis demostrated that during summer, up to 89.0 % of days in Gelendzhik had a climatotherapeutic effect due to a combination of high temperature, low humidity, and an optimal atmospheric pressure. Both cities, Novorossiysk and Gelendzhik, are located in the same climatic-landscape zone and have similar values of meteorological indicators.

In contrast to summer, winter (76.0 %) ($\chi^2 = 66.4$; $p = 0.0001$) and spring (59.0 %) ($\chi^2 = 46.4$; $p = 0.0001$) had a higher number of days with unfavorable climatic factors, primarily leading to sharp rises in blood pressure. In autumn, the number (77.0 %) of climatically favorable days decreased, with the majority of such days occurring in the first month of autumn (Figure 4).

The problem of cases of HC remained unresolved, when the calculation of the logit regression on magnetic quiet days and days with favorable weather gives low values of sensitivity, specificity, and model accuracy (about 50–55 %), which is unacceptable for reliable conclusions. Under the influence of a number of climatic and geomagnetic factors (K-index), the cardiovascular system responds, and these responses are often delayed in time from the moment of exposure.

By performing spectral Fourier analysis on the frequency of ambulance visits for HC, significant periodicities at weekly, three-week, half-year, and annual intervals were observed (Figure 5).

Following the guidelines for time series prediction (2012), the HC series was converted into a stationary form, and model identification was conducted. The autocorrelation and partial autocorrelation functions were used to calculate a prediction of the HC frequency. The autocorrelation displayed an exponential decrease, while the partial autocorrelation showed prominent values at lags 1 and 2.

The obtained model parameters were added into the ARIMA section's menu to generate a forecast using the exact maximum likelihood method. The resulting graph depicted the number of calls to ambulance teams for HC, along with a five-day forecast (Figure 6).

To verify the model's adequacy, several stages of analysis were conducted. First, the presence of autocorrelation was

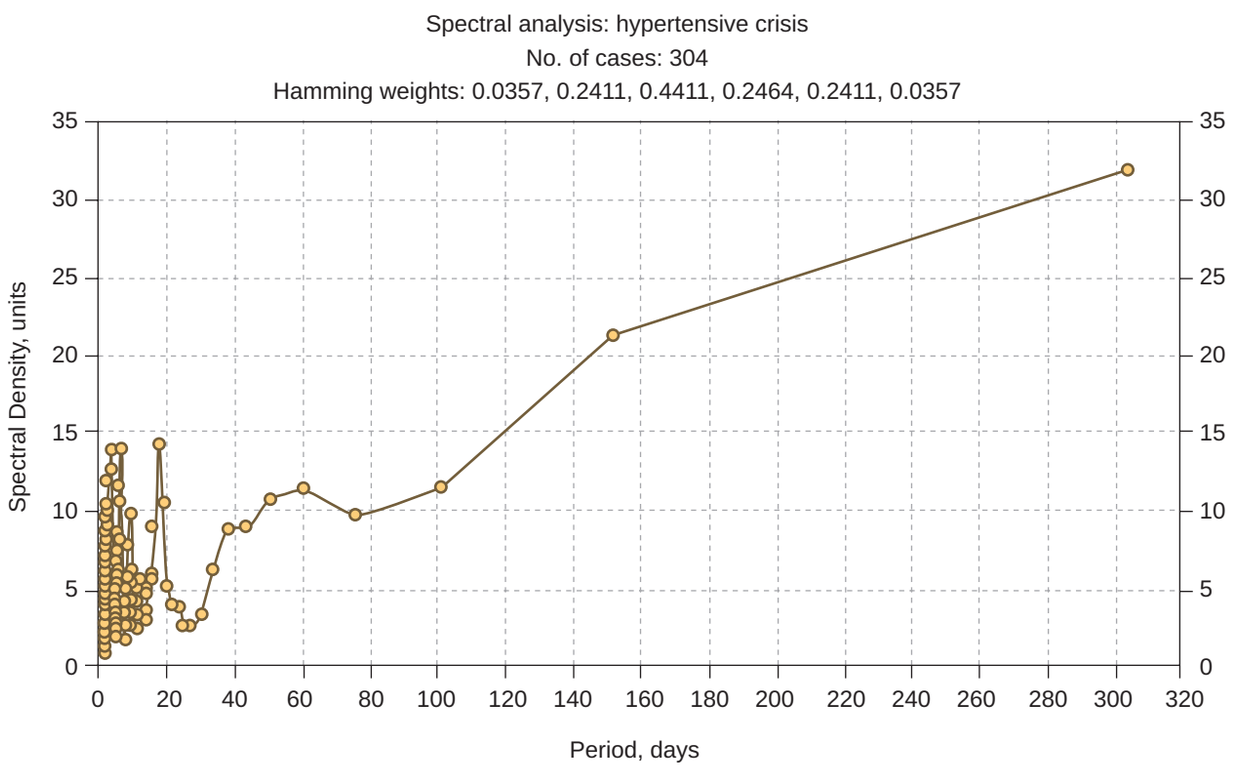

Fig. 5. Periodogram of the «hypertensive crisis» time series using Fourier spectral analysis

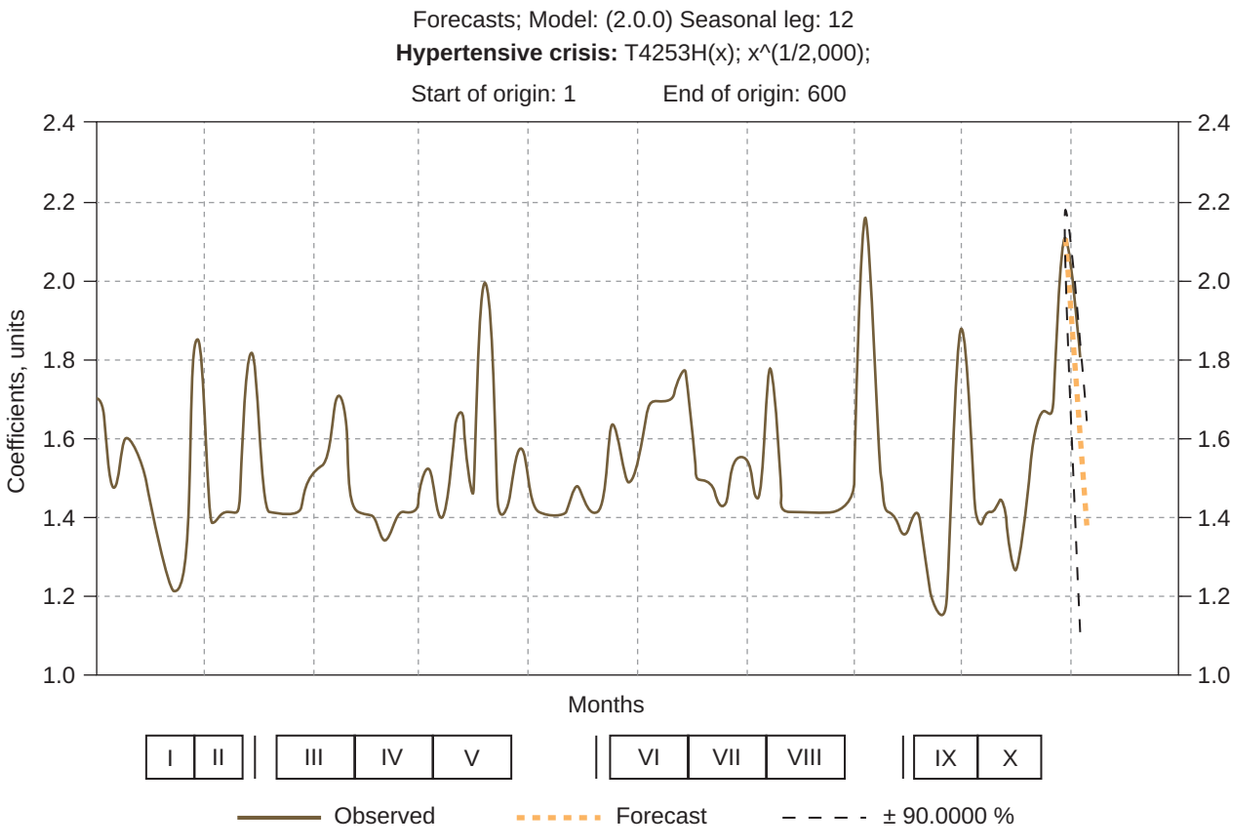

Fig. 6. ARIMA model: short-term forecast for 5 days of the frequency of ambulance calls for HC in Novorossiysk and Gelendzhik

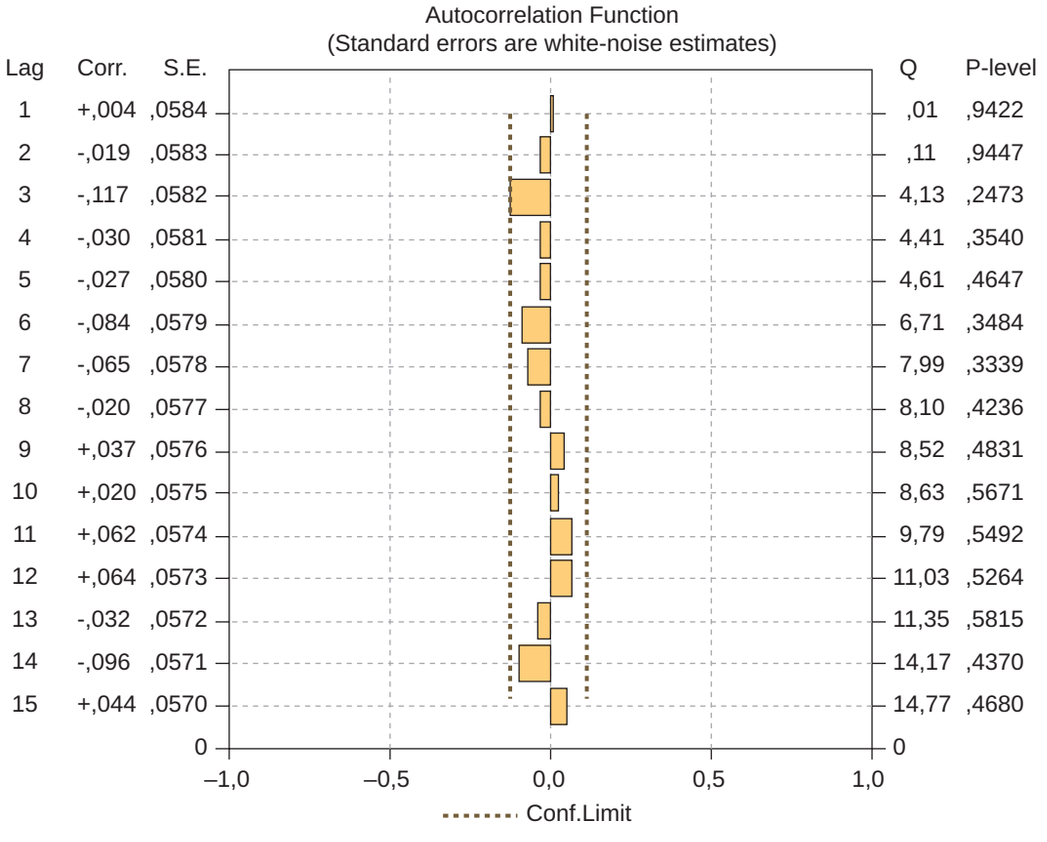

Fig. 7. Auto-correlation function values of the «hypertensive crisis» series after the transformation

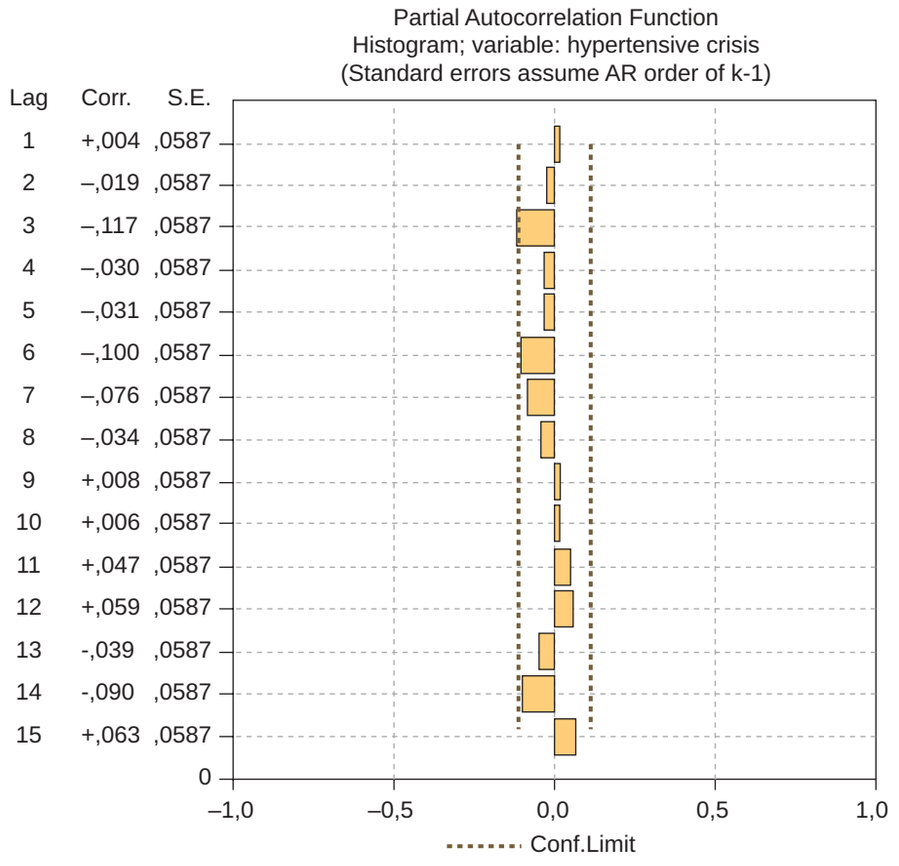

Fig. 8. Partial autocorrelation function values of the «hypertensive crisis» series after the transformation

checked (Figures 7, 8). The graphs indicated that the residuals were mostly uncorrelated, suggesting the model adequately described the time series.

Further examination of the distribution of the residuals proved their normal distribution, further supporting the adequacy of the model (Figure 2). In general, if the model is adequate, the residuals should be independently and equally distributed normal values, without a systematic component.

Subsequently, testing the distribution of the residuals showed that there were no outliers, which further confirms the adequacy of the model. The graph of the residuals is shown in Figure 3. The result of the developed model is shown in Table 3.

Table 3. Calculated predictive values of the frequency of calls for HC

Date	Predictive value of the frequency of calls for hypertensive crisis	–90,0 %	+90,0 %
01 Nov. 19	2,04	1,909198	2,168036
02 Nov. 19	1,99	1,637533	2,142359
03 Nov. 19	1,7	1,353871	2,073850
04 Nov. 19	1,5	1,101611	1,980411
05 Nov. 19	1,4	0,908533	1,883627

Additionally, an analysis was performed considering sex and age stratification, including subjects aged between 18 and 65 and those over 65, of both sexes. However, no significant differences were observed within these stratifications.

5. DISCUSSION

According to global studies, there has been a clear recent trend in global climate change, presumably related to the processes in the outer space, and possibly to anthropogenic (industrial and military) activity, which has tripled in the last 20 years [8, 26]. Global warming is not only accompanied by an increase in average surface temperatures, but also by an increase in the frequency, intensity and duration of extreme temperatures, with 19 of the 20 hottest years of this century occurring in the last 22 years. The national school of climatologists in the 60s-80s of the past century developed the basic methods of climatotherapy and climatic prophylaxis, which are still actively used today, built on the principles of compensation of the natural factor deficiency, relief from their excessive action or stimulation of vital functions, and also defined the seasons of the year, in which these factors influence most effectively in each of the particular resort areas [27, 28]. The current climate changes, however, compel us to rethink the experience accumulated by the previous generations of researchers and determine the need for further research.

When considering the impact of climate on human health, it is relevant to examine the consequences of exposure to non-optimal temperatures [7, 8, 29–31], relative humidity [7], atmospheric pressure [27], increased

heliomagnetic activity [32] and to a lesser extent other meteorological and space factors [26], whose excessive impacts are associated with increased levels of both overall mortality and mortality/disease from certain causes [6, 33] or disease classes [26, 34, 35].

Large international and Russian studies covering a number of populations in different climatic zones have shown a link between weather conditions and morbidity and mortality from circulatory diseases (especially myocardial infarction and other forms of coronary heart disease) [36–39].

Commonly known mechanisms of weather factors affecting patients with cardiovascular diseases include changes in blood rheological parameters (such as increased thrombosis tendency), blood pressure levels, heart rate variability, and lipid peroxidation processes in the body (for example, with increased levels of ozone in inhaled air) [32, 40–42]. Additionally, weather factors can create barriers to implementing necessary lifestyle modifications [7, 26, 43].

Considering these findings, the study design was chosen. Gelendzhik and Novorossiysk were selected as the study sites due to their historical continuity and tradition as "All-Russian health resorts," favorable climatic and geographical conditions, and the high frequency of vacationers from various regions of the Russian Federation seeking spa treatment in these areas.

This study analyzed daily data on the frequency of ambulance visits for patients with hypertensive crisis in Gelendzhik and Novorossiysk, along with daily data on several climatic indicators (such as average temperature, humidity, wind speed, and geomagnetic activity) that exhibit cyclical patterns. Logistic nonlinear regression and ARIMA analysis with model building were used to determine days with low and high probabilities of a hypertensive crisis occurrence. This study is the first to conduct a daily analysis of these parameters and calculate the risk of HC patients with arterial hypertension.

Despite the fact that the factors of the patient's environment are not included in the main risk-metric scales that are currently used to assess the total cardiovascular risk, in recent decade there has been a surge of research interest to study them [36, 44, 45]. Large international studies covering a range of populations in different climatic zones, as well as those conducted by Russian researchers, have shown a link between weather conditions and morbidity and mortality from cardiovascular disease [36–39].

The analysis of time series data is traditionally used as the main statistical tool, both in Russian and international research papers [46–49]. In the course of mathematical calculations, time series of various physiological and geophysical data are analyzed to determine the degree of individual sensitivity of an organism to meteorological and geomagnetic factors [50]. In addition to our study, there are several academic papers that have analyzed the relationship between cardiovascular diseases, weather, and the frequency of ambulance calls using time series data analysis methods [50–52]. Furthermore, our results are consistent with other studies that have examined the impact of meteorological indicators on the occurrence of main symptoms in patients with arterial hypertension undergoing spa treatment in the Crimean Peninsula [53–55]. These studies have calculated the most favorable season and duration of the treatment season with a minimal HC. However, they did not employ ARIMA analysis, logistic nonlinear regression, or other types of models (such as FFLM, SFLM, or DLNM) based on different statistical analyses or primary data.

The strength of our study lies in the analysis of daily data on the frequency of emergency calls for patients with HC, which provides a higher level of accuracy compared to studies that use weekly data.

There are, however, several limitations to our study. Firstly, more precise assessments of the impact could be achieved by considering space-time factors and incorporating socio-demographic and economic characteristics of the region. Secondly, using average outdoor temperature, as is common in most time series studies, introduces systematic errors. Finally, individual tolerance thresholds for high or low temperatures should be taken into account, as every person may have different sensitivities.

6. CONCLUSION

To summarize, our study focused on developing a predictive logit model for HC based on weather factors. The predictive logit model achieved a sensitivity of 56.0 %, specificity of 77.3 %, and an overall accuracy of 76.0 %, indicating its moderate predictive capability. Our analysis provided insights into the seasonal variation of HC risk, with the winter season having no more than 75.0 % of low-risk days, followed by 59.0 % in spring, 89.0 % in summer, and 77.0 % in autumn. Furthermore, the developed model for predicting the onset of HC using the ARIMA time series analysis exhibits a high predictive accuracy (95 %), which was established when the model was validated using ambulance calls data in Novorossiysk and Gelendzhik.

These findings contribute to understanding the relationship between weather factors and HC occurrence, providing valuable insights for healthcare professionals and policymakers in mitigating the risk of HC. Further research incorporating additional socio-demographic and economic factors could enhance the precision of impact assessments in this area.

ADDITIONAL INFORMATION

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Ethics Approval. The authors declare that all procedures used in this article are in accordance with the ethical standards of the institutions that conducted the study and are consistent with the 2013 Declaration of Helsinki. Local ethics committee of National Medical Research Center for Rehabilitation and Balneology approved the study (Minutes No. 4, of 16 April, 2017).

Data Access Statement. The data supporting the findings of this study are available upon reasonable request from the corresponding author.

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Efficacy of Physical Rehabilitation of Patients in the Early Period of Ischemic Stroke Using Stabiloplatform and Balancing Platforms

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ABSTRACT

AIM. The aim of the study was to develop a comprehensive physical rehabilitation program based on the use of stabiloplatform and balancing platforms and to assess the effectiveness of its use in patients in the early period of ischemic stroke at the inpatient stage.

MATERIALS AND METHODS. The study was conducted on the basis of the Department of Restorative Medicine and Rehabilitation of the Medical Complex of the Far Eastern Federal University. Depending on the physical rehabilitation program, three groups were formed by random sampling, comparable in gender, age, presence of risk factors for ischemic stroke, severity of patients. All three groups received drug therapy, neurorehabilitation and physical rehabilitation. The EG1 included patients who were given therapeutic gymnastics classes using balancing platforms. Patients of the EG2 also conducted therapeutic gymnastics classes using balancing platforms and additional training sessions on the stabiloplatform of the ST-150 (Mera-TSP LLC, Russia) with biological feedback. The CG included patients who were engaged in therapeutic physical education under a program provided for neurological patients, which has a general strengthening effect, contributing to the restoration and improvement of self-care skills, balance and movement functions.

RESULTS AND DISCUSSION. Despite advances in medical practice, the task of eliminating the consequences of a stroke remains unresolved. Disability after a stroke is a large percentage, and the search for new technologies to solve the problem of restoring lost body functions, improving the quality of life, returning to normal work is especially significant today. Before the start of comprehensive physical rehabilitation, when analyzing the results of the primary study of patients who had a stroke, according to various tests, movement disorders, imbalances, postural balance were observed. All patients had self-care and mobility problems and needed outside help, all had reduced quality of life scores. The results of the final (after completion of the physical rehabilitation course) testing of maintaining vertical posture and balance, mobility, balance, restoration of social independence and quality of life of stroke patients made it possible to prove the effectiveness of the treatment gymnastics complex using unstable balancing platforms and training on stabiloplatform.

CONCLUSION. The developed comprehensive physical rehabilitation program using unstable balancing platforms and training on stabiloplatform to a greater extent than the traditional therapeutic physical culture program provided for neurological patients contributed to increasing the degree of independence, self-care and mobility in everyday life, reducing the level of personal and situational anxiety, improving the psycho-emotional status of patients.

KEYWORDS: force plate, stabilometric platform, physical rehabilitation, stroke patients.

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Эффективность физической реабилитации пациентов в раннем периоде ишемического инсульта с использованием стабилоплатформы и балансировочных платформ

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РЕЗЮМЕ

ЦЕЛЬ. разработка комплексной программы физической реабилитации на основе использования стабилоплатформы и балансировочных платформ и оценка эффективности ее применения у пациентов в раннем периоде ишемического инсульта на стационарном этапе.

МАТЕРИАЛЫ И МЕТОДЫ. Исследование проводилось на базе отделения восстановительной медицины и реабилитации Медицинского комплекса Дальневосточного федерального университета. В зависимости от программы физической реабилитации методом случайной выборки было сформировано три группы, сопоставимые по полу, возрасту, наличию факторов риска развития ишемического инсульта, степени тяжести пациентов. Все три группы получали медикаментозную терапию, нейрореабилитацию и физическую реабилитацию. В ЭГ1 вошли пациенты, которым проводились занятия лечебной гимнастики с использованием балансировочных платформ. Пациентам ЭГ2 также проводились занятия лечебной гимнастики с использованием балансировочных платформ и дополнительно сеансы тренировочных занятий на стабилоплатформе ST-150 (ООО «Мера-ТСП», Россия) с биологической обратной связью. В КГ вошли больные, которые занимались лечебной физической культурой по программе, предусмотренной для неврологических больных, оказывающей общеукрепляющее действие, способствующей восстановлению и улучшению навыков самообслуживания, функции равновесия и движения.

РЕЗУЛЬТАТЫ И ОБСУЖДЕНИЕ. Несмотря на достижения в медицинской практике, задача ликвидации последствий перенесенного инсульта остается нерешенной. Инвалидизация после инсульта составляет большой процент, и поиск новых технологий решения проблемы восстановления утраченных функций организма, повышения качества жизни, возвращения к нормальной трудовой деятельности является на сегодняшний день особенно значимым. До начала комплексной физической реабилитации при анализе результатов первичного исследования пациентов, перенесших инсульт, по различным тестам, наблюдались двигательные расстройства, нарушения равновесия, постурального баланса. Все пациенты имели проблемы с самообслуживанием и мобильностью и нуждались в посторонней помощи, у всех были снижены показатели качества жизни. Результаты итогового (после завершения курса физической реабилитации) тестирования поддержания вертикальной позы и равновесия, мобильности, баланса, восстановления социально-бытовой независимости и качества жизни пациентов, перенесших инсульт, позволили доказать эффективность воздействия комплекса лечебной гимнастики с использованием нестабильных балансировочных платформ и тренинга на стабилоплатформе.

ЗАКЛЮЧЕНИЕ. Разработанная комплексная программа физической реабилитации с использованием нестабильных балансировочных платформ и тренинга на стабилоплатформе в большей степени, чем традиционная программа лечебной физической культуры, предусмотренная для неврологических больных, способствовала повышению степени независимости, самообслуживания и мобильности в повседневной жизни, уменьшению уровня личностной и ситуативной тревожности, улучшению психоэмоционального статуса пациентов.

КЛЮЧЕВЫЕ СЛОВА: силовая пластина, стабилометрическая платформа, физическая реабилитация, пациенты с инсультом.

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INTRODUCTION

The disability of the stroke patients is mainly due to the severity of motor disorders. According to the research data, no more than 15.0 % of the patients return to work after a stroke, a third of whom are people of working age [1,2]. The frequency of strokes in able-bodied persons aged 25–65 years is 2.5–3 cases per 1000 people for the urban population, and for rural 1.9 cases per 1000 people [3]. At the same time, the state program "Health Development", proved by the Government of the Russian Federation on December, 26, 2017, pays special attention to the problems of health of the able-bodied population [4]. When physically rehabilitating patients who have had a stroke, stabiloplatforms are successfully used, which allow us to provide an objective assessment of the pathology of the equilibrium function, peripheral nervous system, pathology of the vestibular and visual analyzers, and assess the functional state of the human nervous system according to the principle of biological feedback [5–8]. The analysis of the available literature reveals that the data of the biofeedback received at the force plate, are not always used as a simulator of the motor impairment and control of the effectiveness of the complex physical rehabilitation of the stroke patients and today there is a need to obtain an evidence base on the use of the force plate [9–12].

AIM

To develop a comprehensive physical rehabilitation program based on the use of stabiloplatform and balancing platforms and to assess the effectiveness of its use in patients in the early period of ischemic stroke at the inpatient stage.

MATERIALS AND METHODS

The study was conducted on the basis of the Department of Restorative Medicine and Rehabilitation of the Medical Complex of the Far Eastern Federal University (minutes of the meeting of the Local Ethics Committee No. 87, 07.06.2021). To describe the initial condition of the patients after the ischaemic stroke, the analysis of the medical documentation (outpatient cards, patient medical records) were used. Three groups were formed by random sampling in depending on the programme of the physical rehabilitation. The group of the surveyed people included 42 people, 30 of whom composed two experimental groups (EG1, EG2) of 15 persons in each and 12 persons composed the control group (CG). The EG1 included the people who received the therapeutic exercises using the balancing platforms. At the same time, exercises of therapeutic physical culture were selected individually, depending on the severity of paresis and functional disorders. The complex of therapeutic gymnastics using unstable balancing platforms included exercises on thick mats, fitbols, balancing pads of various modifications. The EG2 patients also received therapeutic gymnastics sessions using the balancing platforms and additionally the training sessions on the force plate with biofeedback. Training using different targets made it possible to objectively record the dynamics of equilibrium function in patients through feedback channels. The patient, standing barefoot vertically on a stabilometric platform ST-150 («Mera-TSP» LLC, Russia) and keeping his hands along the body, looks at the monitor located in front of him at a distance of 2 meters. The projection of the patient's center of gravity onto the stabilometric platform (center of pressure) is visualized on the screen as a "mark." To achieve the task, the patient needed to hold the "label," the image of which was created by the software on the screen for 60 seconds. Visualized data on the movement of the patient's common pressure center were used to organize biofeedback trainings. The training on a stabilometric platform made it possible to use several systems at the same time — the visual analyzer, the vestibular system and the muscle apparatus, which had a complex effect on the patient's body. Thus, the means of rehabilitation were aimed at the active participation of the patient in the rehabilitation process, increasing the motivational orientation and included an active motor regime. Sessions on a stabilometric platform and the use of biofeedback contributed to the correction of posturological disorders — balance, vertical posture retention. The CG included the patients engaged in the exercise therapy according to the programme specified for the neurological patients, providing the general tonic effect, contributed to the recovery and improving the self-care skills, balance and motor functions. The structural component of the programme on the basis of the use of the balancing platforms of different kinds, based on the principle of stage-by-stage approach and used by us during the process of rehabilitation of the post-stroke patients are different movements, assisting to the formation of balance and equilibration, dexterity training and movement coordination of the lower and upper limbs. The programme of the movement correction was designed individually depending on the initial characteristics of the pathologic movement pattern of the patient. Exercises of individually oriented therapeutic gymnastics using balancing platforms were consistent with breathing exercises and were performed symmetrically with musical accompaniment. The rehabilitation course in all groups consisted of 14 classes, lasting from 30 to 45 minutes. The training program was developed taking into account the need to solve the following tasks:

- expanding the patient's motor activity by restoring the strength of paralyzed muscles and compensating for movement disorders;
- mastering vertical position and walking, self-service skills;
- psychological and social adaptation.

Patients from all groups (EG1, EG2, CG) in addition to standardized therapy, received massage sessions, physiotherapy, neurorehabilitation, magnetotherapy, kinesiotaping, active-passive mechanotherapy. In addition, all patients underwent psychotherapy sessions aimed at correcting the psychoemotional state. Emotional support was aimed at overcoming the identified violations based on preserved functions, correcting experiences and set goals, restoring a holistic perception of oneself with the formation of readiness to accept responsibility for one's own health, developing a positive attitude to forced changes in life, and improving social interaction. A mandatory addition to this complex was relaxation, self-training and visual imaging. We used several tests to characterize the values of balance, mobility and self-care: Berg balance scale (BBS), Tinneti scale, Timer Walking Test, Barthel index, stabilometrics. The BBS made it possible to assess the possibility of subjects to maintain balance, make transitions from sitting to standing position and back, make turns and turns and perform exercises of various complexity. The severity of the existing violations was assessed by the number of points based on the ability of the subject to independently perform 14 tasks in accordance with certain time and distance requirements. Each component was evaluated on a five-point ordinal scale from 0 (failure to complete the task) to 4 (normal). It was necessary to score 56 points, which corresponded to the norm. To prevent the risk of falling stroke patients, we used Tinetti mobility measures. The test allows you to assess the balance during turns, gait, the need to use walking aids (crutch), and the presence of outside support. The severity of violations was assessed in points. The assessment of the level of daily activity was carried out by calculating the Bartel index, which covers 10 points related to the field of self-service and mobility. At the same time, the maximum amount of points corresponding to complete independence in everyday life is 100. The Timer Walking Test was used to identify local functional abnormalities and assess functional mobility, recording the distance a patient could travel in 6 minutes and the speed of movement. To characterize the values of life quality and degree of independence in daily activities we used the questionnaire MOS SF-36 (J.E. Ware, 1992) and its Russian version SF-36 (according to A.N. Belov's questionnaire) for studying all the components of life quality. This questionnaire allowed us to give the complex assessment of the physical, psychological, emotional and

social functioning, determine the degree of independence in daily life and measure self-care and mobility (walking, moving, climbing and descending stairs) of stroke patients, assess their quality of life. The determination of indicators of the level of situational and personal anxiety was carried out according to the method of C.D. Spielberger, adapted by Yu. L. Khanin. The results of the study were processed using the following methods of mathematical statistics: the method of determining the arithmetic mean indicator and the method of determining the growth rates of indicators V.I. Usakova. The validity of the differences in the obtained data according to the Student's t-test was determined at the normal Gaussian distribution. Differences at $p < 0.05$ were considered statistically significant.

RESULTS AND DISCUSSION

The study participated 42 patients, 28 men (66.6 %) and 14 women (33.4 %). The study included patients whose stroke occurred from 2 weeks to 1 month ago — 5 people (11.9 %), patients whose stroke history ranged from 1 to 3 months — 33 people (78.5 %), and patients with stroke history from 4 to 6 months — 4 people (9.6 %). From the point of view of restoring the functions and tasks of rehabilitation (A.S. Kadykov), the patients whose time after a stroke ranges from 2–3 weeks to 6 months belong to the early recovery period. The age of the tested persons varied from 25 to 80 years. The most numerous occurred the age group from 51 to 60 years — 13 people (30.9 %) and the age group from 61 to 70 years — 12 people (28.5 %). 46.0 % of them were the active working age. Only men were the patients in the age group of 25–40 and 71–80 years. Such risk factors as smoking and alcohol overuse were observed in 23 people (54.7 %) and 13 people (30.9 %) correspondingly. The arterial hypertension was observed in 22 people (52.3 %), atherosclerosis — in 25 people (59.5 %), the combination of arterial hypertension and atherosclerosis was observed in 18 people (42.8 %), discirculatory encephalopathy was observed in 17 patients (40.4 %), ciliary arrhythmia — in 14 patients (33.3 %), ischemic heart disease — in 21 people (50.0 %), chronic cardiac insufficiency in 12 patients (28.5 %) and diabetes mellitus in 6 patients (14.2 %). The concomitant diseases (pneumonia, urinary tract infections, and thrombophlebitis) were observed in 17 patients (40.4 %). 12 (28.5 %) people suffered from obesity, the stressful situation during 6 months before the stroke was observed in 24 (57.1 %) people, and the low physical activity was in 29 people (69.0 %). Thus, modifiable risk factors such as smoking, alcohol consumption, low physical activity and hypertension played a significant role. At the same time patients had from 2 to 4 risk factors. The movement disorders, balance disorders, postural balance disorders observed before the start of the complex physical rehabilitation at the outcome analysis of the initial examination of the patients after the stroke according to different tests. All the patients had the problems with self-care and mobility and required outside help; all of them had the reduced indicators of quality of life. The developed comprehensive physical rehabilitation program using unstable balancing platforms and training on stabiloplatform to a greater extent than the traditional therapeutic physical culture program provided for neurological patients contributed to increasing the degree of independence, self-care and mobility in everyday life, reducing the level of personal and situational anxiety, improving the psycho-emotional status of patients [13,14]. The study made it possible to prove positive changes: according to Berg Balance Scale in CG the indicators increased by 19.2 % (from 35.5 to 42.3 points), in EG1 — by 26.2 % (from 35.5 to 44.8 points) and in EG2 — by 29.6 % (from 36.1 to 46.8 points). According to the results of the Bartel Index, the increase in the level of household activity related to the self-service sector: in CG by 15.8 % (from 61.5 to 71.2 points), in EG1 by 18.6 % (from 62.2 to 73.8 points) and in EG2 by 26.9 % (from 62.1 to 78.8 points). There was a significant ($p < 0.05$) improvement of the balance and walking parameters, estimated according to the Tinneti scale, that reduced the risk of falling of the patients in EG2 by 41.0 % (in CG by 24.0 %, in EG by 27.0 %). When the balancing platforms and trainings on the force plate are included into the programme of the physical rehabilitation, reliable improvement of the locomotor function indicator ($p < 0.05$) compared with the initial values in the all groups according to the Time Walking Test of the speed indicators of walking and covered distance. The positive impact of the programme of the physical rehabilitation with the use of the balancing platforms and training on the force plate upon the increasing of the independence degree was observed,

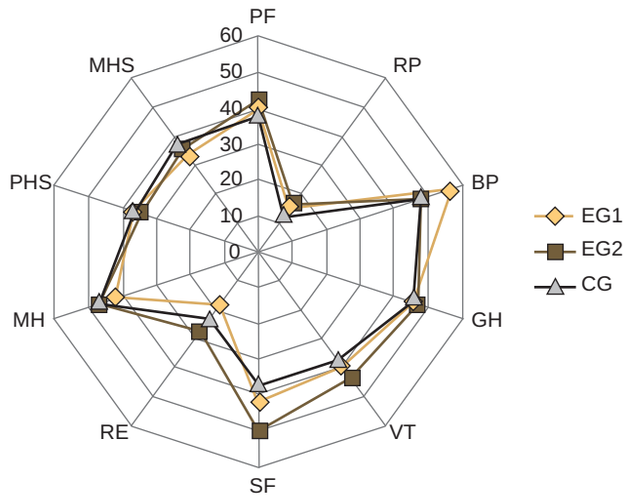

Fig. 1. Quality of life indicators of stroke patients before the physical rehabilitation ($n = 42$)

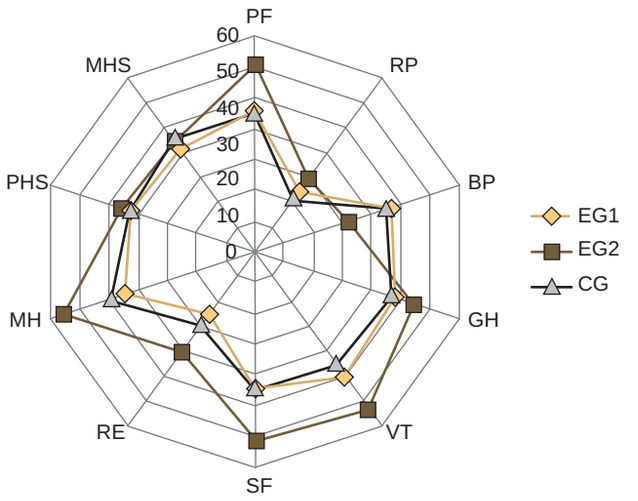

Fig. 2. Quality of life indicators of stroke patients after the physical rehabilitation ($n = 42$)

and consequently the improvement of the quality of life was observed in EG2, where the PF indicator achieved 61.1 points. The higher values according to the subscales VT (62.7 points) and MH (65.7 points), SF (61.1 points) out of maximum 100 were also registered in this group (Figure 1, 2). The RP indicator, objectifying the degree of physical well-being influence upon the daily life, increased during the treatment process, at the same time remaining at rather low level (29.5 points). The less significant improvement was revealed according to the subscales, forming the psychological component of the quality of life. The significant ($p < 0.05$) decrease of the personal (by 30.35 %) and state (by 25.6 %) anxiety among the patients of EG2 was found, characterizing the increase of the activity and motivation of the patients to work and responsibility in solving their health problems. The analysis of the indicators of the stabilometrical research demonstrated positive changes in the balance of the verticalis standing and walking.

It was found that the area of pressure center and its vibrations, measured in the frontal and saggital planes significantly change. The speed of the pressure center, the total amplitude in the frontal plane and the square (S, mm^2) of the statokinesiograms ($p < 0.05$) significantly decreased (Table 1).

mobility, restoration of the social-domestic independence and quality of life of the stroke patients made it possible to prove the effectiveness of the therapeutic exercises complex using unstable balancing platforms and trainings on the force plate. At the current stage, it remains relevant to develop physical rehabilitation programs that increase the effectiveness of the recovery process for patients who have had a stroke in the early recovery period, including unstable balancing platforms and training on stabiloplatform.

CONCLUSION

Testing of the initial state of patients at the preliminary stage of the study revealed a violation of motor function, a decrease in quality of life, an imbalance in the psycho-emotional state of patients in the early period of ischemic stroke at the inpatient stage. A close relationship was established between improving the function of body balance, the patient's ability to maintain a stable vertical position of the body in space when walking, during motor actions and improving the quality of life. The obtained results confirmed the high efficiency of integrated physical rehabilitation using unstable balancing platforms and training on stabilometric platform aimed at increasing mobility, balance, improving motor qualities, improving the quality of life of stroke

Table 1. The area of the pressure center and the speed of its movement in patients after a stroke before and after physical rehabilitation ($n = 42$)[1]

Test results	EG1 ($n = 15$)		p	EG2 ($n = 15$)		p	CG ($n = 12$)		p
	before	after		before	after		before	after	
S (o), mm² (open eyes)	429 [380; 441]	347 [326; 358]	0.025	307 [290; 315]	239 [326; 358]	< 0.01	427 [410; 445]	305 [286; 320]	< 0.05
S (c), mm² (close eyes)	660 [642; 678]	541 [530; 552]	0.025	646 [628; 662]	505 [490; 512]	< 0.01	651 [630; 670]	580 [558; 596]	< 0.05
V (o), mm/s (open eyes)	14 [12; 16]	11 [9; 13]	0.025	14 [13; 15]	11 [9; 13]	< 0.01	14 [12; 16]	12 [10; 14]	< 0.05
V (c), mm/s (close eyes)	23 [21; 25]	20 [18; 22]	0.025	18 [17; 19]	11 [10; 12]	< 0.01	20 [18; 21]	19 [18; 20]	< 0.05

Note: *[1]The analysis of intra-group differences was carried out according to the Mann-Whitney criterion.*

The decrease of the average balancing parameters was registered in the group with open eyes S (o), mm2 in EG2 by 54.7 %, while in the CG — by 39.9 % and in EG1 by 23.7 %. The change of the balancing parameters was found in the group with close eyes S (c), mm2 in EG2 by 28.7 %, while in CG by 12.1 % and in EG1 by 22.0 %. Significant reducing of the results of conveyance speed of pressure center was found in the patients with open eyes V (o) in EG2 by 27.1 %, while in CG it decreased by 18.9 % and in EG1 by 21.0 %. A significant decrease of the results of conveyance speed of pressure center was found in the patients with closed eyes V (c) in EG2 by 40.1 % while in CG it decreased by 4.5 % and in EG1 by 12.8 %. The patients of EG2 achieved the statutory indicator to the fullest extent V (o) = 10.9 mm/s at the norm < 10.6 and to the statutory indicator V (c) = 11.1 mm/s at the norm < 11.5. In CG and EG1 these indicators differed from the standard ones. These changes objectively reflect the improvement of balance stability. Thus, the results of the final test of the support of the vertical posture and balance, patients at the inpatient stage in the early recovery period. At the current stage, it remains relevant to develop physical rehabilitation programs that increase the effectiveness of the recovery process for patients who have had a stroke in the early recovery period, in which, among other things, unstable balancing platforms and training on stabilometric platform can be used. Thus, a comprehensive physical rehabilitation program developed and tested in the conditions of the Center for Restorative Medicine and Rehabilitation of the Medical Center of the Far Eastern Federal University using unstable balancing platforms in therapeutic physical culture and training on stabilometric platform with biological feedback to a greater extent. than the standard therapeutic physical education program provided for neurological patients, promotes independence, self-care and mobility in daily life, accompanied by a decrease in the level of personal and situational anxiety, an improvement in the psycho-emotional status of stroke patients in the early recovery period of rehabilitation.

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Ethics Approval. The authors declare that all procedures used in this article are in accordance with the ethical standards of the institutions that conducted the study and are consistent with the 2013 Declaration of Helsinki. The study was approved by the Local Ethics Committee of the Far Eastern Federal University (Protocol No. 87, 07.06.2021).

Data Access Statement. The data that support the findings of this study are available on reasonable request from the corresponding author.

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High-Intensity Pulsed Magnetotherapy in the Rehabilitation Programme of Patients with Chemotherapy-Induced Peripheral Polyneuropathy: a Prospective Randomized Clinical Study

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ABSTRACT

INTRODUCTION. Chemotherapy-induced peripheral polyneuropathy (CIPN) is one of the most frequent side effects caused by anticancer drugs, with a prevalence ranging from 19 % to 85 %. For effective multicomponent rehabilitation of patients with CIPN at different stages, a number of non-medicinal methods are recommended to improve the tolerance of chemotherapy and reduce the side effects of the antitumor treatment performed.

AIM. Study of the effect of high-intensity pulsed magnetotherapy on clinical manifestations and microcirculation state in patients with CIPN.

DESIGN. This is a randomized controlled study.

SETTING. Randomization, organization of the study and data analysis were performed on the premises of the Department of Medical Rehabilitation in National Medical Research Centre for Rehabilitation and Balneology, Moscow, Russia.

POPULATION. Sixty patients with CIPN were included in this study and were randomized by a simple random distribution method in a ratio of 1:1 into 2 groups of 30 people.

METHODS. Sixty patients with CIPN four weeks after completion of chemotherapy were examined. The first group, the main group, included patients who received high-intensity pulsed magnetotherapy (HIPMT) in combination with drug therapy. In the second group (control group), the patients received only drug therapy. The EORTC-QLQ-C30 questionnaire (version 3) was used to assess the quality of life. The HADS scale was used to assess the severity of anxiety and depression symptoms. The state of microcirculation was assessed using laser Doppler flowmetry (LDF). The severity of CIPN was assessed according to the CTS-NCIC scale, version 3.0.

RESULTS. According to the results of this study, there is a statistically significant difference in the scores on the EORTC-QLQ-C30 questionnaire (version 3), HADS scale and LDF data between the groups in favour of the group receiving HIPMT in combination with drug therapy.

CONCLUSION. Based on the LDF study, significant disturbances at the microcirculatory level were detected for the first time in patients with CIPN. The obtained results convincingly demonstrate that the use of HIPMT in patients with CIPN leads not only to improvement of microcirculation in the extremities due to normalisation of arterial vessel tone, elimination of venous stasis and increase in the nutritive blood flow, but also has an analgesic effect, improves initially impaired sensitivity, and improves the quality of life of these patients.

CLINICAL REHABILITATION IMPACT. The use of HIPMT in combination with drug therapy in patients with CIPN was more effective than drug therapy alone.

KEYWORDS: CIPN, cancer rehabilitation, chemotherapy, magnetic field therapy, polyneuropathy.

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Высокоинтенсивная импульсная магнитотерапия в реабилитационной программе пациентов с периферической полинейропатией, индуцированной химиотерапией: проспективное рандомизированное клиническое исследование

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РЕЗЮМЕ

ВВЕДЕНИЕ. Периферическая полинейропатия, индуцированная химиотерапией (ПНПИХ), является одним из наиболее частых побочных эффектов, вызываемых противоопухолевыми препаратами, с распространенностью от 19 % до 85 %. Для эффективной многокомпонентной реабилитации пациентов с ПНПИХ на различных этапах рекомендован ряд немедикаментозных методов с целью улучшения переносимости химиотерапии и снижения побочных эффектов проводимого противоопухолевого лечения.

ЦЕЛЬ. Изучение влияния высокоинтенсивной импульсной магнитотерапии (ВИМТ) на клинические проявления и состояние микроциркуляции у пациентов с ПНПИХ.

ДИЗАЙН. Это рандомизированное контролируемое исследование.

МЕСТО ПРОВЕДЕНИЯ ИССЛЕДОВАНИЯ: Рандомизация, организация исследования и анализ данных были выполнены на базе отделения медицинской реабилитации ФГБУ «НМИЦ РК» Минздрава России, Москва, Россия.

НАСЕЛЕНИЕ. В это исследование были включены 60 пациентов с ПНПИХ, которые были рандомизированы в соотношении 1:1 на 2 группы по 30 человек.

МЕТОДЫ. Были обследованы 60 пациентов с ПНПИХ спустя четыре недели после завершения химиотерапии. Первая группа — основная включала пациентов, которые получали ВИМТ в сочетании с медикаментозной терапией. Во второй группе (контрольной) пациенты получали только медикаментозную терапию. Для оценки качества жизни использовали опросник EORTC-QLQ-C30 (версия 3). Для оценки выраженности симптомов тревожности и депрессии применяли шкалу HADS. Состояние микроциркуляции оценивали, применяя лазерную доплеровскую флоуметрию (LDF). Степень тяжести ПНПИХ оценивали согласно шкале CTC-NCIC, версия 3.0.

РЕЗУЛЬТАТЫ. Согласно результатам этого исследования, существует статистически значимая разница в оценках по опроснику EORTC-QLQ-C30 (версия 3), шкале HADS и по данным лазерной допплеровской флоуметрии (ЛДФ) между группами в пользу группы получавших ВИМТ в сочетании с медикаментозной терапией.

ЗАКЛЮЧЕНИЕ. На основании проведенного исследования с помощью ЛДФ впервые у пациентов с ПНПИХ были выявлены существенные нарушения на микроциркуляторном уровне. Полученные результаты убедительно демонстрируют, что применение ВИМТ у пациентов с ПНПИХ приводит не только к улучшению микроциркуляции в конечностях за счет нормализации тонуса артериальных сосудов, устранения венозного застоя и увеличения нутритивного кровотока, но и оказывает обезболивающее действие, улучшает исходно нарушенную чувствительность, а также улучшает качество жизни данных пациентов.

ВЛИЯНИЕ РЕАБИЛИТАЦИИ. Применения ВИМТ в сочетании с медикаментозной терапией у пациентов с ПНПИХ было более эффективно чем применение только медикаментозной терапии.

КЛЮЧЕВЫЕ СЛОВА: полинейропатия, индуцированная химиотерапией, реабилитация при раке, химиотерапия, терапия магнитным полем, полинейропатия.

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INTRODUCTION

One of the urgent problems of modern medicine is the development of effective methods of rehabilitation of cancer patients after radical surgery against the background of specific antitumour therapy, including the use of a number of physical factors. Chemotherapy-induced peripheral polyneuropathy (CIPN) is one of the most frequent side effects caused by antitumour drugs, with a prevalence ranging between 19 % and 85 % [1]. In the pathogenesis of CIPN, great importance is attached to direct diffusion of cytostatics into nerve fibres from the surrounding interstitial fluid, disturbances of microtubular architectonics of axons through increased tubulin polymerisation, which causes impaired axonal transport, diffuse or segmental demyelination of neurons, degeneration of neuronal bodies, and induction of neuronal apoptosis. At the moment, there is no single effective method of prevention of CIPN, moreover, the treatment options for this syndrome are very limited [2].

For effective multicomponent rehabilitation of patients with CIPN at various stages, a number of non-medicamentous methods are recommended to improve tolerance to chemotherapy and

reduce side effects of the antineoplastic therapy. Among the non-medicinal methods, acupuncture, manual therapy, massage, and therapeutic exercises are used [3–14]. A number of studies evaluated the effectiveness of low-frequency magnetotherapy, percutaneous electroneurostimulation, low-intensity laser therapy. However, the results of studies on the effectiveness of these methods are not convincing enough [15–25].

In this connection, the development of new physiotherapeutic methods for rehabilitation of patients with CIPN is an important medical and social problem. The method of HIPMT based on the induction of eddy electric currents of significant density affecting excitable structures of deep tissues seems promising in this respect. HIPMT has a significant analgesic effect due to the blockade of pain impulse transmission in the central nervous system, as well as a pronounced trophic, anti-edematous and anti-inflammatory effect [26].

AIM

Study of the effect of HIPMT on clinical manifestations and microcirculatory state in patients with chemotherapy-induced peripheral polyneuropathy.

MATERIALS AND METHODS

Participants

Starting from March 2021 until January 2023, 60 patients (51 women and 9 men) with CIPN four weeks after completion of chemotherapy were sent to the departments of medical rehabilitation of the National Medical Research Centre for Rehabilitation and Balneology Moscow, Russia for examination and treatment.

Recruitment for this randomized trial approved by the local ethics committee, was carried out in the local community. This trial was followed by the recommendations of the CONSORT statement [27].

Prior to their inclusion in the study, all the patients had received potentially neurotoxic chemotherapy (oxaliplatin or periwinkle alkaloids) as part of their cancer treatment. The mean number of cycles of chemotherapy received by the patients was 11 [6;15] in both groups, and the mean period between the last chemotherapy and the start of rehabilitation was 65 [49;186] days in both groups. All patients were provided with information about the planned rehabilitation and gave their written consent.

Participants were informed about the possibility of being randomly assigned to one group or another. Participants were randomized in one of two treatment groups — main group and control group. The randomization schedule was generated using the random.org website. The allocation schedule was printed on cards. These cards were sequentially numbered in opaque and sealed envelopes, each containing the name of one of the groups. The envelopes were selected by an external person who was not enrolled in the trial (Figure 1).

Inclusion Criteria

Age of patients — 56.5 ± 5.7 years; presence of peripheral polyneuropathy induced by chemotherapy, I–II degree of severity according to STS-NCIC scale version 3.0; four weeks after completion of chemotherapy.

All patients received information about the planned rehabilitation. They gave their written consent. Materials of the planned clinical study were submitted to the Local ethics committee at the National Medical Research Centre for Rehabilitation and Balneology Moscow, Russia and approved by it (Protocol No. 2 of 14 January 2021).

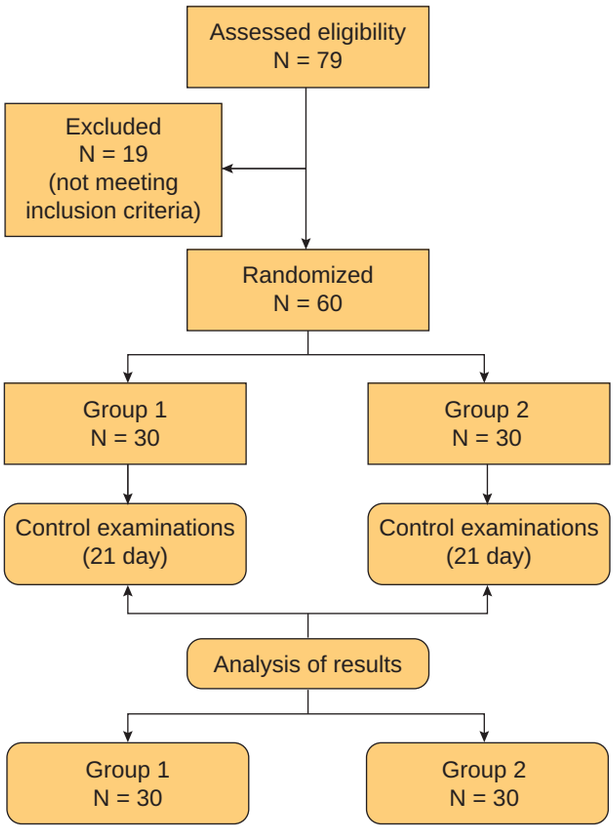

Fig. 1. CONSORT diagram illustrating the process from recruitment to data collection (21day follow-up)

Exclusion Criteria

Under 18 years of age and over 75 years of age; women during pregnancy, childbirth; diabetes mellitus; history of polyneuropathy prior to chemotherapy; acute cardiovascular disease, thrombosis or arterial occlusive disease in the limb to be treated; cognitive impairment; presence of metal implants in the area of exposure; presence of pacemaker, acute infection, and lack of written informed consent from the patient.

Exclusion Criteria for Patients

Development of serious adverse events during the study, patient's refusal to participate in the study.

The patients of the 1st and 2nd groups were comparable by the main clinical and demographic indicators: sex (p = 0.75), age (p = 0.69), average duration of the main disease (p = 0.092), average duration of polyneuropathy (p = 0.38), as well as the studied clinical manifestations of polyneuropathy.

Study Design

A prospective randomized clinical study was conducted. The study complied with the Declaration of Helsinki and the guidelines of good clinical practice and was approved at the meeting of the Local Ethical Committee of National Medical Research Centre for Rehabilitation and Balneology, Moscow, Russia (Protocol No. 2 of 14.01.2021). The patients with CIPN were included in this study and were randomized by a simple random distribution method in a ratio of 1:1 into 2 groups of 30 people.

The first group (main group) included patients who received HIPMT in combination with drug therapy. The patients in the second group (control group) received only drug therapy.

An online calculator (https://www.sealedenvelope.com) was used to calculate the necessary sample sufficient to determine the planned impact (the clinical benefit response effect was 89 % in the main group and 65 % in the control group). When calculating the required sample size based on the outcome of the frequency of achieving a clinical response, the hypothesis of the superiority of binary outcomes was used. The sample size was calculated with a given statistical power of 90 % and a level of "error of the first kind" of 5 %.

Randomization, organization of the study and data analysis were performed in the Department of Medical Rehabilitation, National Medical Research Centre for Rehabilitation and Balneology, Moscow, Russia. The authors developed the study protocol and all the authors had access to the original data after the completion of the study. All the authors attest to the accuracy of these results.

Data were collected and analyzed only by the principal investigator. Decisions regarding the content of this article were made by the principal investigator and other authors.

All data about the patients were stored using standard documentation. The data collected in such manner were computerized for further evaluation and analyzed using a statistical program.

Clinical intervention: Depending on the degree of manifestation of clinical symptoms, the upper limbs (hands) or lower limbs (feet) were treated. High-intensity pulsed magnetotherapy (HIPMT) procedures were performed using a high-intensity magnetotherapy device — Super Inductive System (SIS) BTL-6000 (United Kingdom), using 6 modes, which were changed stepwise one after another. Consecutively for 30 seconds a frequency of 5Hz, pulse/pause ratio 1:1 was applied, for the next 30 seconds a frequency of 1Hz, pulse/pause ratio 1:1 was applied, for 2 minutes a frequency of 10Hz pulse/pause ratio 12: 6 was applied, for 1 minute a 1Hz frequency, pulse/pause ratio 1:1 was applied, for 2 minutes a 10Hz frequency pulse/pause ratio 12:6 was applied and, finally, a 1Hz frequency was applied, for 1 minute a pulse/pause ratio 1:1 was applied. The intensity value on the surface of the inductor coil was changed in the following mode: during the first procedure the magnetic induction intensity was 200 mTl, the second — 300 mTl, the third — 400 mTl, the fourth — 500 mTl, from the fifth to the tenth — 600 mTl. Total exposure time per procedure was 14 minutes, 7 minutes per limb. For a course of 10 procedures, performed every second day.

The EORTC-QLQ-C30 questionnaire (version 3) was used to evaluate the quality of life. The current version 3 includes 30 questions and consists of 5 functional scales: physical function (PF), role function (RF), cognitive function (CF), emotional function (EF), and social function (SF); symptoms scale: fatigue (F), nausea/vomiting (N/V), and pain (P); general health status (GHS) scales; 6 single items — insomnia (I), loss of appetite (LA), constipation (C), diarrhoea (D), dyspnoea (D), financial difficulties (FD). For the functional and general health status scales, the patient's best condition corresponds to 100 % (or points), and the worst condition corresponds to 0. For all symptoms scales, the best condition corresponds to 0 and the worst condition corresponds to a score of 100 points.

To assess the severity of CIPN, the disease-specific EORTC QLO-CIPN20 questionnaire was used, which is an add-on module to the main EORTC-QLQ-C30 questionnaire with 20 items assessing sensory, motor and autonomic symptoms experienced by patients during the past week. Each item can be scored from 1 (no symptoms at all) to 4 (very many), with higher scores indicating worse symptom severity.

To assess the severity of symptoms of anxiety and depression we used the HADS (Hospital Anxiety and Depression Scale), which consists of two parts: the HADS-A subscale (A — anxiety) and the HADS-D subscale (D — depression) and includes 14 items, each of which corresponds to 4 response options, reflecting the degree of symptom progression. The patient should choose the answer that most closely matches how he or she has been feeling over the past week. The total score for each subscale determines the result: 0–7 points «norm» — absence of reliably expressed symptoms of anxiety and depression; 8–10 points «subclinically expressed anxiety/depression»; 11 points and above "clinically expressed anxiety/depression".

Spectral analysis based on wavelet transformation of periodic oscillations of the laser Doppler flowmetry (LDF) signal was used to analyse skin blood flow. LDF grams were recorded on the anterior surface of the forearm and in the foot area — volar (plantar) surface of the big toe.

Periodic oscillations were registered with frequencies of about 0.005–0.0095 Hz and 0.0095–0.02 Hz, reflecting the regulation of the vascular tone due to endothelial activity; with frequencies of 0.05–0.15 Hz, characterizing myogenic mechanisms of the vascular tone regulation; with frequencies of 0.02–0.05 Hz, reflecting neurogenic sympathetic vasomotor activity, as well as with frequencies of 0.45–1.6 Hz and 0.2–0.45 Hz, which carry information about the influence of cardiac contractions and chest movements on the peripheral blood flow.

The severity of CIPN was assessed according to the CTS-NCIC scale, version 3.0:

- 1st degree (mild) — impairments not affecting quality of life (e.g., loss of tendon reflexes);
- 2nd degree (moderate) — objective neurological disorders that impair limb function but do not affect the patient's daily activity;
- 3rd degree (severe) — severe objective disorders impairing limb function and daily activity of the patient.
- 4th degree (extremely severe) — complete loss of limb function.

The subjective and objective status of the patient was assessed before and after the course of medical interventions (on the 21st day of the study).

In all patients (n = 60), subjective and objective status was assessed before and after the course of medical interventions (on day 21 of the study).

Statistical Analysis

The results of the studies were analysed using IBM SPSS Statistics 23 application software package and Microsoft Office Excel 2016. The Mann-Whitney U-criterion, Wilcoxon test were used to compare two independent samples.

RESULTS

The patients were admitted for outpatient treatment to the medical rehabilitation department after a course of special anti-tumour therapy. Most of them (75.0 %) received chemotherapy for breast cancer. Characteristics of the patients by cancer localisation, age and severity of polyneuropathy are presented in Table 1.

Table 1. Participant baseline characteristics

Parameters under study	Group 1 (main), *n* = 30		Group2 (control), *n* = 30	
Age (years), mean (SD)	56.5 [49.1; 61.7]		56.9 [48.2; 62.2]	
Cancer primary, *n* (%)				
Cervical cancer	3	10	3	10
Bladder cancer	2	6.7	2	6.7
Breast cancer	22	73.3	23	76.6
Lung cancer	3	10	2	6.7
Neuropathy grade (%)^				
1	12	40	11	36.6
2	18	60	19	63.4

Note: *The data are presented in the form of median (Me) and quartile [Q1, Q3]. All differences were not statistically significant with p > 0.05.*

The 1st degree of CIPN severity was detected in 40 % of patients, which was characterized by complaints of numbness and tingling in the fingers of both hands and feet, while objective examination revealed decreased tendon reflexes. The 2nd degree of CIPN severity was observed in 60 % of patients, in which numbness, weakness in hands and feet were noted. Objective examination revealed swelling of hands, shins, pain sensitivity hypoesthesia of »gloves» and «socks» type. Using the EORTC QLQ-CIPN 20 questionnaire, baseline scores in all observed patients were: 18 [15; 20] for sensory symptoms, 15.8 [13;21] for motor symptoms, and 3.36 [2;5] for autonomic symptoms. Signs of polyneuropathy predominated in 75 % of the subjects predominantly in the distal upper extremities, and in 25 % in the lower extremities.

According to pre-intervention LDF data, 57 % of patients with predominantly upper extremity lesions had an increased contribution of myogenic and neurogenic oscillations to the total vasomotions level. The presence of endothelial dysfunction was observed. An increase in the contribution of cardiac oscillations was revealed, indicating an increased inflow of arterial blood into the microcirculatory bed. The predominance of oscillations in the range of 0.01 Hz (of endothelial origin), combined with high-amplitude cardiac oscillations confirms the presence of dilatation of small arteries and large arterioles. Disturbances in the venular section of the microcirculatory channel in the form of obstruction of blood outflow were also detected. Most frequently, this type of microcirculatory disorders was observed in patients with upper limbs lesions and the 1st degree of CIPN severity.

In 43 % of patients with predominant lower limb lesions there was a reduced contribution of myogenic, neurogenic and endothelial vasomotions, suggesting spasticity in arterioles and low perfusion. These microcirculatory disorders were predominant in the patients with the 2nd degree of CIPN severity.

According to the HADS scale, the level of anxiety and depression was high with 9.05 [8.8; 9.4] and 8.84 [8.5; 9.3] points in the main and control groups respectively.

In assessing quality of life, the observed patients had high scores on the role and physical function scales of 84.3 [71.6; 913] and 81.5 [68.6; 89.3], respectively. Emotional function had the lowest score among the functional scales at 71.7 [56.1; 84.2]. The median general health status scale score was only 54.1 [50.6; 67.3] points. Regarding the symptoms, fatigue, pain, and insomnia were the most bothersome for the patients: 25.0 [12.2; 36.1], 11.9 [10.2; 16.1], 24.9 [11.2; 35.1], respectively.

All patients tolerated the treatment well. No serious adverse events developed during the study and no patients withdrew from the study. All 60 subjects completed treatment.

After the clinical intervention, improvement in the subjective and objective parameters was observed. The patients noted a decrease in numbness and weakness in the extremities. Using the EORTC QLQ — CIPN20 questionnaire, it was found in the subjects of the first group: 12 [10; 13] points for sensory symptoms, 8.0 [6; 9] points for motor symptoms, and 2.0 [1; 3] points for autonomic symptoms. The data compared by groups are presented in Table 2.

Table 2. Treatment outcomes of patients with CIPN according to the EORTC QLQ — CIPN20 questionnaire (Me [Q1; Q3])

Observation period	Group 1 (main), *n* = 30	Group2 (control), *n* = 30
EORTC QLQ — CIPN20 Sensory scale		
Before treatment	18.0 [15; 19]	18.3 [15; 20]
After treatment	12.5 [10.2; 13.4]*#	14.8 [13.9; 25.1]
EORTC QLQ — CIPN20 Motor scale		
Before treatment	15.29 [13.4; 20.5]	15.87 [13.6; 21.1]
After treatment	8.51 [6.2; 9.1]*#	13.3 [12.2; 18.7]
EORTC QLQ — CIPN20 Vegetative scale		
Before treatment	2.1 [2.2; 5.4]	3.39 [2.1; 5.51]
After treatment	2.4 [1.2; 3.4]*#	3.1 [2.1; 4.9]

Note: ** p < 0.05 — significance of differences compared to the pre-treatment values (Wilcoxon test); # p < 0.05 — compared to the values in the control group (Mann-Whitney test).*

The patients of the main group showed a significant decrease in the level of anxiety and depression. The data compared by groups are presented in Table 3.

After the clinical intervention, the patients of the first group with disorders in the microcirculation system in the form of vasodilatation of arterioles and with predominant lesions of the upper extremities showed positive dynamics of LDF parameters. Significant improvement of the contribution of myogenic, neurogenic and endothelial oscillations was found, which contributed to the improvement of the blood flow in the capillaries and arterioles. The control group showed no significant changes in the above-mentioned parameters (Figures 2–6).

The subjects of the first group with spasticity in the microcirculation system with predominant lesions of the lower extremities also showed positive dynamics of LDF parameters, which was expressed in the improvement of

Table 3. Dynamics of indicators of anxiety and depression in patients with CIPN according to HADS before/after treatment Me [Q1; Q3]

Observation period	Group 1 (main), *n* = 30	Group2 (control), *n* = 30
HADS / Anxiety scale		
Before treatment	9.14 [8.61; 9.51]	9.27 [8.82; 9.44]
After treatment	7.7 [7.1; 8.52]*#	9.3 [8.34; 9.2]
HADS / Depression scale		
Before treatment	8.84 [8.39; 9.15]	8.7 [8.45; 8.95]
After treatment	7.18 [6.82; 14.2]*#	9.31 [8.1; 12.4]

Note: ** p < 0.05 — reliability of differences compared to the pre-treatment values (Wilcoxon test); # p < 0.05 — compared to the control group values (Mann-Whitney test).*

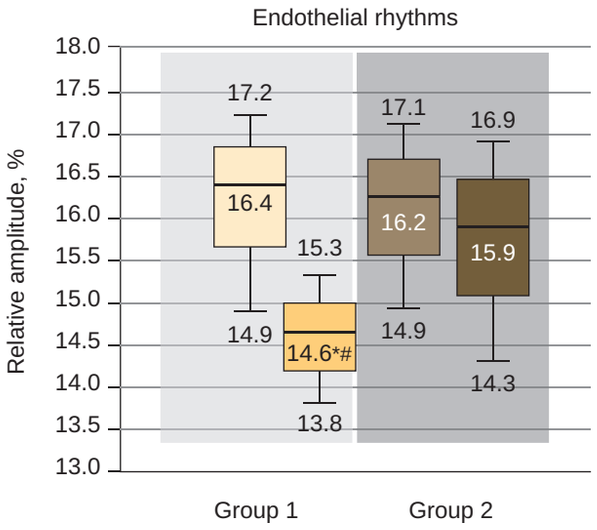

Fig. 2. Dynamics of endothelial rhythms in patients with disorders in the microcirculation system in the form of vasodilatation of arterioles and with predominant lesions of the upper extremities

Note: *The data are represented by the Median (Me), 1 and 3 quartiles [Q1; Q3]. * p < 0.05 compared to the baseline (Wilcoxon test), # p < 0.05 compared to the control group (Mann-Whitney test).*

endothelial function, increase of initially reduced oscillations of myogenic range, indicating the elimination of precapillary constriction and increase of nutritive blood flow. No significant changes in LDF parameters were found in the second group of subjects (Table 4).

After a course of HIPMT application, the patients in the main group, in contrast to the control group, demonstrated an improvement in the role and physical function scales. The emotional function, which had the lowest score among the functional scales, also improved. The median of the general health status scale increased. Symptoms such as fatigue, pain and insomnia significantly decreased (Figures 7, 8).

DISCUSSION

The period of development of new physiotherapy methods of rehabilitation of oncological patients after radical operations against the background of specific antitumor therapy had been preceded by a long stage of experimental and clinical studies to investigate the effectiveness and safety of a particular physical factor for oncological patients. The major areas of application of physiotherapy methods in the rehabilitation of cancer patients are prevention and therapy of complications of specific antitumor treatment and compensation of disturbed functions by restoring and increasing the body's own defense and adaptive mechanisms.

There is now convincing scientific evidence for the advisability of using alternating, pulsed and rotating magnetic fields in oncological patients [28]. It is assumed that the therapeutic effects of magnetic fields are based

Table 4. Dynamics of LDF parameters in patients with spasticity in the microcirculatory system and predominant lesions of the lower extremities (Me [Q1; Q3])

The studied indicator Amax/3 σ × 100 %	Group 1 (main), *n* = 30		Group2 (control), *n* = 30	
	Before treatment	After treatment	Before treatment	After Treatment
E Endothelial rhythms	9.1 [8.8; 10.0]	14.4 [13.8; 15.3]*#	9.2 [8.9; 10.1]	9.9 [9; 10.3]
N Neurogenic rhythms	9.9 [9.6; 11.0]	16.9 [15.9; 17.2]*#	9.68 [9.5; 11]	10.1 [9.7; 11]
M Myogenic rhythms	10.2 [9.8; 11.0]	14.7 [13.8; 16.5]*#	10.78 [9.9; 11]	11.1 [10.2; 12]
R Respiratory rhythms	9.2 [8.9; 10.0]	8.15 [7.9; 9.0]*#	9.08 [8.8; 10.0]	8.65 [7.9; 9.6]
H Heart rhythms	7 [6.7; 8]	6 [5.2; 6.4]*#	7.58 [6.9; 8]	7.25 [6.8; 8]

Note: ** p < 0.05 compared to the baseline level (Wilcoxon test), # p < 0.05 compared to the control group (Mann-Whitney test).*

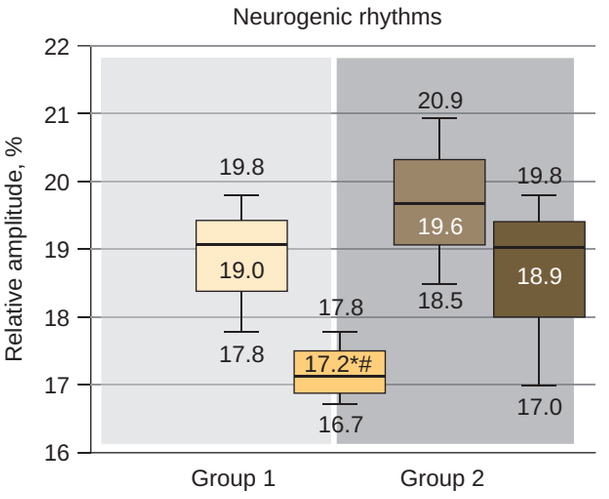

Fig. 3. Dynamics of neurogenic rhythms in patients with disorders in the microcirculation system in the form of vasodilatation of arterioles and with predominant lesions of the upper extremities

Note: *The data are represented by the Median (Me), 1 and 3 quartiles [Q1; Q3]. * p < 0.05 compared to the baseline (Wilcoxon test), # p < 0.05 compared to the control group (Mann-Whitney test).*

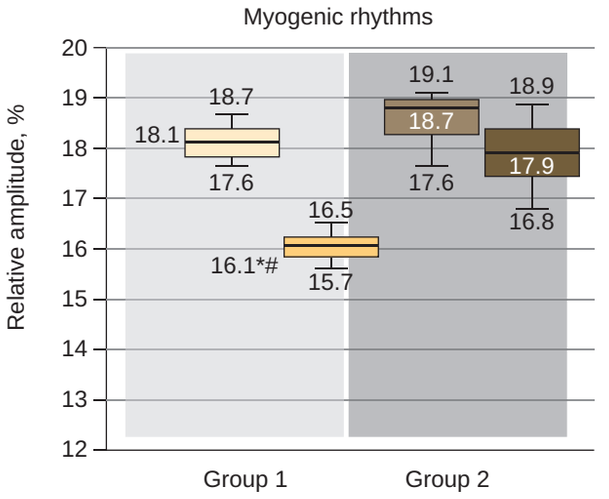

Fig. 5. Dynamics of respiratory rhythms in patients with disorders in the microcirculation system in the form of vasodilatation of arterioles and with predominant lesions of the upper extremities

Note: *The data are represented by the Median (Me), 1 and 3 quartiles [Q1; Q3]. * p < 0.05 compared to the baseline (Wilcoxon test), # p < 0.05 compared to the control group (Mann-Whitney test).*

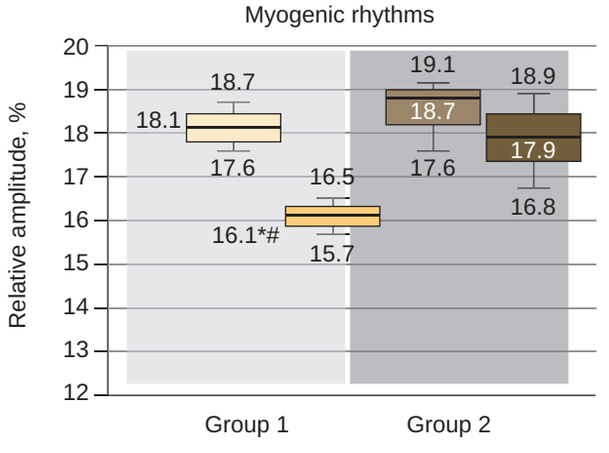

Fig. 4. Dynamics of myogenic rhythms in patients with disorders in the microcirculation system in the form of vasodilatation of arterioles and with predominant lesions of the upper extremities

Note: *The data are represented by the Median (Me), 1 and 3 quartiles [Q1; Q3]. * p < 0.05 compared to the baseline (Wilcoxon test), # p < 0.05 compared to the control group (Mann-Whitney test).*

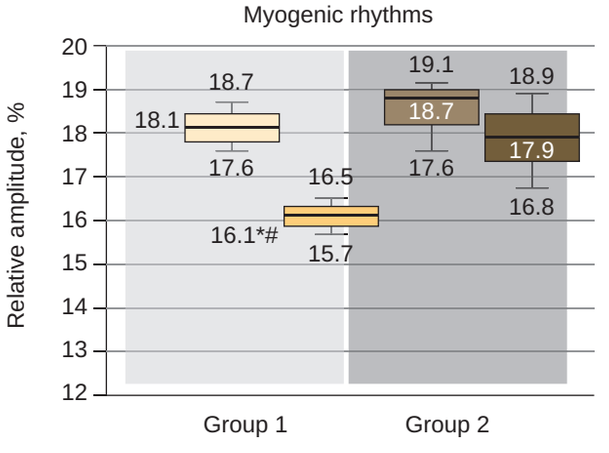

Fig. 6. Dynamics of heart rhythms in patients with disorders in the microcirculation system in the form of vasodilatation of arterioles and with predominant lesions of the upper extremities

Note: *The data are represented by the Median (Me), 1 and 3 quartiles [Q1; Q3]. * p < 0.05 compared to the baseline (Wilcoxon test), # p < 0.05 compared to the control group (Mann-Whitney test).*

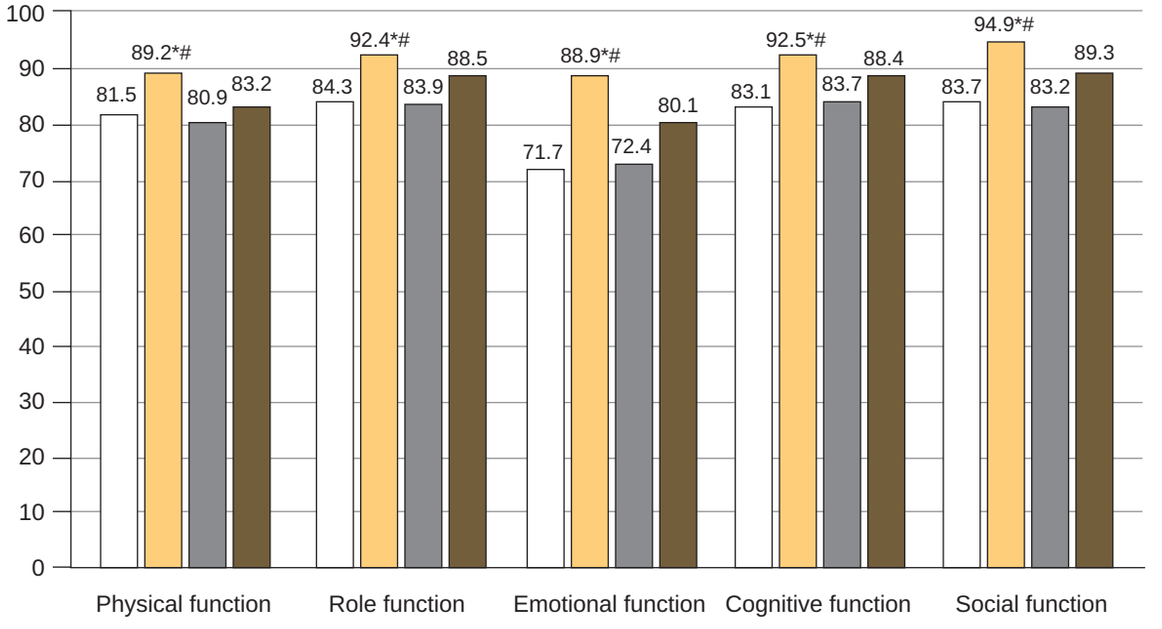

Fig. 7. Dynamics of the quality of life indicators according to the EORTC-QLQ-C30 questionnaire (according to functional scales)

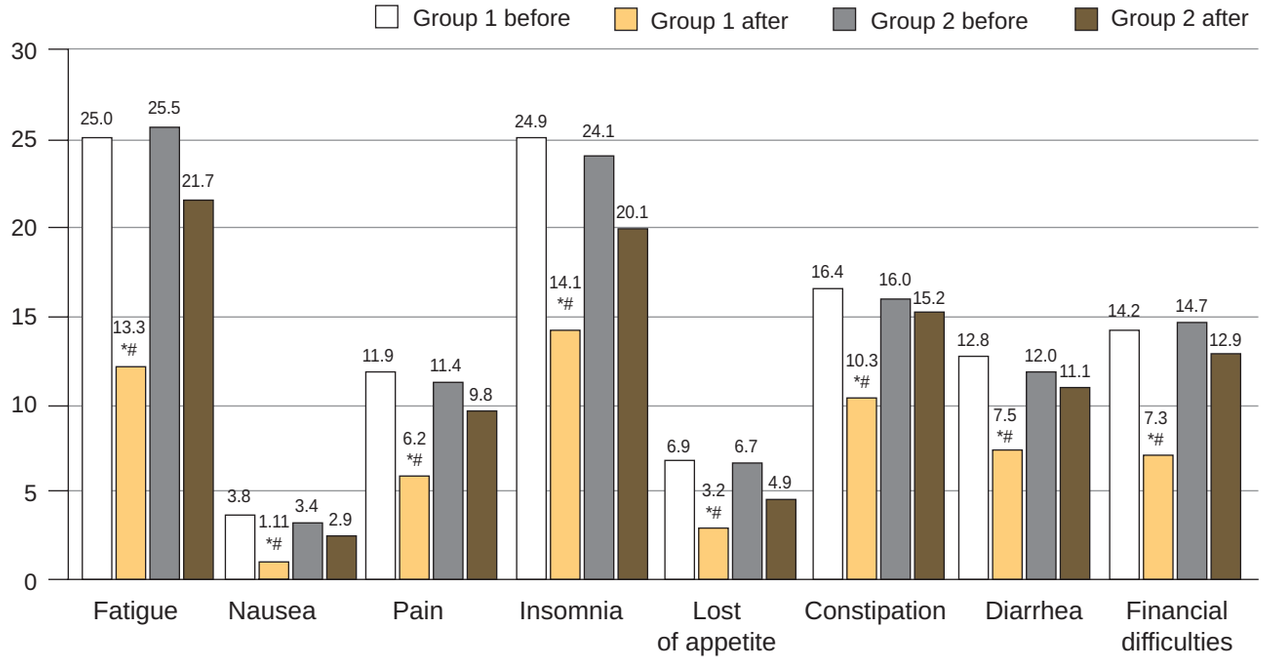

Fig. 8. Dynamics of the quality of life indicators according to the EORTC-QLQ-C30 questionnaire (based on the symptoms scales)

on the increase in the rate of metabolic processes, improvement of microcirculation and enhancement of resorption of decay products in the focus of inflammation, changes in the dispersibility of colloids and permeability of cell membranes, which contributes to the reduction of oedema, decrease in inflammation and pain management. Randomized clinical trials have reported positive effects of magnetotherapy in patients with chemotherapy-induced polyneuropathy in terms of the main clinical symptoms of CIPN and most neurophysiological parameters [29].

In recent years, there have been isolated publications on the successful use of HIPMT in patients with CIPN [26]. The authors used a portable magnetotherapy device consisting of four 45-degree segments made of special magnetic material mounted symmetrically on a 6-cm-diameter, 28-cm2 rotating disc with a magnetic flux density of 420 mTl. The treatments were performed for 5 minutes on each affected limb, daily, 2 times a day, for 3 weeks. At the end of the course, the researchers found a statistically significant difference with the placebo group in terms of sensory neurotoxicity of the ulnar and peroneal nerves (nerve conduction velocity increased ($p = 0.015$) and subjectively perceived neurotoxicity by the patients ($p = 0.04$).

HIPMT is superior to low-frequency magnetotherapy in terms of myostimulating, analgesic and anti-inflammatory effects. The advantages of pulsed magnetotherapy are the possibility of wider variation of dosimetric parameters, availability of impact on more deeply located organs and tissues, more pronounced specificity and physiological effect of exposure [31].

Analysis of the available data in the literature allowed us to propose a hypothesis about the therapeutic effect of HIPMT on clinical manifestations and the state of microcirculation in patients with peripheral polyneuropathy induced by chemotherapy.

According to the results of the randomized study, it was found that under the influence of HIPMT, in contrast to the control group, there was an improvement in the quality of life, which was confirmed by the positive dynamics of indicators of the scales of role, physical and emotional functions (EORTC-QLQ-C30).

One of the important objectives of the present study was to investigate the state of microcirculation in patients with CIPN and to evaluate the effect of HIPMT on the cutaneous blood flow in this category of patients, since to date there are only few studies on the state of microcirculation in patients with CIPN. Using laser Doppler flowmetry we evaluated skin microcirculation in 60 subjects. Based on the data obtained by LDF, 43 % of patients with predominant lesions of the lower extremities initially showed spasticity in the arterioles and low perfusion, whereas 57 % of patients with predominant lesions of the upper extremities showed dilatation of the small arteries and large arterioles. After 10 HIPMT procedures, the patients with spasticity showed an increase in the initially reduced cutaneous microhemodynamics. One can make a hypothesis that this increase was caused by the registered strengthening of oscillations of endothelial genesis in comparison with the initial values, as well as by the direct effect of HIPMT on the vascular wall. The latter is confirmed by the established improvement of intrinsic myogenic vasomotions 0.07–0.145 Hz, which indicates the state of the oscillatory component of the precapillary muscle tone regulating the blood flow in the nutrient channel. Our data correlated with the results of experimental studies by Smith et al. on rats [30]. The authors found that when pulsed electromagnetic fields were used, a 9 % increase in the diameter of the arteriolar microvessels was observed, which, according to the Hagen-Poiseuille law, implies an increase in the blood flow by about 40 %. Tepper et al. showed a positive effect of pulsed electromagnetic fields (PEMF) on angiogenesis. In vivo the exposure to PEMF increased angiogenesis by more than two times [31]. The above findings are supported by the study of Diniz et al., who found that PEMF results in increased synthesis of nitric oxide (NO), which has an effect on the vascular wall in addition to its vasodilatory effect [32]. Klopp RC et.al. in their work investigated the effect of low-frequency pulsed electromagnetic field (< 35 μTl) on the state of microcirculation in patients with diabetic polyneuropathy and trophic lesions of the foot [33]. Their series of placebo-controlled studies on a random sample of patients with the above pathology resulted in the improvement of microcirculation by restoring physiological vasomotion of the small arterioles and venules.

After 10 HIPMT procedures, a decrease in the initially increased cutaneous blood perfusion was found in patients, who initially had had predominant vasodilatation of the arterioles. It can be assumed that the decrease was due to the reported decline of initially increased oscillations of the endothelial genesis. Before the course application of HIPMT in these patients, these slow nitric oxide (NO)-related oscillations had dominated the overall level of vasomotion, causing vasodilation and increased blood perfusion. However, the use of HIPMT resulted in the elimination of microcirculatory disturbances. A decrease in the contribution of the heart and respiratory oscillations was observed, indicating unloading of the venular link.

Based on the LDF study, significant disturbances at the microcirculatory level were detected for the first time in patients with CIPN. Our results convincingly demonstrate that the use of HIPMT in patients with CIPN has a corrective and regulating effect on the microcirculatory system.

The main limitations of our proposed clinical intervention are acute infections, blood diseases and haemorrhagic syndromes, and the presence of a pacemaker in the patient. This technique is used in cancer patients who have undergone radical anti-tumour treatment in the absence of metastases and relapses.

CONCLUSION

Thus, we can conclude that the developed HIPMT technique is effective and safe in patients with CIPN. We have obtained reliable positive changes in the main efficacy criteria characterizing the state of microcirculation. It was found that HIPMT leads not only to the improvement of microcirculation in the extremities due to the normalization of the arterial vessel tone, elimination of venous stasis and increase of the nutritive blood flow, but also has an analgesic effect, improves the initial impaired sensitivity and generally improves the quality of life in patients with CIPN. The data obtained give grounds to continue scientific research with the use of HIPMT in rehabilitation programmes for patients with CIPN in other medical institutions in compliance with treatment protocols.

ADDITIONAL INFORMATION

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Ethics Approval. The authors declare that all procedures used in this article are in accordance with the ethical standards of the institutions that conducted the study and are consistent with the 2013 Declaration of Helsinki. The study was approved by the Local Ethical Committee of National Medical Research Centre for Rehabilitation and Balneology, Moscow, Russia (Protocol No. 2 of 14.01.2021).

Data Access Statement. The data that support the findings of this study are available on reasonable request from the corresponding author.

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Low Back Pain: a New Comprehensive Pathogenetic Model Supporting Methods of Medical Rehabilitation

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ABSTRACT
The pathogenesis of chronic low back pain remains elusive. It is still considered a «non-specific» condition, with severity loosely related to anatomical alterations of the lumbar spinal canal (e.g., disc herniation, spinal stenosis). Signs and symptoms may appear contradictory, such as pain aggravated by rest or spinal loading, opposite lumbar postures (flexed or extended) adopted by different patients, and others. Guidelines and reviews oscillate between a restrictive nerve compression model to large sets of epidemiologic factors (from lifestyle to chronic lumbar stress to genetic determinants). A new pathogenetic model is presented here, based on the variable interaction between three possible determinants: compression of nerve endings by disc herniation or arthritic spurs, engorgement of the epidural (Batson) venous plexus, and inflammation triggered by focal thrombophlebitis and fostered by fibrinolytic defects. Hence, the name Compressive-Venous-Inflammatory (CoVIn) is given to the model. Biological and clinical studies provide evidence for each of the three cited determinants. The integrated model explains many «unexplained» characteristics of LBP and provides a rationale for mechanical treatments targeting one or more of the three determinants. Active Lumbar Traction (auto-traction), water exercise, and Williams' flexor exercises look highly consistent with the model, which can explain their effectiveness.

KEYWORDS: low back pain, pathogenetic model, epidural venous plexus, active lumbar traction, balneotherapy, flexor exercises.

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Боль в пояснице: новая комплексная патогенетическая модель, подкрепляющая методы медицинской реабилитации

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РЕЗЮМЕ

Патогенез хронической боли в пояснице остается неясным. Она до сих пор считается «неспецифическим» состоянием, выраженность которого слабо связана с анатомическими изменениями поясничного отдела позвоночного канала (например, грыжа диска, спинальный стеноз). Признаки и симптомы могут быть противоречивыми, например, боль, усиливающаяся в покое или при нагрузке на позвоночник, противоположные позы в поясничном отделе (сгибание или разгибание), принимаемые разными пациентами, и др. Руководства и обзоры колеблются между ограничительной моделью компрессии нерва и большим набором эпидемиологических факторов (от образа жизни до хронического поясничного стресса и генетических детерминант). Новая патогенетическая модель основана на вариабельном взаимодействии трех возможных детерминант: компрессии нервных окончаний в результате грыжи диска или артритных шпор, ущемления эпидурального (по Бэтсону) венозного сплетения и воспаления, вызванного очаговым тромбофлебитом и способствующего развитию фибринолитических дефектов. Отсюда возникло название «компрессионно-венозно-воспалительная» (CoVIn) модель. Биологические и клинические исследования подтверждают наличие каждой из трех указанных детерминант. Комплексная модель объясняет многие «необъяснимые» характеристики боли в пояснице и дает обоснование для механических методов лечения, направленных на одну или несколько из трех детерминант. Активное вытяжение поясницы (ауто-тракция), водные упражнения и упражнения Уильямса на сгибание выглядят в высшей степени соответствующими модели, что может объяснить их эффективность.

КЛЮЧЕВЫЕ СЛОВА: боль в спине, патогенетическая модель, эпидуральное венозное сплетение, активное вытяжение в поясничном отделе, бальнеотерапия, упражнения на сгибание.

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Low Back Pain: a Set of Elusive Syndromes

«Benign» chronic low-back pain (LBP), i.e., pain lasting for more than six weeks, with or without radiation to the lower limbs, is the most prevalent disabling condition globally. Lifetime prevalence in adults of any age is estimated to be around 84 % [1], and prevalence around 23 % [2]. The «benign» qualification refers to syndromes caused by some mechanical dysfunction of the spine, excluding traumatic, inflammatory, infectious and neoplastic causes. This adjective may be over-optimistic. LBP is often chronic and intractable. It causes relevant individual suffering and loss of working capacity in the adult population [3]. The survival of a descriptive diagnosis reveals the scarce understanding of LBP pathophysiologic mechanisms. The state-of-the-art medical knowledge is well summarised in an authoritative «seminar» to which the interested reader is referred [2]. Attempts to classify the various clinical pictures abound [4–7], to say nothing of the proposed treatments, which have always been seen as contradictory (from rest to exercise, from drugs to surgery, from electrotherapy to psychiatric counselling) [8].

The Birth of the Discal-Arthritic Compressive Model

LBP and sciatica (for simplicity, including here also pain radiating anteriorly to the lower limbs) are still considered a «nonspecific» condition [2] mainly consisting of generic, unexplained suffering of back muscle or lumbosacral roots. The proposed aetiologies are multifactorial, variegate and controversial, from anatomical alterations to behavioural and psychological factors to genetic predisposition. The contemporary dominant model in clinical practice is based on the compression of the many nerve endings [9] inside the spinal canal. This model took off after Mixter and Barr's [10] seminal article, which identified disc herniation as a distinct nosologic entity (formerly considered a «chondroma») and associated it with neurological symptoms, including radicular pain. Until the '70s of the 20th century, the in vivo diagnosis could only be made with myelography adopting dangerous lipidic contrasts. Therefore, the diagnosis was limited to frank radicular syndromes, presenting with sensory or motor signs, root-related pain distribution, and the Lasègue's sign. This confirmatory approach probably explains the persistent belief that back pain without sciatica cannot be ascribed to lumbar disc herniation (by the way, the concept of «herniation» will include here, for simplicity, the related pictures of «protrusion» and «prolapse») [11]. Extruded disc herniation, despite its peculiar imaging, will also be included. With hydro-soluble contrast media for myelography and CT and MRI, diagnosis of lumbar disc herniation and spinal stenosis (see below) became easier and virtually harmless (Figure 1).

It also became apparent that herniation of lumbar discs is extremely common in adults, with a peak prevalence between 35 and 60 years of age. The posterior longitudinal ligament, reinforcing the posterior annulus, is tapering from L2 caudally so that lower discs are more prone to disc herniation (in 80 % of herniations, the 4th and 5th discs are affected). Disc herniation could be either asymptomatic or associated with a wide range of conditions, from a mild localised back pain to dramatic cauda syndromes. The CT and the MRI also made evident that another common source of compression of the lumbar spinal root is developmental spinal stenosis, first described by Verbiest [12]. In acquired spinal stenosis, compression of the nerve roots is caused by arthritic changes in the facets (posterior, inter-apophyseal joints), which cause typical claudication more frequently than pain [13]. Many other anatomical structures beyond the spinal roots may generate pain following compression or inflammation within the spinal canal: the discal annulus fibrosus, the posterior longitudinal ligament, the dural sac, the facet joints and the arterial and the venous vessels [9]. No lymphatic vessels can be found inside the vertebral canal [14]. Ganglion compression is enough to cause pain. By contrast, a compression of cauda roots alone causes paraesthesia and sensory loss without pain unless some inflammation exists. This «anatomy of pain» will be considered again in the following paragraphs.

Looking for a Unifying Rationale for Treatment

The disc-compression model soon provided a rationale for the most popular exercise methods, from the classic «flexor» Williams exercises [15] to the prevalently «extensor» McKenzie exercises [16].

These methods claim to fight the «compressive» pathophysiology by striving to widen the vertebral canal section and remodelling the disc herniation. However, results remain unsatisfactory in many single instances. Not surprisingly, most of the traditional treatments, like heat, cold, massage, electrotherapies, manipulations, acupuncture, etc., are merely symptomatic in that they target pain. From guidelines and reviews, LBP emerges as a uniform condition with no clear pathophysiology («non-specific»). The literature leans towards epidemiologic rather than pathophysiologic explanations. These explanations support a widely multifactorial (physical, psychological, environmental) origin of the syndrome and suggest various treatments in various combinations [2, 6]. The literature tends

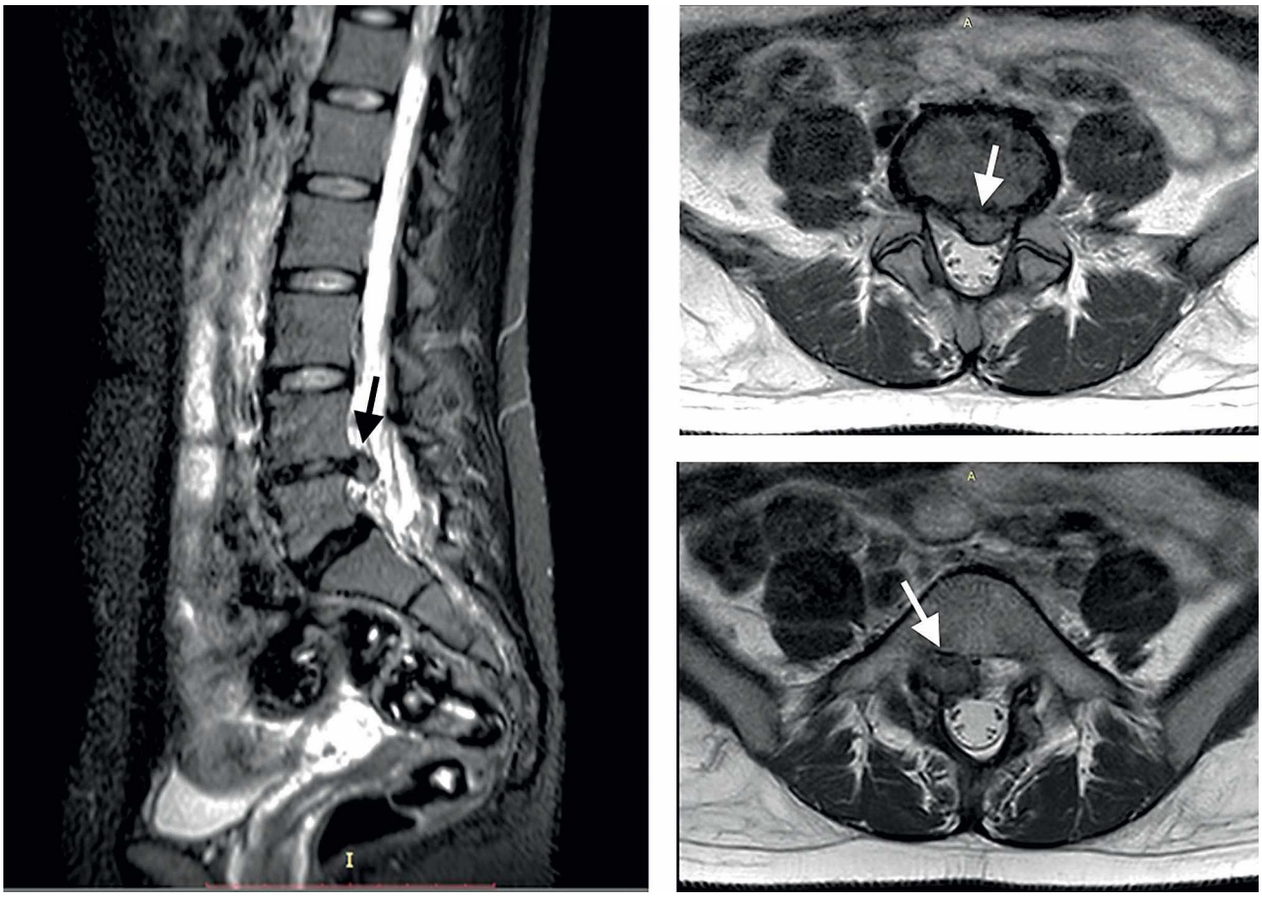

Fig. 1. Typical MRI images (T2 weighted) of a 4th lumbar disc, herniated bilaterally (though prevalently to the right).

Note: *In the sagittal view, on the left, an extruded nucleus pulposus is evident at the 4th disc level (black arrow). The 4th and 5th discs are dehydrated («black» discs). In the axial view, the disc herniation appears on the top right panel in the mediolateral left position (white arrow). The extrusion spreads downward in the bottom right picture and obliterates the right L5-S1 foramen. The patient is a 30-year-old woman. Five weeks before she suffered from an acute onset in the right back and sciatic pain (L5 territory) up to the foot dorsum. There was moderate weakness of foot dorsal flexion. A complete recovery was achieved at the time of the visit after the steroid treatment. The pictures highlight the precise details available on lumbar spine anatomy through MRI and, on the other hand, the scarce consistency between the radiological severity and the clinical findings (personal observation).*

to accept chronic LBP as an intractable condition. Current therapeutic approaches consider pain more like a disease than a symptom, so prevention of worsening and increased tolerance is recommended. Therefore, the most various treatments are attempted, with no clear classifications of patients. This may explain why evidence of the effectiveness of «exercise» is still weak [17]. This defeatist attitude is a waiver for research on a deeper pathophysiologic model.

Limitations of the Compressive Model

A pathophysiologic model should explain most of the available observations. Unfortunately, the discal-arthritic compression model is far from satisfactory in this respect. The main eight observations missing a convincing explanation are listed in Table 1. A point-by-point explanation will be attempted in the following paragraphs based on the model proposed in this article.

The Venous Theory: the Core of a New Model

Backpain Following Visceral Problems

A seminal article by Batson [19] raised awareness in the medical community of the neglected epidural venous plexus. This is the fourth venous system (after the portal, caval and pulmonary systems). It runs in the epidural space merged with the epidural fat. It drains the venous outflow from the pelvis and the entire spinal column and has extensive anastomoses with retroperitoneal and intracranial veins. The epidural veins are valveless. They are virtually collapsed but can become engorged due to increased central venous pressure (e.g., in case of heart failure or pulmonary hypertension, or any increase of the abdominal strain), obstruction of the caval system, compression inside the spinal canal, or increased blood circulation (as in the case of pregnancy). Batson was only interested in understanding the spread of metastases (e.g., prostate metastases bypassing the liver and spreading to the lung, vertebrae, and skull). In the following years, LaBan highlighted the association of back pain with simple recumbency and with several visceral conditions like liver cirrhosis, chronic obstructive pneumonitis, and heart failure [20–23]. Pregnancy [24] and even the obstruction of the left renal vein in the aorto-mesenteric «nutcracker» [25] could also be related to LBP by mediating the plexus engorgement. Spinal stenosis also emerged as a condition favouring vein-related symptoms. The restless legs syndrome could also be ascribed to this mechanism [26]. Angiographic and MRI studies confirmed venous engorgement in these conditions [23].

«Primitive» Back Pain and Venous Engorgement

Curiously enough, the possibility that venous engorgement could contribute to «benign» LBP, beyond being a consequence of visceral problems, was not exploited. In 1991, Tesio formulated this hypothesis explicitly [27].

He looked for an explanation of the puzzling effectiveness of the Swedish auto-traction treatment (now Active Lumbar Traction) he imported to Italy in 1984 (see below). The technique, paradoxically, increases the discal pressure. Its effectiveness challenged the view that disc herniations were the dominant cause of pain, i.e., the the rationale for «decompressive» exercises [16]. Clinical observations suggested other relevant predisposing factors. These might be, for instance, sitting or erect posture (increasing the hydrostatic venous pressure at the trunk), increased abdominal pressure (e.g., constipation or Valsalva manoeuvres implied by coughing and sneezing), and spinal stenosis, all pointing toward epidural venous congestion as a possible pain generating mechanism, consistently with Batson's and LaBan's studies. Tesio also extended the «venous» hypothesis to the possibility of local phlebitis caused by venous stasis and fostered by fibrinolytic defects. This vascular-inflammatory hypothesis was supported by a series of rigorous studies by Jayson and coworkers [28–32]. These authors, however, emphasised the role of inflammation (e.g., triggered by the acid content of the nucleus pulposus or by fibrinolytic defects) while overshadowing the hydraulic mechanism provided by the a-valvular Batson plexus, prone to engorgement in a restricted space.

Based on the positive response to the paradoxical auto-traction treatment, Tesio also revitalised the potential role of venous stasis in back pain appearing during pregnancy, a well-known and substantially unexplained condition [33].

Table 1. Characteristics of benign chronic back pain unexplained by a purely disc-compressive hypothesis

a)	The discrepancy between the number and size of disc herniations and the severity of pain (if any)
b)	The pain-relieving posture adopted by the patients with evidence of lumbar disc herniation. As a rule, patients prefer a flexed/crouched lumbar stance. In some cases, an extended posture is chosen. Subjects selecting an extended pose usually suffer from a recent/acute episode
c)	LBP aggravated by rest or initiation of movement after rest: typically, with exacerbation in the morning after a nocturnal sleep. Paradoxically, recumbency and rest make the intradiscal pressure decrease
d)	LBP in pregnancy is a frequent condition [18] that is not significantly associated with lumbar disc herniation
e)	Evidence that the risk factors for developing LBP, with or without lumbar disc herniation, overlap with the risk factors for cardiovascular accidents (i.e., sedentary lifestyle, smoking, dyslipidaemia, fibrinolytic defects)
f)	Some LBP syndromes are permanent, while some can resolve spontaneously after various periods. The CT or MRI imaging is usually unrelated to the time course of pain
g)	When a conservative treatment effectively relieves or resolves pain, imaging before and after treatment may not change
h)	The long-lasting results of transient mechanical treatments

In the following years, anatomic [34] and refined imaging studies [35] confirmed Batson's anatomical findings and the association of epidural vein dilatation with back pain or sciatica [36, 37]. Consistently with the critical role of the venous outflow in back pain syndromes, a human peculiarity was evidenced by other authors in the vascular supply of lumbosacral roots. These are exceptionally long in humans and are stretched some 3 cm during lumbar and lower limb flexion, challenging blood supply. Cauda's roots contain arterio-venous anastomoses with a spiraliform (pig-tail) shape. This may ensure an arterial flow through the veins during root stretching. Of course, the venous pressure must not be too elevated [38]. However, the above observations and research lines did not converge in an organic model. Furthermore, some observations remain to be explained (see Table 1 and below). An updated pathophysiologic model is simplified and suggested here.

The Compressive-Venous-Inflammatory (CoVIn) Back Pain Model

The puzzling observations listed in Table 1 can all find a reasonable explanation if the discal/arthritic compression model is integrated with the hypothesis of epidural venous engorgement and local thrombophlebitis. I dubbed this model Compressive-Venous-Inflammatory (CoVIn). The model is sketched in Figure 2.

What follows is a step-by-step response to the questions covered in Table 1.

a) The discrepancy between anatomical and clinical findings can originate from the variable concurrence of discal compression, canal section reduction, epidural veins' engorgement, patient's harmful movements, and local inflammation. Not all of these factors are detectable through CT or MRI.

b) The flexed lumbar posture widens the spinal canal. A colourful debate originated around the displacement of the nucleus pulposus. It seemed reasonable to sustain the idea that it migrates toward the direction of a widening intervertebral distance, e.g., posteriorly in flexion and anteriorly in extension. Clinical experience, however, clearly shows that chronic LBP patients tend to avoid lumbar extension. Several studies on anatomical specimens and living subjects (even with invasive contrast discography) gave contradictory results for decades. Looking at the heterogeneous literature on this topic I think that the following convincing conclusions can be drawn:

- During flexion, the nucleus tends to migrate posteriorly, without causing meaningful discal bulging, only if the annulus is integer. In any stage of disc degeneration, the nucleus migrates anteriorly. The phenomenon reflects the loss of elastic resistance of the annulus so that on the side of vertebral rapprochement (i.e., anteriorly), the annulus sags and opposes less resistance to the internal hydraulic pressure. The posterior annulus (and the posterior longitudinal ligament) is elongated and tightened during flexion.
- The opposite occurs during extension. Extension causes a disc prolapse of 1 to 4 mm even in recumbency, primarily due to the annulus sagging. It has been shown that extension alone restricts even by 20 % or more the osseous transverse section of the spinal canal at L3-L4 and L4-L5 levels compared to flexion because of the increased overlap between the posterior joint facets, much more than because of disc prolapse [39, 40]. This restriction is even more prominent in the case of posterior bulging of the disc and can become dramatic in spinal stenosis [35].

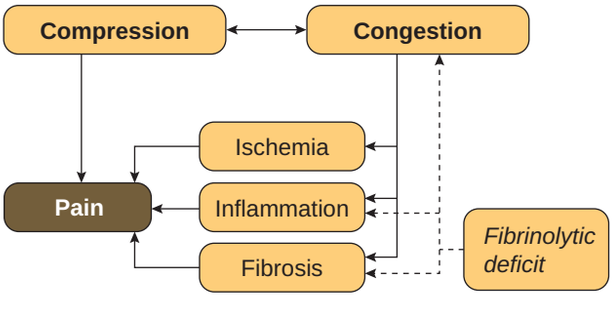

Fig. 2. A sketch of the Compressive-Venous-Inflammatory (CoVIn) pathogenetic model of low back pain
Note: *Compression of neural endings and dilation of the epidural veins (Batson's plexus) can both lead to pain either alone or by reciprocal enhancement. Venous congestion may act through ischemia of nerve endings or an inflammatory thrombophlebitic process, possibly evolving into local fibrosis. Fibrinolytic defects foster the phlebitic processes. Ideally, physical rehabilitation should contrast both arms of this model.*

Patients preferring an extended posture usually represent acute cases suffering from the classic «witches' blow». In this case, a dural sac involvement must be considered. Defensive reactions to meningeal pain overtake the responses to other forms of pain (including discal-arthritic pain). The dural sac is elongated during spine flexion and shortened during extension [41]. Therefore, in case of inflammation, any manoeuvre stretching the sac (spinal flexion but also the neurologic signs of Lasègue, Kernig, and Brudzinski) exacerbates pain. Spinal extension attenuates pain. The acute pain (witch's blow) is usually transient, lasting no more than a couple of days, and can respond quickly to steroid medication (primarily dexamethasone). The «extended» patient frequently turns into a «flexed» patient after the acute phase has elapsed.

c) Rest may decrease the discal pressure but prevents the muscles' physiological «venous pumping» activity. Therefore, venous volume is increased during any static posture, particularly during night recumbency. In restricted bony spaces, venous congestion can become very painful because of direct compression on nerve endings or ischemia; the same happens with sinusitis, dental pulpitis, and osteomyelitis. Back pain looks just a variant of this phenomenon. Of course, increased pressure on the disc and overload on the facet joints may result from heavy physical activity thus contributing to pain. It may well happen that some patients suffer from pain both at rest and during certain motor activities or only during the latter.

d) Pregnancy causes a remarkable increase in blood flow. In the last three months of pregnancy, the caval venous return shows a 6-fold increase. The epidural plexus thus becomes a timely escape route at the cost of venous engorgement within the narrow, inextensible spinal canal.

e) Venous stasis may be the first step towards potential phlebitis, implying thrombosis and chronic fibrosis. The

epidural fat in patients undergoing repeated unsuccessful surgery for disc herniation (causing arachnoiditis) is similar to the subcutaneous fat in superficial thrombophlebitis [29]. This explains why chronic LBP and cardiovascular diseases share some risk factors (sedentary lifestyle, smoking, dyslipidemia), all known to decrease the fibrinolytic capacity of the plasma. This notwithstanding, concerning these associations (in particular, smoking), «the underlying mechanisms remain obscure» for the dominant Literature [2].

f) Venous stasis and inflammation may be transient phenomena, as it is well known for other conditions (from haemorrhoids to subcutaneous phlebitis to deep vein thrombosis). The venous-inflammatory component of the model may thus explain both the chronicity and the temporality of the pain symptoms in chronic LBP.

g) A successful treatment must not necessarily modify the CT or MRI images of the spine. First, imaging does not highlight the pressure exerted by compressive structures (disc or arthritic spurs) on nerve endings. Micro-displacements may cause clinically meaningful decompressions. Second, routine MRI imaging does not target the decrease of venous engorgement, although it should be possible to conduct specific studies nowadays [42–44].

h) The favourable results can be permanent for many reasons (e.g., slow neural adaptation and long-term atrophy of a prolapsed nucleus pulposus). Still, the end of a phlebitis status is a sufficient explanation in most cases.

The Efficacy of Some Mechanical Treatments Supports the CoVIn Model

If the CoVIn model and the above explanations hold, conservative mechanical treatments (i.e., physiotherapy) should aim at

- Widening the lumbar canal section.
- Fostering decongestion of the epidural plexus.

Ideally, both of these related aims should be pursued. I'm now describing three mechanical treatments with established effectiveness that seem most consistent with the CoVin model. These treatments are Active Lumbar Traction (originally, Auto-traction), «flexor» (Williams's) lumbar exercises, and water exercises. The perspective is not one of asserting that, among the dozens of other conservative approaches available, these should receive priority in any instance. Instead, they are brought as clinical evidence further supporting the CoVIn pathophysiological model.

Auto-Traction Treatment / Active Lumbar Traction

Active Lumbar Traction (originally «auto-traction») is a mechanical treatment of benign chronic LBP performed on a specially designed traction bench. Auto-traction was invented by the Swedish physician Gertrud Lind in 1974 [45]. The original table was manually operated. It was provided by electro-hydraulic mechanisms by Lind's pupil Emil Natchev. Natchev also formalised and disseminated the method through a manual, seminars and one-week intensive courses [46]. In 1984 Luigi Tesio attended one of Natchev's courses in Stockholm, introduced the technique in Italy, designed a simplified bench and further simplified the method, which a physiotherapist can now learn in a few days [47, 48]. As shown in Figure 3. (Tesio's method), the technique requires a bench electrically operated. The bench is transversally divided into two sections.

Depending on the response to the treatment, the patient lies supine, prone or side position while «anchored» to the foot end of the bench by a corset and a chain. Each section of the table can be tilted or rotated by the therapist. Whichever position the therapist selects, the patient exerts «auto-traction» manoeuvres, lasting 4–6 seconds, by grasping ad hoc bars on the head section of the table. Gradual relaxation then follows for the next 6–10 seconds. During the traction efforts with the upper limbs or between subsequent pulling actions, the patient can exert pushing efforts with the lower limbs against ad hoc bars on the foot end of the table to modify the lumbosacral orientation. The treatment begins with the search for the least painful back position. The patient is then asked to provide subsequent traction efforts (about 20 per session). The therapist gradually moves the patient towards the formerly painful positions by tilting and/or rotating the table's sections during the efforts or the pauses. Efforts should become painless. In 3 to 9 half-hour sessions in 5 to 10 working days, the whole range of lumbar movement must become painless or much less painful. As a consequence, active trunk mobility also increases. Neurological and thermographic signs can also improve, likely due to removing pain-related neural inhibition [33]. The treatment is discontinued if no significant improvement is observed after three sessions. Results are usually stable (at least three months, but several years — if not permanently — in the Author's experience). In about 75 % of the cases, pain can disappear or decrease to less than 30 % of the pre-treatment values (whichever pain scale is adopted) [49, 50]. No aftercare of any type is advised. The clinical and radiological severities

Fig. 3. The active lumbar traction (auto-traction) method for low back pain (see text and Manual for details; pictures from [48] — permission granted)

are loosely related to prognosis [51, 52]. The method may be successful in chronic LBP in pregnancy [53]. Lind's, Natchev's, and Tesio's method versions provide superimposable results [52]. Contraindications and side effects are minimal (see Tesio's Manual for details). Two isolated reports suggest that other custom-made exercises, inspired by Lind's method, might work without a dedicated bench [54, 55].

How Does it Work? Active Lumbar Traction is a Form of Vigorous Exercise

Evidence for the effectiveness of Active Lumbar Traction is sound [47]. However, the orthopaedic community was sceptical from the beginning of the method because the traction manoeuvres increase the discal pressure [56] through the contraction of paravertebral muscles. The name of the method may have needed to be more accurate. Lind thought that «auto» traction caused vertebral distancing and disc decompression, a mechanism ascribed (quite optimistically) to a traditional passive lumbar traction. For this reason, Tesio highlighted that Lind's «auto-traction» is a form of active exercise and renamed the method Active Lumbar Traction [48]. In light of the CoVIn model, the most likely mechanism of action appears to be the decongestion of the Batson plexus — preventing or attenuating local phlebitis — through the muscular venous pump, associated with selective canal widening and remodelling of the interface between the disc and painful nerve endings. From his perspective, a transient increase in discal pressure looks no longer like a paradox; the same holds for many of the «unexplained» features of LBP syndromes listed in Table 1. The accurate 3D positioning of the patient is consistent with the validated principle of matching the patient's «directional preference» [57]. From the CoVIn perspective, this ensures that the increase of discal pressure is harmless and funnels both the venous outflow and the disc remodelling in the right direction.

Water Exercise

For centuries, balneotherapy has been adopted for treating LBP and various rheumatic disorders. Its effectiveness in this field is established [58–61]. The effects of the chemical and thermal properties of the various types of water adopted and the purely physical properties of water still need to be disentangled. The physical effects of immersion in «neutral» water will only be considered here. A temperature of around 34 °C is considered «neutral» because immersion does not cause any physiological response to heat or cold in humans. Other physiological responses, however, abound. The immersed body receives a push towards the surface (Archimedes principle), which is stronger the greater the water density and the volume of the body submerged. The body lightening, minimising the need for muscular contractions, probably explains the notorious relaxing effect of immersion. Most importantly for the present discussion, the body is «wrapped» by a hydrostatic pressure increasing with the depth of the body immersion. In the case of vertical immersion, the highest effect on venous «squeezing» occurs when the water level reaches the compressible abdomen, thus generating an extra-venous flow towards the heart. In a human with a height of 1.8 m, the heart volume can increase from about 560 to 800 ml when vertically immersed up to the axillae [62]. The over-distension of the right atrium is (erroneously) interpreted by the heart as hypervolemia. The heart stroke becomes stronger (Starling's law), the systolic pressure increases, the diastolic pressure decreases, and the heart rate drops by at least 15 %. In addition, atrium distension enhances the secretion of the atrial natriuretic hormone and elicits, via the Vagus nerve and the Hypothalamus, an increased diuresis [63]. In 20–30 minutes, the interstitial fluid is also «squeezed» into the venous network, thus prolonging the cardiac and diuretic reaction to immersion. Meanwhile, the plasma is diluted, its viscosity decreases, and blood cells' concentration decreases. These changes attenuate the heart overwork. All these effects may outlast an immersion period of 30–40 minutes by a couple of hours [64–66].

Immersion in neutral water can thus be beneficial in many instances, from lymphoedema to heart failure, cirrhosis, chronic kidney diseases, varicosities, and hypertension [67–70] and, not surprisingly, oedema in pregnancy [71]. Not surprisingly, a simple «tank» dedicated to immersion therapy was projected [72]. However, it is of interest here that immersion may help decongest the epidural venous plexus. This looks like the most reasonable mechanism explaining its effectiveness in LBP and, in so doing, most of the «paradoxes» listed in Table 1.

Williams' «Flexor» Exercises

Two seminal twin papers by Williams must be recalled here. In the first paper, Williams proposed a typical history of lumbar spine degeneration [73]. Chronic traumas (mostly minimal and unnoticed) on the lumbosacral joints would trigger disc degeneration and increase lordotic posture. This leads to posterior 5th disc prolapse and a rapprochement of the adjacent vertebrae. Collision, subluxation and arthritic deformation of the facet joints cause the vertebral canal to be restricted. Williams also cited that local venous engorgement in a restricted canal might contribute to pain. The attention paid to the canal section inspired the second paper [15]. This paper proposed a set of exercises fostering a less lordotic lumbar posture. These exercises included stretching the hip flexors, strengthening the hip extensors, and active flexion (self-elongation) of the lumbar spine. Since the 1930s, Williams's exercises have been a popular standard. They are entirely consistent with the CoVIn model as long as they emphasise the widening of the spinal canal. In successive decades, the original set of passive and active exercises was widened, but still, they bear Williams' name. Their effectiveness is established, although, like for all types of exercises designed for LBP, evidence is of low grade (grade III or IV) [17, 74, 75].

Final Considerations

The CoVIn model is supported by epidemiological, clinical, anatomical, biochemical and in vivo imaging studies. The CoVIn model can also accommodate other «benign» syndromes (their discussion goes beyond the scope of the present article). One example is provided by the acute «extensor» cases (witch's blow), which can be explained based on a meningeal irritation. Another example is provided by post-surgical arachnoiditis, which is, in essence, a phlebitis/fibrosis process imprisoning nerve roots [76]. The CoVIn model explains more characteristics of the elusive chronic-benign back pain syndromes than other, more popular models. On an «anatomical» extreme, the latter rest

on root compression, generic «inflammation», or «stress» of muscles and joints. On an epidemiologic extreme, they rest on environmental causes (lifestyle, occupational hazards), psychological predisposition and genetic constitution. Given the complex and variable pathogenesis of pain, the former approach seems too simple, while the latter seems applicable to populations, not individuals.

Can we derive therapeutic suggestions from the CoVIn model? Regarding Physical and Rehabilitation Medicine, the model legitimises at least Active Lumbar Traction, water exercises, and flexor (Williams's) exercises. The above methods might be proposed as reasonable first-line approaches before more invasive procedures (e.g., surgery, epidural injections) are attempted. Of note, these three treatments may claim for an aetiologic, not only symptomatic, rationale. Therefore, they seem preferable to purely symptomatic procedures, mainly targeting pain as a symptom (e.g., painkillers, electrotherapy, acupuncture, massage, diathermy, etc.). Further reflection, however, is needed on drugs. The venous arm of the model suggests that old drugs might play a new, more-than-symptomatic role: these drugs are, for instance, flavonoids and heparinoids, whenever a phlebitis/fibrosis process can be suspected.

The CoVIn model is not conceived as a mechanistic prescription but as a logical framework helping medical reasoning. Two notes of wisdom, therefore, are needed. First, each patient is unique. Depending on medical judgment, invasive or purely symptomatic treatments may be more indicated than, or compatible with, treatments inspired by the CoVIn model. Second, despite converging evidence of various kinds, the effect of any mechanical treatment of LBP on epidural venous engorgement still waits for direct experimental demonstration, reinforcing a large list of clinical studies.

ADDITIONAL INFORMATION

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Skeletal Muscle Apoptosis: a Debated Issue Now Well Resolved in Favor of the Padua School of Skeletal Muscle. A Review

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ABSTRACT

In my research I have often found myself on the wrong side of the flow of international beliefs. I have generally been wrong and wasted my time and resources and my co-workers, but, sometimes, we have been on the right side. Such was the case with the role of apoptosis, also known as the programmed cell death, in biology and pathology of skeletal muscle tissue. Indeed, our original and pioneering findings have led to a change of direction in this research area. This role had been dismissed by the leading myologists, but using electron microscopy and molecular analyzes we demonstrated that accepted markers of apoptosis were present in mouse skeletal muscles two days after one night of voluntary running (up to 5 km during the first night). In a few years we have extended this fundamental observation to other experimental models in vivo and in vitro and in human cases of muscular dystrophies. In this paper I will give an overview of how the story began, but I must emphasize that Marzena Podhorska-Okolow and Marco Sandri deserve the highest praise for their most notable roles in the beginning and after, the roles and services that are still notable today.

KEYWORDS: skeletal muscle tissue, apoptosis, programmed cell death, skeletal muscle regeneration.

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Апоптоз скелетных мышц: обсуждаемый вопрос, который в настоящее время успешно решен в пользу Падуанской школы скелетных мышц. Обзор

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РЕЗЮМЕ

В своих исследованиях я часто оказывался не на той стороне потока международных убеждений. Как правило, я ошибался и тратил впустую свое время и ресурсы моих коллег, но иногда мы были на правильной стороне. Так обстояло дело с ролью апоптоза, также известного как запрограммированная гибель клеток, в биологии и патологии скелетно-мышечной ткани. Действительно, наши оригинальные и новаторские результаты привели к изменению направления в этой области исследований. Ведущие миологи отвергли эту роль, но с помощью электронной микроскопии и молекулярных анализов мы продемонстрировали, что общепринятые маркеры апоптоза присутствовали в скелетных мышцах мышей через два дня после одной ночи добровольного бега (до 5 км в течение первой ночи). Через несколько лет мы распространили это фундаментальное наблюдение на другие экспериментальные модели in vivo и in vitro, а также на случаи мышечной дистрофии у людей. В этой статье я расскажу о том, как начиналась эта история, но должен подчеркнуть, что Марцена Подгорска-Околоу и Марко Сандри заслуживают самой высокой оценки за их самые заметные роли в начале и после, роли и заслуги, которые заметны и сегодня.

КЛЮЧЕВЫЕ СЛОВА: скелетная мышечная ткань, апоптоз, запрограммированная гибель клеток, регенерация скелетных мышц.

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ABSTRACT

In my research life I have sometimes found myself on the wrong side of the stream of internationally published results. Often I was wrong and I wasted my time and my resources, but in a few cases I was on the right side. Either way, surfers say it is exciting to go against the tide. This typescript offer a short account of one of the few examples proving that sometimes I was right. In fact, it led to a change of direction towards an interesting area of research: muscle apoptosis, also known as programmed cell death. Rejected by leading myologists, we used electron microscopy and molecular analyzes to show that accepted markers of apoptosis were present in the mouse muscle two days after a night of voluntary running (up to 5 km during the first night). We extended this pioneering observation to other experimental models in vitro and in vivo and in human cases of muscular dystrophies [1–8]. For a recent general review of muscle cell apoptosis, please read: Kopeina G.S., Zhivotovsky B. [9], but now thousands of papers are listed in PubMed if one search for: skeletal muscle apoptosis. Thus, I was right.

Prof. Claudio Franceschi, an immunologist specialized in the study of centenarians, spent three years at the University of Padua, Italy working in a lab together with Paola Arslan, Marcello Cantini and a few pupils. On a spring day of 1994 he entered my lab asking for support to demonstrate that both myocardiocytes and skeletal muscle fibers may undergo apoptosis, a process that occurs every day in cells that die and regenerate continuously in labile tissues, e.g., skin epidermal cells and blood cells. The strange name describes the leaf fall that occurs each autumn in deciduous trees, with leaves falling to the ground to nourish the trees the following spring. Apoptosis is indeed a Greek word that describes the fall from the top of the tree (apoptosis means from high-fall). Though we know well now that the skeletal muscles (but not the cardiac cells, at least in large mammals) may die and regenerate, it was obvious for me that a kind of normal event must occur unrecognized in the tissue to explain the impressive potential of regeneration of the skeletal muscle tissue after a trauma or myotoxic injuries. Why not unrecognized cycles of death by apoptosis and regeneration?

On the other hand, only a severe trauma and ischemia or genetic muscle diseases were accepted as causes of death and regeneration of the muscle fiber of our muscles [10, 11], not functional events like those occurring in runners.

However, we had previously studied the impressive damage and regeneration that occurs in mice, which are released (offered an exercise wheel) after months or years of sedentary life in small cages. The mice follow their instincts and run up to 5 km during the first night, exhibiting extensive muscle damage and regeneration during the following week. It was in my mind the ideal experiment to

study skeletal muscle apoptosis during the first two days after running [1].

Starting from the first in vivo observations, we then demonstrated also in vitro that a stressed muscle tissue presents the well-known ultra-structural and molecular markers that characterize and allow to quantify apoptosis in labile tissues (blood cells and epidermal cells of skin and internal mucosae) [2–8].

In the spring of 1995 I organized the first world meeting on the role of apoptosis in the development, damage and repair of skeletal muscle and heart in mammals in Abano Terme (balneological resort in Padova, Italy). In addition to Italian and international clinical neurologists and cardiologists, the event was attended by molecular, cellular and structural myologists. We have successfully presented our results on skeletal muscle apoptosis in dystrophic mice after a night of spontaneous running in freewheeling cages [12]. We subsequently published two reviews [3, 7] that helped establish muscle apoptosis as an important topic also for human muscle biology and pathology [13]. A dream had come true.

Sudden Spontaneous Exercise Increases Apoptosis of Dystrophin Deficient Muscle

An apoptosis or a programmed cell death is an active multistep process characterized by morphological, biochemical and molecular events, which requires coordinated regulation of specific genes [14]. This program of cell suicide plays a major role in development, in tissues with high cellular turnover and contributes to the pathogenesis of several human diseases [15]. In vitro experiments on normal and dystrophin deficient myoblasts [1, 16] add information on regulation of myoblast proliferation, differentiation and death during regeneration of the skeletal muscle, but a little information is available on the role of apoptosis in adult muscles. Some observations come from studies on myocardium, since it can display apoptosis after ischemia and reperfusion [17, 18]. Accordingly, consistent with other published results, we showed apoptosis in the skeletal muscles of adult mdx mice in vivo [1, 16, 19–21].

One of the first genes up-regulated during programmed cell death is the ubiquitin gene [22]. In mammalians, different conditions of muscle wasting reveal an increased expression of ubiquitin [23]. To determine whether ubiquitin plays a role in progressive damage of dystrophic muscle we studied myofibers of mdx mice after a light spontaneous exercise. Sedentary mdx mice and congenit BALB/c mice were used as controls.

Light mycroscopy of muscles of dystrophic mice, both al rest and exercised, shows foci of muscle injury with inflammatory cells, small regenerating myofibers and myofibers with centrally located myonuclei, while muscles of sedentary BALB/c mice present homogeneous welldefined fibers with peripheral myonuclei. After immunoreaction with an anti-ubiquitin antibody BALB/c myofibers appeared to show poor reaction due to low level of ubiquitin expression in physiological conditions, while some cytoplasmic stain distinguishes between slow and fast fibers. Myofibers of sedentary mdx mice present a positive reaction in some peripherally-located nuclei, and in small regenerated myofibers.

On the other hand, in mdx muscle after exercise many centrally located myonuclei are positive both in small regenerating and in mature myofibers, while the foci of inflammation are negative. The high turnover of ubiquitin and the 24 hr of rest after exercise exclude that ubiquitin is induced in parallel with Heat Shock Proteins by the stress due to exercise per se. On the other hand, it is well documented that ubiquitin is tightly bound to histones or to some other proteins of the nuclear matrix after the DNA damage.

When the slides were processed for in situ analysis of DNA fragmentation, numerous myonuclei in exercised muscles of mdx mice were positive for apoptosis. As we described, muscles of sedentary mdx mice show 2–3 % of apoptotic myonuclei while BALB/c muscles are negative [2]. The increase of the percentage of positive myonuclei for ubiquitin in mdx muscles after exercise correlates with the increased number of apoptotic myonuclei.

When DNA analysis by pulsed field gel electrophoresis is performed on isolated myonuclei the results reveal that: i) No DNA fragments are detectable in BALB/c muscles; ii) some fragments at 200 kb and at 50 kb are present in muscles of sedentary mdx mice in good correlation with the 2–3 % of apoptotic myonuclei found with Apo-Tag kit; and iii) an increased amount of DNA fragments are detected in muscles of mdx mice after a sudden spontaneous exercise together with a smeared pattern of DNA, which suggests a complete digestion of DNA typical of the necrotic process.

The possibility that inflammatory cells contributed to DNA fragmentation is not excluded, but a myonuclear origin of the DNA fragments is suggested by the presence in myonuclei of apoptotic features detected by in situ nick-end labelling and by electron microscopy. Normal myofibrillar fields around apoptotic nuclei distinguish myonuclei from nuclei of satellite cells, endothelia, fibroblasts and eventual invading macrophages. In 15 % of nuclei of mdx muscles after exercising, electron microscopy detects typical features of apoptosis with a condensed chromatin around myonuclear membrane.

Massive activation of proteases is one candidate in triggering cell apoptosis and it is implicated in nuclear proteins catabolism and in lamin-DNA fragmentation. Which protease system it is associated with is not yet known; ubiquitin may be one candidate. Ubiquitin binding proteins for successive degradation, influences life of several important proteins for apoptosis such as p53, cmyc, BAG-I, and a relationship between ubiquitin and DNA fragmentation was clearly shown. When the distribution of ubiquitin and ubiquitin-conjugated proteins was investigated by SDS-PAGE and Western blot in supernatants and myofibrills of muscle homogenates, low level of free ubiquitin is constantly shown in all studied muscles, which is in good agreement with the published data. This observation could be related to the ceased expression of stress proteins two days after exercising, since shock and other stressors cause only a transient increase in free ubiquitin. In the soluble fraction of exercised mdx muscle we detect an increased content of ubiquitin-conjugated proteins compared with muscles of both mdx and BALB/c mice at rest: the exercised mdx muscles contain at least ten times of the amount present in the muscles of sedentary mice. Similar results are obtained in the myofibrillar fractions. The highest level of ubiquitination is detected in mdx mice after exercise. Densitometry of ubiquitin-reacting bands shows that ubiquitin

linked to contractile proteins increased two-three times in comparison with the ubiquitin amount of the mdx and BALB/c sedentary mice muscles. On the other hand, in situ analysis suggests that exercise-induced ubiquitin is preferentially linked with the nuclear proteins. This has been associated with DNA damage and could be important for fragmentation of histones or nuclear matrix proteins, as lamin, or for changes of the nuclear structure during the apoptotic process. Also, some myoplasm proteins were labelled indicating that proteinase activity is generalized. The widespread expression of ubiquitin and its capacity to link with multiple nuclear and cytoplasmic proteins suggests a major role in regulating apoptosis and other mechanisms of muscle damage. Recent in vitro studies underlay the role of cell death in regulating myoblast proliferation and fusion and this could be relevant in regenerating myofibers of mdx mice, in particular after exercise. On the other hand, in vivo apoptotic myonuclei were found in mature myofibers indicating a pathogenetic role of the mechanisms of programmed cell death in exercise-induced muscle damage in dystrophynopathies. The secondary pathogenetic processes by which a lack of dystrophin/dystrophin associated glycoproteins leads to progressive muscle degeneration in muscular dystrophies is an open issue. A number of possible mechanisms have received attention: changes in plasma membrane permeability, a specific defect in muscle intracellular free calcium homeostasis, and a decreased mechanical stability of the muscle plasma membrane and of the sarcomers. It is general expectation that exercise-induced damage plays a role in the myodystrophic process and that modifications of the training programs of muscles may have some importance in influencing muscle degeneration in patients with muscular dystrophies. It is well known that exercise in an unaccustomed muscle provokes mild injury, soreness and lactic acid accumulation. Our observations that a sudden spontaneous running in unaccustomed animals increases the number of apoptotic myonuclei in differentiated muscle fibers of adult mdx mice shed a light on the pathogenesis of the post-exercise muscle injury. We suggest that exercise-induced damage or fatiguing exercise itself activates the program of cell suicide in mdx muscle possibly because of unbalanced calcium homeostasis or because of an increased generation of reactive oxygen species during reperfusion. Muscle cells initiate the apoptotic process activating the process of DNA fragmentation and the protease system. Only some myofibers reach the final steps of apoptosis, i.e., chromatin condensation and apoptotic body formation. In spite of the clear difference between sedentary and exercised mdx mice observed, myonuclei showing apoptotic features by electron microscopy were one/half of positive myonuclei for both ubiquitin and in situ DNA end-labeling.

In conclusion, exercise-induced muscle damage in mdx mice suggests new roles of ubiquitin related to nuclear events, and it provides evidence for a new and provoking pathogenesis in dystrophinopathies, which could open new pharmacologic strategies in managements of exercise-induced muscle damage and muscle dystrophies.

The view that apoptosis precedes necrosis in the death of dystrophin-deficient muscle fibers of the mdx mouse, an animal model presenting mild muscular dystrophy, has been well substantiated [3, 7]. Additionally, apoptotic myonuclei have been reported to increase in dystrophin-deficient mice 2 days after sudden spontaneous runn [1, 2, 12]. To investigate the role of apoptosis in human muscular dystrophy, the muscles of 11 patients of different ages with Duchenne muscular dystrophy were analyzed for apoptosis [4]. Muscle apoptosis was evaluated by terminal deoxynucleotidyl transferase test and expression of bcl-2 and bax was examined by immunohistochemistry. Very rare in normal muscles of age-matched controls (less than 0.1 %), apoptotic nuclei have been detected in dystrophic muscles, particularly at the interstitial level. Furthermore, dystrophin-deficient myofibers with centrally located nuclei (regenerating myofibers?) showed a positive reaction for DNA fragmentation. A mosaic pattern of bcl-2 / bax-positive myofibers characterized the dystrophic muscles, so the relative proportion of pro- and anti-apoptotic proteins differs between muscle fibers in correlation with the presence of apoptotic myonuclei. In the interstitium, apoptotic cells were identified as macrophages and activated satellite cells. This was the first worldwide study to show an apoptotic process in the adult muscle fibers of patients with Duchenne muscular dystrophy [4]. It added an additional pathogenetic mechanism, shedding new light on muscle damage and its progression in dystrophinopathies.

Apoptosis has been detected in several muscle diseases, including severe dystrophin deficiency [3], but apoptotic mechanisms are not fully described in diseases of adult skeletal muscle [7]. Studying patients with Duchenne muscular dystrophy (DMD) and facio-scapulohumeral dystrophy (FSHD) we have shown an increase of apoptotic myofibers and of bax and bcl-2-positive myofibers [8]. A positive correlation was found between apoptotic nuclei and bax expression. Caspase expression was analyzed by RNase protection. DMD muscles expressed caspase 8, 3, 5, 2, 7 and Granzyme B mRNAs. Low transcription levels of caspase 6, 3 and Granzyme B were detected in FSHD patients. Tissue levels of the caspase 3 protein were significantly correlated with apoptotic myonuclei and with bax expression. Caspase 3 activity was increased in all DMD cases, while FSHD samples were heterogeneous. Caspase transcription was not detected in normal skeletal muscle.

These data indicate that human skeletal muscle fibers during the dystrophic process modulate the expression of caspases and that caspase 3 is involved in the death and progression of myofibers, opening new perspectives in pharmacological treatments of dystrophinopathies, such as the use caspase inhibitors.

ADDITIONAL INFORMATION

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Review
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Medical Rehabilitation and Sanatorium Treatment of Patients after Medical Care in The Field of Oncology: a Review

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ABSTRACT

INTRODUCTION. Physical therapy, natural healing resources, spa treatment technologies and other medical rehabilitation reduce the negative effects of treatment-related symptoms and improve the physical function of patients with cancer. Despite a growing body of evidence and recommendations to better integrate medical rehabilitation into cancer care, rehabilitation is a relatively underutilized service.

AIM. To summarize the available Russian studies on the use of medical rehabilitation and spa treatment in patients after care, in the field of oncology.

MATERIALS AND METHODS. Analysis of the published scientific literature. Meta-analyses, systematic reviews, cohort, prospective and controlled studies for the period from 2014 to 2022 were selected for consideration.

RESULTS. Treatment of a cancer patient should not only focus on eliminating the disease directly and restoring the physical functions of the body, but also on restoring the person's ability to live as acceptably as possible in and after the disease. Medical rehabilitation is carried out by the efforts of various specialists in a multidisciplinary team, and their work should consider the peculiarities of the course of the underlying disease, the condition of the cancer patient and his/her (the patient's) individual characteristics.

CONCLUSION. Improving rehabilitation care in accordance with the recommendations can have a significant impact on the functioning and quality of life of cancer patients.

KEYWORDS: rehabilitation, oncology, physical therapy, health resort, magnetic therapy, climate therapy, massage, balneotherapy, breast cancer, prostate cancer, colorectal cancer.

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Медицинская реабилитация и санаторно-курортное лечение пациентов после оказания медицинской помощи по профилю онкология. Обзор

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РЕЗЮМЕ

ВВЕДЕНИЕ. Лечебная физкультура, физиотерапия, природные лечебные ресурсы и другие технологии медицинской реабилитации и санаторно-курортного лечения уменьшают негативное влияние симптомов, связанных с лечением, и улучшают физические функции пациентов, страдающих онкологическими заболеваниями. Несмотря на растущее количество доказательств и рекомендаций по лучшей интеграции медицинской реабилитации в оказание онкологической помощи, реабилитация является относительно малоиспользуемой услугой.

ЦЕЛЬ. Обобщить имеющиеся российские исследования по применению медицинской реабилитации и санаторно-курортного лечения пациентов после оказания помощи по профилю онкология.

МАТЕРИАЛ И МЕТОДЫ. Анализ опубликованной научной литературы. Для рассмотрения произведен отбор мета-анализов, систематических обзоров, когортных, песпективных и контролируемых исследований за период с 2014 по 2022 годы.

РЕЗУЛЬТАТЫ. Лечение онкологического пациента должно быть направлено не только на устранение непосредственно болезни и восстановление физических функций организма, но и на максимально приемлемое восстановление способности человека жить в условиях заболевания и после него. Медицинская реабилитация осуществляется усилиями различных специалистов из мультидисциплинарной бригады, которым в своей работе необходимо учитывать особенности течения основного заболевания, состояние онкологического пациента и особенности его личности.

ЗАКЛЮЧЕНИЕ. Улучшение реабилитационной помощи в соответствии с рекомендациями может оказать существенное влияние на функционирование и качество жизни пациентов по профилю онкология.

КЛЮЧЕВЫЕ СЛОВА: реабилитация, онкология, физиотерапия, санаторий, магнитотерапия, климатотерапия, массаж, бальнеотерапия, рак молочной железы, рак предстательной железы, колоректальный рак.

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INTRODUCTION

Patients receiving combined treatment for malignant neoplasms (MNT) have impaired physical and cognitive functions, which generally negatively affect a person's life activity, his (the ir) position in society, and largely reduces survival rates.

The integrated use of physical therapy, physiotherapy, natural healing resources and other technologies of medical rehabilitation and sanatorium-resort treatment significantly reduces the negative impact of symptoms associated with the treatment of cancer and its consequences, improves a person's physical functions and quality of life in general. Despite the growing number of foreign studies devoted to medical rehabilitation of cancer patients, there are not many similar studies in our country today, which underpins the need for a large-scale research into this problem.

AIM

To summarize the available Russian data on the use of medical rehabilitation and sanatorium-resort treatment of patients after medical care in the field of oncology.

MATERIALS AND METHODS

An analysis of the published scientific literature was carried out using keywords: medical rehabilitation, spa treatment, oncology. Meta-analyses, systematic reviews, cohort, prospective and controlled studies between 2014 and 2022 were selected for review.

RESULTS

Principles of Rehabilitation for Cancer Patients

According to order of the Ministry of Health of the Russian Federation dated July 31, 2020 No. 788н «On approval of the

Procedure for organizing medical rehabilitation of adults,» today a new strategy for providing medical care for medical rehabilitation to patients of all nosologies, including patients with cancer, is being introduced in our country. More and more works are devoted to this issue. One of the largest of them is a study conducted by D.V. Kovlen, in which, for the first time in Russia, the main approaches to the development of clinical recommendations for physical and rehabilitation medicine, including rehabilitation after cancer treatment, were identified. The author notes that the most commonly reported problems after cancer treatment are physical (such as pain and fatigue) and psychosocial problems (such as fear of relapse). Patients after combined treatment of cancer also have an increased risk of developing concomitant pathologies. According to the author, medical rehabilitation of cancer patients should be aimed at eliminating physical and psychological impairments to maintain or restore function, reduce the severity of symptoms, maximize independence and improve quality of life [1]. In addition, the author draws attention to the fact that physical activity is an important component of rehabilitation measures for cancer patients. To date, interdisciplinary oncology rehabilitation programs have been implemented, based on physical exercises and complemented by interdisciplinary education and lifestyle counseling for patients with cancer.

The paper by M.F. Balluzek et al. assessed the effectiveness of organizing medical rehabilitation programs for cancer patients based on an interdisciplinary approach, which is fully in line with current trends worldwide. The authors analyzed 845 cases of hospitalization of cancer patients in a multidisciplinary clinic for the purposes of oncological rehabilitation at the stages of specialized treatment for the correction of complications, diagnosis and treatment of comorbid diseases, or for palliative care. Low commitment of oncologists to refer patients to multidisciplinary hospitals for programs of supportive overall somatic treatment involving multidisciplinary rehabilitation teams, especially at the initial stages of cancer, has been found; in 94.1 % of the cases, on the recommendation from oncologists of specialized institutions, patients were admitted only at an advanced stage of the tumor process. At the same time, 64.8 % of patients admitted only for the purpose of palliative care were able to continue combined treatment. Among the patients referred for palliative care, in 4.9 % of cases the severity of their condition was mistakenly assessed as a relapse of cancer, whereas it was due to comorbid pathology. At the same time, the low interest of cancer patients themselves in rehabilitation measures was noted in cases of lack of recommendations from their treating oncologists. It has been shown that not only patients with advanced manifestations of the malignant process, but also patients with stages I–II of cancer need maintenance therapy based on the principles of an interdisciplinary approach [2].

The need for an integrated approach to medical rehabilitation of cancer patients is reflected in literature reviews conducted in the Russian Federation. Thus, Stepanova A.M. et al. considered the issues of complex restorative treatment in oncology. The authors note that restorative treatment in oncology is one of the rapidly developing areas of medicine. A fully-fledged, personalized and comprehensive medical rehabilitation helps to significantly reduce the number of complications and improve the quality of life of patients with cancer. The main principles of rehabilitation treatment for cancer patients are the early start of medical rehabilitation, continuity at all stages of combined treatment, continuity, comprehensive nature, including physical, psychological, social rehabilitation, etc., phasing and an individual approach to treatment and restoration of lost functions. In the complex medical rehabilitation of cancer patients, the combined use of such methods as: mechanotherapy, exercise therapy, aerobic exercise, early mobilization (activation and verticalization) of patients from 1–2 days after surgery, massage, physiotherapy (low-frequency magnetic therapy, low-intensity laser therapy, electrotherapy, inhalation therapy, deep oscillation) and psychotherapy is considered. As part of psychological rehabilitation, the authors study methods of psychological influence: person-oriented, suggestive, behavioral, cognitive, art therapy, creative visualization, which are intended for both individual and group psychological work [3]. This is confirmed in a later review by the authors, which focuses on the technologies used for medical rehabilitation of patients with cancer, used throughout the world [4].

Physical Rehabilitation Techniques

The review by Kasparov B.S. et al. features a scientometric analysis of evidence-based studies of physical factors in the rehabilitation of patients with breast cancer (BC). An analysis of publications that had been made before 2018 showed that physical exercises for patients with breast cancer are reliably indicated both in the neoadjuvant preoperative period and in the adjuvant stage, including radiation and drug therapy. Physical activity is effective both at home and in the form of exercise therapy in a medical facility. Aquatic exercises as one of the options for hydro-kinesiotherapy is recommended both for patients with early forms and metastatic breast cancer. The effectiveness of low-intensity laser therapy, low-frequency low-intensity electrotherapy, lymphatic drainage massage, acupuncture, acupressure, and electroacupuncture has been proven in a number of studies, but requires clarification. In addition, according to the analysis, the ineffectiveness and/or harm of using kinesio taping and ultrasound therapy has been proven. Also, according to the results of the analysis, regarding the use of phototherapy, normobaric hypoxic therapy, transcranial electrical neurostimulation, magnetic therapy, their quality is low, or studies have not been conducted (the technique is recommended based on the consensus of experts) [5].

Today, physical rehabilitation is given priority among cancer patients all over the world. Numerous studies on this issue have been published in our country.

Chechelnitskaya S.M. et al. consider personalized physical rehabilitation of children after treatment for various oncological diseases. The feasibility and effectiveness of partner medicine programs conducted in part-time and part-time mode in the medical rehabilitation of children with cancer have been studied. The authors developed a personal program of physical rehabilitation, which was carried out in a cyclical mode: a hospital period for examination, development of a personal program and training in implementation (2 weeks), an interhospital period of independent training with remote support from a doctor and exercise therapy methodologists (from 6 to 12 months). The effectiveness of the developed model was assessed

using three criteria: parents' satisfaction with participation in the program (questionnaire), adherence to recommended physical activity (questionnaire) and assessment of basic mobility (Terrencourt test). The rehabilitation protocol was tested in 135 children 6–18 years old with hematological malignancies, brain tumors, solid tumors, malignant tumors of bones and skeletal muscles. According to the data obtained, participation in the program increased the parents' confidence in their own ability to help their child with physical exercises at home and formed their willingness to continue the course at home. As a result of the study, the feasibility and desirability of partnership interaction with a team of specialists for the patients' parents was confirmed [6].

The paper by Sidorenko L.V. et al. examined complex physical activity as an effective method of rehabilitation of patients cured of various malignant neoplasms (MNT). During the training process, each participant developed an individual style — a stable individual-specific system of psychological means, techniques, skills, methods, and ways of engaging in sports activities [7].

The article by Terentiyev F.V. and Mainazarova E.S. discusses the possibility of using the means of adaptive physical culture in the process of medical rehabilitation of adolescents with oncological hematological diseases and demonstrates the importance of the socializing and pedagogical orientation of adaptive physical culture in the process of rehabilitation activities for adolescents after hematopoietic stem cell transplantation. During the work, indicators of their physical condition were assessed at different stages of the study. The analysis showed a decrease in all studied scales at the second stage, which was due to the transplantation of hematopoietic stem cells and their approach to the initial level at the third stage, while the indicators of the physical condition of adolescents using adaptive physical exercises were higher than those of adolescents without exercises on all the scales under study [8].

The research paper by Rud I.M., dealing with stabilization training in the rehabilitation of patients with postural instability of various origins, points out that in order to draw up an individual plan for medical rehabilitation, patients with postural instability due to diseases of the musculoskeletal system, consequences of injuries, including after endoprosthetics of the joints of the lower extremities, should be divided into groups in accordance with the rehabilitation potential regarding the restoration of postural function, according to the developed algorithms [9]. The author draws attention to the fact that during medical rehabilitation of this category of patients, the method of choice is computer stabilization training with biofeedback, which has an advantage over the methods of therapeutic physical culture for restoring balance in relation to restoring the stability of the main stance.

Nutrition Support

Nutritional support (NS) for cancer patients today is also recognized throughout the world as the main technology for medical rehabilitation of patients in this category due to the widespread prevalence of nutritional deficiency (ND) and its steady progression in the process of combined treatment of cancer. Particular attention is paid to this issue in our country. The study by Gameyeva E.V. et al. assessed the effect of the NS on the course of the postoperative period using the example of 400 patients who underwent surgical treatment in P.A. Herzen Moscow Research Institute of Oncology between 2019 and 2021. The patients were divided into 2 groups: main (n = 200) and control (n = 200). The patients of the main group received a full-fledged NS. The control group consisted of patients, according to a retrospective analysis of patients, with a traditional approach to the NS. The study included patients with malnutrition and cancer of the upper gastrointestinal tract (GIT), colon and rectum, as well as head and neck. In his study, the author draws attention to the fact that the NS in the perioperative period improved nutritional status, increased the level of total protein and serum albumin and reduced the total number of surgical complications by 36 %, including the incidence of anastomotic leakage by 3 times (p = 0.014), infectious complications — 1.5 times (p = 0.074), reduce the length of stay in the intensive care unit, as well as in the hospital by 0.3 and 1.08 bed days, respectively (p < 0.05) [10].

A similar positive effect was noted when carrying out the NS against the background of the systemic therapy for cancer. Another study by the same author [11] assessed the dynamics of the nutritional status of 632 cancer patients with cancer of the upper gastrointestinal tract (esophagus and stomach), colon and rectum, head and neck, and lungs who underwent drug antitumor treatment. The patients were also divided into 2 groups: the main group (n = 316), in which NP was performed, and the control group (n = 316). The work noted a tendency towards an increase in body weight of patients in these subgroups, while in the control group there was a statistically significant decrease in body weight compared to the initial indicators. Also, nutritious clinical nutrition contributed to an increase in the level of total protein and albumin. At the same time, according to the study, the improvement in nutritional status during systemic therapy led, within the statistical trend, to a decrease in the frequency of prolongation of intercourse intervals by 6 %, the need to reduce drug doses by 0.2–3.4 %, which increased the completion of the antitumor stages treatment by 2.9–11.1 %, which was confirmed in the work of N.A. Brish. et al. [12], which assessed the effect of nutritional deficiency (ND) correction on the effectiveness of neoadjuvant chemotherapy (NACT) in patients with locally advanced gastric cancer using the example of 200 patients, 100 of whom received the NS against the background of systemic therapy, 100 — a control group that didn't receive the NS. The authors noted that after completion of NACT in the NACT + NS group, the frequency of ND was 1 %, in the NACT without NP group — 62 %. In patients with ND, partial regression was recorded in the NACT+NP group (n = 54) in 51.9 % of patients, in the NACT group (n = 47) — in 27.6 % (p < 0.05). The incidence of complications in the NACT+NS group was lower than in the NACT group. Two-year event-free survival in patients without ND in the NACT+NS group was 100 % versus 68.5 % in the NACT group (p < 0.001); in patients with ND — 72.5 % versus 60.6 %, respectively (p < 0.05).

Psychological Rehabilitation

Our country has one of the strongest schools of oncology psychology, so there is enough work devoted to the use of

this technology of medical rehabilitation, especially taking into account the fact that psychological rehabilitation is the main technology of a complex of rehabilitation measures for patients with cancer.

The paper by Fedorenko M.V. et al considered the issues of psychological rehabilitation of cancer patients after radical antitumor treatment for thyroid cancer. The study involved 119 patients with thyroid cancer after radical antitumor treatment, receiving L-thyroxine replacement therapy and who did not have a relapse of the disease at the time of the study. The main group of thyroid cancer patients who underwent psychological training, demonstrated significant improvement of their well-being and mood ($p < 0.05$) according to the SAN test. After the psychological training, indicators of situational and personal anxiety decreased. According to the Mini-mult test, the scores on the hypochondria and hysteria scales are significantly different. In the profile, according to the indicators of the Minimult personality questionnaire in the group of patients with thyroid cancer before psychological training, the T-units of the hysteria scale and the hypochondria scale were the highest. The behaviour of individuals of this type unconsciously transforms the struggle with illness into a struggle for the right to be considered sick. After the psychological impact, the profile of patients with thyroid cancer changed, the T-units on the scale of hypochondria, hysteria, and psychasthenia decreased. This shows that after the training, patients became more emotionally stable, less sensitive to environmental influences, and resistant to stress loads. T-units on the scale of hypomania or optimism and indicators on the impulsivity scale increased, which indicates the activity of the individual, the predominance of motivation to achieve a goal, and confidence in decision-making compared to the control group [13].

The study by Tkachenko G.A. et al. assessed the effect of laryngectomy on the mental state of patients. The study included 38 patients at various stages of treatment for laryngeal cancer. To assess the mental state, the Hospital Anxiety and Depression Scale (HADS) and the Severity of Psychopathological Symptoms Questionnaire (SCL-90-R) were used. The authors note that before surgery, the mental state of the patients in general was not statistically significantly different from the conditionally standard indicators (presented in the academic literature), although there was a slight increase in the scores on the depression and anxiety scales, as well as the distress severity index. Moreover, after the operation, all the patients' scores increased on all scales, but a statistically significant increase was recorded only on the scales of anxiety, depression, somatization, hostility, and interpersonal sensitivity. 6 months after laryngectomy, the patients showed high levels of distress; the average anxiety score decreases compared with the postoperative level, although it remains high relative to the preoperative level and normative indicators. There was a statistically significant increase in scores on the depression and interpersonal sensitivity scales. With such work, the team of authors emphasizes the need to create special programs for psychological rehabilitation of patients with laryngeal cancer, aimed at teaching them methods of independent regulation of their mental state in order to increase their resistance to stress [14].

Similar work is being carried out among patients with colorectal cancer. Another study by the same author [15], the results of which were published in 2022, included 26 patients who underwent surgical treatment for colorectal cancer 6 to 12 months before. The patients were divided into two groups: the main group — 12 patients who, in parallel with medical rehabilitation, received individual psychotherapy for 14 days; the control group — 14 patients who underwent only medical rehabilitation and a single psychologist's consultation with questionnaire completion (without psychotherapy). Psychological rehabilitation in this work included cognitive behavioral psychotherapy and biofeedback methods. The effectiveness of the psychological rehabilitation program was assessed using the Hospital Anxiety and Depression Scale (HADS) before the start of rehabilitation and after its completion. According to the findings, the psychological rehabilitation made it possible to reduce the level of anxiety in patients of the main group from 8.6 ± 0.5 to 7.4 ± 0.3 points ($p = 0.052$). A qualitative analysis of the test results also showed that after a course of medical rehabilitation, including psychotherapeutic measures, the number of patients in the main group without depression significantly increased (41.7 %).

Rehabilitation of Patients with Malignant Tumors of Various Localizations

Mammary Gland

Given the prevalence of breast cancer in the world and the socially active position of women, medical rehabilitation of breast cancer patients tends to be the most widely studied.

V.A. Kluge et al. [16] conducted a study, which included 228 patients with early breast cancer who received complex treatment for breast cancer took part, of which 114 patients were included in a prospective study and during the treatment were exposed to rehabilitation measures as part of the biopsychosocial approach and 114 were selected into the control group retrospectively using the paired selection method and were subjected to physical and psychological rehabilitation as prescribed by a doctor. Rehabilitation measures in the main group of patients were carried out in accordance with the biopsychosocial model. The authors came to the conclusion that medical rehabilitation of patients with early breast cancer should be carried out within the framework of a biopsychosocial model, taking into account both biological (genetic, anatomical, physiological, biochemical, etc.) disorders and psychological factors, including mental processes, individual psychological characteristics personality and behavior, as well as social. This work focuses on the fact that rehabilitation measures within the framework of the biopsychosocial model improve event-free survival rates in a group of patients with early breast cancer: event-free survival was 18.3 months ($p = 0.0034$).

Evstigneeva I.S. et al. studied the effectiveness of the use of fluctuating currents in combination with pneumocompression, general magnetotherapy, local magnetotherapy, low-temperature argon plasma in patients after radical surgical treatment of breast cancer in the early postoperative period. It was a prospective simple randomized study including 190 women after Madden radical mastectomy or radical breast resection. The main group included women who were exposed to fluctuating

currents in the course of medical rehabilitation (physical therapy, balance therapy and sessions with a medical psychologist). Analysis of the obtained clinical and functional data showed that in the early postoperative period, against the background of standard drug therapy and a course of medical rehabilitation, the combination of fluctuating currents with intermittent pneumocompression, general and local magnetic therapy significantly reduced the degree of edema of the upper limb and the volume of lymphorrhea. The decline in the level of anxiety and depression, pain syndrome and general condition of cancer patients was most pronounced in the groups additionally receiving magnetotherapy. The authors concluded that an integrated approach to medical rehabilitation at stage I led to the preservation of results in the long-term period 1.5 and 6 months after surgery and did not cause adverse events [17].

The scientific article by Gerasimenko M.Yu. et al. considers the use of physiotherapy in medical rehabilitation programs for patients after surgical treatment of breast cancer. The study included 70 patients. The first group (n = 24) underwent 10 procedures of fluctuating currents in the muscles of the shoulder girdle and upper limb on the side of surgery, the second group (n = 23) underwent 10 procedures of fluctuating current therapy in combination with pressotherapy, and the third group (n = 23) in addition to fluctuating currents and intermittent pneumocompression, received low-frequency magnetotherapy. In all patients, postoperative swelling decreases, pain syndrome decreases, the number of postoperative complications in the wound area decreased (inflammation, infectious processes, pain, suture dehiscence), the duration of lymphorrhea reduced, the volume and quality of movements increased, and sensory disturbances in the upper limb decreased. The authors concluded that the inclusion of fluctuating currents, intermittent pneumatic compression and low-frequency magnetic therapy in the medical rehabilitation program reduces the risk of postoperative complications and helps reduce the recovery period [18].

Considering the incidence of disabling nature of secondary lymphedema after the combined treatment of breast cancer and gynecological oncological diseases, research into the correction of this complication continues both throughout the world and in our country.

The most significant study in our country to date is the study by T.I. Grushina, the results of which were published in 2011, in which the long-term observation of 1460 patients with upper limb edema after a radical treatment of the primary breast cancer showed high efficiency of medical rehabilitation and significant persistence of the obtained results. The author used pneumocompression, electrical muscle stimulation and low-frequency magnetic therapy as therapeutic methods. At the same time, emphasis is placed on the fact that medical rehabilitation of patients should not only be early and comprehensive, but also individual and continuous [19].

Also the work by Grushina T.I. et al. (2015) presents a list of physiotherapeutic techniques that have shown their effectiveness in the treatment of lymphedema. The author included pneumatic compression, electrical neurostimulation of lymphatic drainage, electrical stimulation of the muscles of the shoulder girdle on the side of the operation, and low-frequency electrostatic therapy as such methods [20].

The study by Agranovich N.V. et al. assessed the effectiveness of conservative therapy for postmastectomy syndrome on the example of 105 women. The subjects were divided into 4 representative groups depending on the prescribed rehabilitation treatment complexes including exercise therapy, pressotherapy, LED photomatrix therapy, manual lymphatic drainage massage of the affected upper limb, massage of the cervical-collar region, as well as electrotherapy techniques, in particular, therapy with sinusoidal modulated currents (SMT therapy) and electrostatic massage of the upper limb on the side of the operation, which are used both separately and in combination in different groups. The authors noted a pronounced decrease in the volume of the upper limb in groups where, in addition to the standard regimen, electrostatic massage and SMT therapy were used. The inclusion of additional physiotherapeutic treatment methods in the standard program, in particular, electrostatic massage of the upper limb on the affected side and SMT therapy significantly enhances the therapeutic effect [21].

The study by Blinova K.A. et al. evaluated the effectiveness of a complex of rehabilitation measures for the treatment of moderate postmastectomy syndrome in women after a combined treatment of breast cancer. This study involved 30 patients whose therapy included psychotherapy, bicycle ergometry, various types of massage (pneumo- and lymphatic drainage), whirlpool baths, magnetic therapy, and group exercise therapy. The complex treatment helped to improve the overall well-being and resulted in a decrease in the volume of the upper limb, an increase in the range of motion in the shoulder joint, and restoration of sensitivity in the area of innervation of the axillary nerve on the side of the operation [22].

A similar trend was noted in the work of Sharzhanova N.A. et al., which included 50 patients with secondary lymphedema after combined treatment for breast cancer. A complex medical rehabilitation in this work included in the first group of patients (n = 23) pneumocompression, electrical stimulation of the muscles of the shoulder girdle and magnetic therapy; in the second group, in which pain syndrome prevailed and limitation of movements in the shoulder joint, magnetic and electrotherapy without a pressotherapy were prescribed (27 patients). The procedures were received daily, for 14 days. As a result of a 14-day rehabilitation course, the pain syndrome was eliminated in all patients, and swelling of the soft tissues of the upper limb decreased [23].

The effectiveness of the combined approach, but with the additional prescription of a manual lymphatic drainage in accordance with all international recommendations, was noted in a study by A.M. Stepanova. et al., which describes the results of complex medical rehabilitation of 287 patients with postmastectomy syndrome and lymphedema of varying severity. All the patients were recommended a compression therapy in the form of wearing compression hosiery II–III compression classes during the day or bandaging, while for stage III lymphedema (according to the classification of the International Society of Lymphology — Society of Lymphology, ISL), elastic bandaging with the Mobiderm system was used. In the given work, the compression therapy was combined with an exercise therapy (ET), manual lymphatic drainage, the pressotherapy, a low-frequency

magnetotherapy on the limb area, and a selective vasoactive electrical stimulation. The procedures were carried out for 12–15 days, daily, and the course was repeated after 3 months. The work also compared the effectiveness of a classical compression therapy (compression hosiery/bandaging) with the method of kinesiological taping, which was carried out using a standard decongestant technique (fan technique), in combination with complex rehabilitation (kinesiological taping, n = 15; classical compression therapy — group control, n = 15). Interestingly, the work also evaluated long-term oncological outcomes in 120 patients. The frequency of progression and local relapses was compared in the group receiving comprehensive rehabilitation according to the scheme described above (n = 67) and the control group, which received only compression therapy and exercise therapy (n = 53). The groups were comparable in terms of oncological prognosis and received treatment for breast cancer. Long-term results and survival of patients were calculated using the Kaplan-Meier method. According to the authors, patients with grade 1 lymphedema experienced persistent complete regression of lymphedema in 76 % of cases, which was confirmed by perometry data; the effect persisted for 1.5 years. In the case of lymphedema of the 2nd–3rd degree, during complex rehabilitation, regression of edema was noted by 78.2 ± 4.1 % ($p < 0.03$). In the presence of fibrotic tissues (stages III–IV lymphedema), the additional use of the Mobiderm bandage system led to a «softening» of fibrosis, which made it possible to achieve satisfactory results even in such advanced cases. When comparing groups of patients receiving compression therapy and kinesio taping, along with complex rehabilitation, less effectiveness was noted in the kinesio taping group compared with the control group ($p > 0.05$). When comparing the frequency of progression and local relapses in patients receiving comprehensive rehabilitation according with the above scheme and the control group (compression therapy, exercise therapy), it was noted that the difference in relapse-free survival and progression-free survival in these groups was statistically insignificant (p = 0. 10) [24].

The study conducted by Sidorova D.B. evaluated the effectiveness of the combination of conservative and surgical treatment of secondary lymphedema, namely subcutaneous surgical correction in the rehabilitation of breast cancer patients with advanced lymphedema of the upper limb. The author noted that the complex use of local low-frequency electro- and magnetic therapy, pneumatic compression and subcutaneous surgical correction in patients with late secondary lymphedema of the II–IV degree allows a statistically significant reduction in the excess volume of the edematous limb by an average of 85.9 %, the thickness of the subcutaneous fatty tissue in the hand area by 63.2 %, forearm — by 69.1 %, shoulder — by 49.5 %, regardless of the order of application of conservative methods [25].

Reproductive System

Much research is devoted to tumors of the female reproductive system. The article by Kovalenko N.V. et al. considers comprehensive rehabilitation of patients after a treatment for endometrial cancer. The authors developed and evaluated the effectiveness of a staged medical rehabilitation system for 457 patients after combined treatment for endometrial cancer. Staged medical rehabilitation was carried out in 357 patients (the main group), and 100 patients formed a comparison control group. The first stage of rehabilitation was carried out on an oncology bed and included antibiotic prophylaxis, prevention of thromboembolic complications, psychological support, and exercise therapy. Stages II and III were carried out in the rehabilitation department (24-hour stay and day hospital) and outpatient department. The program of stages II and III included: organization of a daily routine, diet therapy, sessions with a psychologist (individually and in groups), special physical exercises, therapeutic massage/hardware lymphatic drainage massage/electrostatic therapy of the lower extremities, transcranial electrotherapy using a sedative technique, general magnetic therapy, low-intensity cutaneous laser therapy, electrical stimulation (SMT) of the bladder. The number of postoperative inflammatory and urodynamic complications in the main group was minimized to 2.2 % (versus 6 % in the control group), manifestations of post-castration syndrome were observed in 24 % of young patients (versus 95 % in the control group), lymphatic edema of the lower limb/s — in 46 % of patients (versus 75 % in the control group). There was no negative impact of the used methods of physical rehabilitation on the course of the underlying disease. The authors showed that medical rehabilitation of patients after combined treatment for endometrial cancer should be comprehensive and continuous, then it will be effective. The implementation of a sequential transition of patients from the first stage of medical rehabilitation to subsequent ones on the basis of specialized medical organizations allows them to adequately address the issues of their rehabilitation treatment [26].

The article by Vlasina A.Yu. et al. presented a modern view on the rehabilitation of patients with gynecological oncological pathology. Physiological and psychological problems (post-variectomy and pain syndromes, sexual dysfunction, distress, general intoxication, chronic fatigue associated with malignancy) that arise in women after antitumor treatment are considered, and ways to solve them are outlined. Not only traditional methods of correcting complications are covered, but also the possibilities of alternative and adjuvant (auxiliary) therapy. Particular attention was paid to the importance of preventing relapses during the rehabilitation period, emphasizing the need to develop and implement a multidisciplinary approach to this group of patients with the mandatory participation of doctors of different specialties — oncologists, obstetricians-gynecologists, rehabilitation specialists, psychiatrists, psychologists, etc. According to the authors, medication should be combined and non-drug correction methods, develop and implement effective medical rehabilitation programs aimed at normalizing body functions after aggressive treatment of oncogynecological pathology: issues of normalizing hormonal imbalance using probiotics, prebiotics and synbiotics to restore the vaginal biotope, introducing exercise therapy at the stage of medical rehabilitation, and using physiotherapy are considered to normalize body functions in gynecological cancer patients (electrosleep), to improve blood circulation — ultrasound therapy, ascending and circular showers, electrostatic and vacuum massages, the use of methods of psychological rehabilitation of gynecological cancer patients: yoga, rehabilitation of cognitive-behavioral injuries using eye movements, art therapy, hypnotherapy, occupational

therapy, dance therapy. The authors note that it is important to conduct scientific research and familiarize doctors with the possibilities of recovery and resocialization of this category of patients. A correctly selected and implemented set of rehabilitation measures is the key to a high level of quality of life after treatment [27].

The study by Filonenko E.V. et al. evaluated the effectiveness of magnetic laser therapy in the rehabilitation of 78 patients with cervical cancer during the period of radiotherapy. According to the results obtained, the use of this technique during the radiation therapy resulted in radiation reactions in 24 (31 %) of 78 patients. When a concomitant magnetic laser therapy was used, radiation reactions corresponded to a predominantly mild degree of severity (stage I reactions were observed in 16 (21 %) patients, stage II — in 8 (10 %)), which made it possible to carry out the entire course of radiation therapy in 73 out of 78 patients in the planned volume and without interruptions [28].

The article by Berdichevsky B.A. et al. reviewed the rehabilitation of the functional state of the lower urinary tract after combined radiation treatment for cervical cancer. The effectiveness of various schemes for drug rehabilitation of lower urinary tract dysfunction was analyzed using the example of combined radiation treatment for cervical cancer. Clinical, laboratory and morphofunctional studies were carried out during radiation treatment and 12 months from the start of medical rehabilitation of post-radiation complications. The data obtained indicate a certain effectiveness of various schemes of drug protection of the tissue structures of the lower urinary tract from radiation exposure, however, only its combination with instillation of the bladder with a drug containing hyaluronic acid (Uro-hyal) allows achieving more effective medical rehabilitation, ensuring an acceptable quality for patients life. At the same time, instillation of the bladder with preparations containing hyaluronic acid (Urogyal) turned out to be the most effective [29].

Quite a few studies in our country have been devoted to the problems of medical rehabilitation of patients with cancer and urinary dysfunction. So, the work by Orlov A.E. et al. assessed the effectiveness of medical rehabilitation of prostate cancer patients suffering from urinary incontinence. The study included 152 patients, divided into 2 groups. Some of them (n = 74) underwent neuromuscular electrical stimulation for 10 days in order to strengthen weakened bladder muscles and improve urinary control. The second group (78 patients) received neuromuscular stimulation procedures in combination with a course of specialized physical therapy. The authors noted that the implementation of a therapeutic complex including neuromuscular electrical stimulation and specialized exercise therapy (with continued implementation of the complex daily at home) had a more pronounced effect than the effect of electrical stimulation alone [30].

Head and Neck

Head and neck tumors remain the subject of active study from the point of view of medical rehabilitation. So, the study by Kozlov S.V. et al. included 94 patients operated on for thyroid cancer. All the patients were divided into 2 groups, representative by age, stage of the disease, extent of surgical intervention and nature of concomitant pathology. The main group consisted of 48 people, the control group — 45 people. All the patients of the main group, along with standard methods of breathing exercises, underwent: medicinal inhalation therapy (solutions of ambrobene, lazolvan, fluimucil, tinctures of calendula and eucalyptus), light therapy in the area of postoperative sutures, cutaneous projection of the larynx, areas of the neck on the right or left with lateral lymph node dissection. In case of hypertension in patients of the main group, a low-frequency magnetic therapy was prescribed to the collar area. Transcranial electrical stimulation was prescribed to 10 patients with severe pain, sleep disorders and complaints of a depressed emotional state. In addition, the patients in the main group underwent psychocorrectional sessions with a psychologist. In addition to breathing exercises, the patients in the second (control) group were prescribed only drug inhalation therapy with the above medications for the same period. The treatment effectiveness was assessed clinically at the end of the course of procedures, which were carried out daily, for 10 days. The authors noted a significant positive effect of complex rehabilitation measures in the form of restoration of voice, disappearance of sore throat and discomfort when swallowing, regression of soft tissue swelling in the surgical area, stabilization of arterial blood, restoration of skin sensitivity and reduction of neurological symptoms, normalization of sleep and emotional status to a greater extent compared to the control group. Also, in the first group, the rate of postoperative scar formation was three to four days longer than in patients of the second group. There were no complications during treatment in both groups, which allowed the patients to complete their stay in the surgical hospital in a timely manner and begin in an adapted physical and psychological state. According to the data obtained by the authors, the individuals in the main group had higher quality of life scores on the scales of physical functioning (FF, p = 0.001), vital activity (V, p = 0.01) and lower pain intensity scores (B, p = 0.01), which indicates a better state of physical health. The results of the study indicate that the quality of life of patients in the main group is significantly higher than that of the control group [31].

Voice-speech rehabilitation of patients with OHSS continues to develop in the Russian Federation and more and more studies are devoted to this issue. The article by Krasavina E.A. et al. examined the possibilities of speech rehabilitation of patients with cancer of the oral cavity and oropharynx after reconstructive plastic surgery. The study included 56 patients with cancer of the oral cavity and oropharynx, stages II–IV, who received combined treatment and speech rehabilitation in the Oncology Research Institute of Tomsk National Research Medical Center between 2012 and 2019, which included five stages: rational psychotherapy; breathing exercises; articulatory gymnastics for the muscles of the cheeks and lips; articulatory gymnastics for the tongue; correction of sound pronunciation disorders. Speech rehabilitation in this work began on days 16–32 after the operation. At the first stages, the aim of the exercises was to restore the activity and coordination of the muscles of the articulatory apparatus, speech exhalation and the reconstructed tongue, and then they began to correct sound pronunciation. Postoperative speech rehabilitation made it possible to improve the state of speech function in 100 % of cases (56 patients); a complete restoration of speech was achieved in 7 patients (12.5 %) [32].

Other Localizations

Medical rehabilitation of orthopedic cancer patients is an urgent topic today, since primary bone tumors develop in patients of the working age. In addition, this service for patients in this category is currently paid for by the DRG «medical rehabilitation of oncological orthopedic patients».

The work by T.I. Grushina et al. included 36 patients (16 men, 20 women) aged from 19 to 67 years (mean age — 42 years) with primary malignant and metastatic tumors of the long bones. Endoprosthetics (EP) with the inclusion of a reconstructive plastic component of the knee joint was performed in 17 patients, hip joint — 13, shoulder joint — 5 and elbow joint — 1 patient. At the stage of pre-rehabilitation, medications (low-molecular forms of heparin, etc.) were used to prevent disorders of the hemostatic system and associated thrombotic complications. From the first day after surgery, in the scope of endoprosthetics of long bones and joints with the inclusion of a reconstructive plastic component, pharmacotherapy was carried out (anticoagulants, antibiotics, analgesics (including epidural anesthesia), muscle relaxants, neuroprotectors and sedatives), exercise therapy according to developed special methods, after which passive resection of the operated joint using the Artromot mechanotherapeutic device, local low-frequency magnetic therapy on the operation area, local low-intensity infrared laser radiation, multi-channel low-frequency electrical stimulation of the muscles of the operated limb. The authors noted that the combined use of a reconstructive plastic component with radical surgery and physical therapy made it possible to obtain a good functional result on the MSTS scale in 63.9 % of patients at the time of discharge, and in 36.1 % of patients. Early activation of patients also became possible, significantly shortening their stay in the surgical department; the period of activation was 1–9 days (Me 4.2 days), the average bed day was 13 (9–17) days [33].

More recent studies have confirmed the need for early activation of this category of patients. A study in P.A. Herzen Moscow Research Institute of Oncology carried out an analysis of stage I rehabilitation measures in 32 patients with primary and metastatic lesions of the long tubular bones and axial skeleton, who received surgical treatment of varying extent. 18 (56 %) patients underwent resection of long tubular bones with endoprosthetics of large joints (group 1), 14 (44 %) patients underwent decompressive and stabilizing operations on the spine and sacrum (group 2). For all patients, from the first day after surgery, isometric exercises began, including on the operated limb, exercises on the distal parts of the upper and lower extremities, and breathing exercises with an emphasis on diaphragmatic breathing. Subsequently, the exercise therapy complex expanded depending on the characteristics of the operation. In the group of patients who underwent decompression and stabilization surgery, from the first day after surgery, isometric exercises for all major muscle groups, breathing exercises with an emphasis on diap hragmatic breathing, and exercises for the distal parts of the upper and lower extremities began. From the second day, active and, if necessary, active-passive exercises were started on the main muscle groups of the upper and lower extremities with a gradual increase in the intensity of the loads and a change in starting positions. In the presence of a neurological deficit, postural correction techniques, active (lightweight) exercises on the lower extremities, and passive gymnastics were additionally used. The timing of activation and verticalization, their technique in the early postoperative period differed depending on the level of surgery. The group of patients who underwent organ-preserving surgeries on the limbs showed positive dynamics in their general condition after completing the course of medical rehabilitation. There was a pronounced positive dynamics in the general status, improvement in motor function, and an increase in the range of motion in the operated joint [34].

The study by Ivanov V.E. et al. reviewed the medical rehabilitation of cancer patients after endoprosthetics of large joints. Functional rehabilitation included passive development of the operated joint, block therapy, and hydrokinesitherapy. The study included 70 patients (20 (29 %) children aged 11 to 18 years, 50 (71 %) adults). The average assessment of limb function after hip arthroplasty was 72 %, after knee arthroplasty in patients with a tumor of the distal femur — 83 %, after replacement of the proximal bone — 76 %, after total femoral arthroplasty — 67 %. Functional results after ankle replacement were 83 %, and after reconstructive interventions on the humerus they were 80 %. The authors note the need for further development of methods of medical rehabilitation of orthopedic cancer patients in specialized departments [35].

There are studies dealing with the rehabilitation of disseminated patients. Such as the work by Stepanova A.M. et al. that analyzed the influence of early postoperative rehabilitation on the functional results of patients with metastatic tumors of the axial skeleton using the example of 289 patients who received decompressive, decompressive and stabilizing operations on the spine and sacrum. The patients were divided into two groups: those receiving early postoperative comprehensive rehabilitation (n = 169 (study group)) and the control group (no rehabilitation (n = 120)). The groups were comparable in terms of neurological status and pain intensity at the start of medical rehabilitation. In addition to exercise therapy, from the first day after the surgery, in the absence of thrombosis of the veins of the lower extremities, all the patients were prescribed massage of the lower extremities and electrotherapy from the third day. In the case of using a plastic component, moving flaps during operations on the sacrum, the volume of rehabilitation was supplemented from fifth day after the surgery with low-intensity laser therapy (LILT) and low-frequency magnetotherapy (LFMT) from the third day after the surgery. The author noted the positive dynamics of pain syndrome, frequency of pain relief, general condition and quality of life [36].

There are few studies on the medical rehabilitation of patients with central nervous system tumors all over the world, but our rehabilitation specialists pay great attention to this pathology. The work by E.A. Bukreeva et al. examined the medical rehabilitation of children with tumors of the central nervous system. According to the authors, comprehensive rehabilitation measures are necessary to facilitate the restoration and maintenance of the patient's physical performance, as they are of great importance for improving the quality of life and progressive development of a child who has suffered from cancer. The study included 54 children

aged from 7 months to 14 years; among children with ataxia older than one and a half years, 31 (57.4 %) patients were assessed by the Hauser Walking Index with a mean score of 2.8 ± 0.22, SD = 1 ,24, Me = 4.00, [2.00; 3.00]. When assessed after medical rehabilitation, the mean score increased to 3.8 ± 0.20, SD = 1.16, Me = 3.0, [3.00; 5.00]. It was concluded that the combination of physical rehabilitation methods used by the authors can be used not only in a hospital setting, but also at the 2nd and 3rd stages of medical rehabilitation, which is of absolute practical significance and allows minimizing the consequences of special treatment and, as a consequence, improve the quality of life of children and their parents [37].

Medical Rehabilitation in Health Resorts

In our country, there are not many studies with a particular focus on sanatorium-resort treatment of patients with cancer.

A large study by M.G. Estenkova et al. evaluated the effectiveness of sanatorium-resort treatment for 348 people with different localizations of oncological pathology: gastrointestinal tract — 57, respiratory organs — 17, mammary gland — 76, female genital organs — 52, male genital organs — 41 people, the duration of the diseases varied from several months to 23 years. The programs of sanatorium-resort treatment in this category included technologies such as climate and landscape therapy, drinking mineral water, indifferent isothermal baths, therapeutic swimming, exercise therapy in the hall and pool, walking along the health path, inhalation therapy, certain types of hardware physiotherapy (low-frequency magnetic therapy, pressotherapy, lymphatic drainage procedures, sinusoidal modulated currents), diet therapy, psychotherapy. The authors noted an improvement in the general condition of patients, restoration of impaired functional indicators, and a pronounced psychotherapeutic effect of sanatorium-resort treatment associated with a decrease in psychosomatic manifestations and an increase in resistance to various stress factors [38].

Another study conducted by Yanchenko T.S. considered sanatorium-resort treatment of children in the period of remission of oncohematological and oncological diseases, taking into account the psychosomatic status. The work applies a differentiated approach to the use of a combination of various technologies of sanatorium-resort treatment, taking into account disorders of the psychosomatic status, concomitant diseases during the period of remission. Sanatorium-resort treatment for children contributed to a 1.6-fold reduction in negative psycho-emotional manifestations and an improvement in interpersonal relationships in the children's team. In addition, this study noted that the use of drinking courses of mineral water from the Kremenchug deposit (packaged) and bicarbonate-chloride-sodium water from the Evpatoria deposit (pump room) in children during the period o remission of cancer contributed to the restoration of metabolic processes, reducing the increased activity of the glycolytic enzyme LDH ($p < 0.05$), improvement of the state of intestinal microflora. The feasibility of prescribing electrosleep therapy and chamber whirlpool baths is confirmed by the formation of a regulatory effect on the state of mental health and sympathetic-adrenal processes, strengthening the compensatory capabilities of the body [39].

The work by Khudoev E.S. et al. conducted a review of medical rehabilitation of patients after combined treatment of breast cancer in a sanatorium-resort institution. Sanatorium-resort treatment is considered as an option for medical rehabilitation, indications and contraindications, late stage of medical rehabilitation, physical therapeutic resort factors for this category of patients. The authors note that medical rehabilitation at a resort is an insufficiently developed problem; approaches to its solution proposed by various authors are not widely used in practice. The authors emphasize that the medical rehabilitation program for this category of patients must be comprehensive, and rehabilitation measures must begin from the moment the diagnosis is made with the participation of a team of specialists, including an oncologist, psychologist, physiotherapist, physical therapy instructor and prosthetist [40].

The study by Meltsev E.M. et al. evaluated the effectiveness of spa treatment in 215 children receiving programme therapy for haemoblastosis and 32 children operated for thyroid cancer who were in remission. The author studied the long-term (after 1–3–5 years) results of the proposed complex in 42 children with hemoblastosis, 14 of them with a 3-time annual stay at the Evpatoria resort and 13 children with thyroid cancer. The complex carried out involved the influence of natural healing factors on the entire body as a whole with maximum rehabilitation of the immune, hormonal, skeletal systems and psycho-emotional sphere. The authors concluded that prescribing a course of medical rehabilitation in a sanatorium-resort organization for children with cancer pathology in remission is justified, as evidenced by the improvement in the general condition of children, the positive dynamics of clinical symptoms, a decrease in the number of colds during the period after recovery, and an improvement in indicators characterizing adaptive capabilities body, immune reactivity, hormonal mirror, antioxidant protection, psycho-emotional sphere, as well as the absence of complications and relapses [41].

CONCLUSION

Recovery of a cancer patient should be aimed not only at eliminating the disease itself and restoring the physical functions of the body, but also at the most acceptable restoration of a person's ability to live in conditions of the disease and after it. Rehabilitation is carried out through the efforts of various specialists, who in their work need to consider the condition of the cancer patient and the characteristics of his personality. As the international guidelines increasingly recommend the development of patient rehabilitation programs, it is important to understand the experiences of oncology physiotherapists to assist in the development of effective oncology physiotherapy services. Sanatorium-resort and rehabilitation treatment of patients after oncology care needs investment and advocacy to ensure optimal care for all patients with cancer and meet standards of care. Improving rehabilitation care in accordance with recommendations can have a significant impact on the functioning and quality of life of oncological patients.

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Review
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The Role of Continuity in the Provision of Medical Care to Patients Diagnosed with Coronary Heart Disease

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ABSTRACT

INTRODUCTION. More than 36 million people die from NCDs each year (63 % of deaths worldwide), of which 14 million people die prematurely, that is, before the age of 70 years, the majority could be prevented through the organization of continuity and consistency in the organization of health care. In 2021, based on the experience of developed countries of the world, a standard form of the «Algorithm» for patient care in an outpatient setting after hospital treatment was developed (including stages of observation, periods of clinical examination and mechanisms for organizing rehabilitation services, including diet, exercise therapy and sanatorium-based treatment). A study was conducted among patients diagnosed with coronary heart disease regarding the organization of continuity and consistency of rehabilitation services after inpatient treatment in conditions outpatient clinics in the Yakkasaray district of Tashkent.

AIM. To study the practice of applying the organization of continuity and consistency in the provision of medical care for NCDs in Uzbekistan.

MATERIALS AND METHODS. The materials were the results of a study of patients diagnosed with coronary heart disease in 2021 — 537 patients and in 2022 — 596 patients in the Yakkasaray district of Tashkent. Retrospective, analytical research methods were used for the analysis.

RESULTS. In 2021, a total of 537 patients diagnosed with coronary heart disease received inpatient treatment in family clinics of the Yakkasaray district, and only 195 (36 %) brought discharge summaries, 195 (100 %) patients were taken for treatment as prescribed by doctors at outpatient clinics — control, 173 (88 %) 10 (5 %) underwent ECG and EchoCG, respectively, and 12 (6 %) patients were sent to sanatorium treatment. In 2022, in family clinics of the Yakkasaray district, a total of 596 patients received inpatient treatment, of which 535 (89 %) brought a discharge summary of inpatient treatment, 535 (100 %) patients were taken for D-control as prescribed by doctors from outpatient clinics, 535 (100 %) active patronage was established with an explanation of proper nutrition, physical activity, physiotherapeutic treatment, and 84 (16 %) patients were sent to sanatorium treatment.

CONCLUSION. Continuity and consistency are important in improving the quality of medical care, so healthcare organizers need to introduce new methods and improve existing approaches to improve the relationship between inpatient and outpatient clinics.

KEYWORDS: continuity, extract from medical records, coronary heart disease.

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Непрерывность как основной принцип работы учреждений первичной медицинской помощи пациентам с ишемической болезнью сердца

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РЕЗЮМЕ

ВВЕДЕНИЕ. Ежегодно от неинфекционных заболеваний умирает более 36 млн. человек (63 % смертей в мире), из них 14 млн человек умирают преждевременно, т.е. в возрасте до 70 лет, причем большую часть можно было бы предотвратить путем обеспечения непрерывности и последовательности в организации медицинской помощи.

ОБСУЖДЕНИЕ. В 2021 г. на основе опыта развитых стран мира была разработана стандартная форма алгоритма ведения пациента в амбулаторных условиях после стационарного лечения (включающая этапы наблюдения, периоды диспансеризации и механизмы организации реабилитационных услуг, в том числе диеты, лечебной физкультуры и санаторно-курортного лечения). Проведено исследование среди пациентов с диагнозом ишемической болезни сердца по организации преемственности и последовательности реабилитационных услуг после стационарного лечения в условиях амбулаторно-поликлинических учреждений Яккасарайского района г. Ташкента.

ЦЕЛЬ. Изучить практику применения организации непрерывности и последовательности оказания медицинской помощи при неинфекционных заболеваниях в Узбекистане.

МАТЕРИАЛЫ И МЕТОДЫ. Материалом послужили результаты исследования больных с диагнозом ишемической болезни сердца в 2021 г. — 537 пациентов и в 2022 г. — 596 пациентов в Яккасарайском районе г. Ташкента. Для анализа использовались ретроспективный, аналитический методы исследования.

РЕЗУЛЬТАТЫ. В 2021 г. в семейных клиниках Яккасарайского района на стационарном лечении находилось 537 пациентов с диагнозом ишемической болезни сердца, из них только 195 (36 %) пациентов имели при себе выписки из истории болезни, 195 (100 %) пациентов были приняты на лечение по назначению врачей в амбулаторных клиниках — контроль, 173 (88 %) 10 (5 %) пациентов прошли ЭКГ и ЭхоКГ соответственно, 12 (6 %) пациентов были направлены на санаторно-курортное лечение. В 2022 г. в семейных клиниках Яккасарайского района стационарное лечение получили 596 пациентов, из них 535 (89 %) принесли выписки о стационарном лечении, 535 (100 %) пациентов были взяты на D-контроль по назначению врачей из амбулаторных клиник, над 535 (100 %) был установлен активный патронаж с разъяснением правильного питания, физической активности, физиотерапевтического лечения, 84 (16 %) пациента были направлены на санаторно-курортное лечение.

ЗАКЛЮЧЕНИЕ. Непрерывность и последовательность важны для повышения качества медицинской помощи, поэтому организаторам здравоохранения необходимо внедрять новые методы и совершенствовать существующие подходы для улучшения взаимоотношений между стационаром и поликлиникой.

КЛЮЧЕВЫЕ СЛОВА: непрерывность, выписка из медицинской карты, ишемическая болезнь сердца.

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INTRODUCTION

According to the World Health Organization (WHO), noncommunicable diseases (NCDs) (cardiovascular diseases, cancer, chronic respiratory diseases and diabetes) are the leading causes of death in the world. More than 36 million people die from NCDs each year (63 % of global deaths), of which 14 million die prematurely, that is, before the age of 70 years. Low- and middle-income countries already bear about 80 % of the burden of such premature mortality, which is attributable to the four most common risk factors—tobacco use, unhealthy diet, physical inactivity and harmful use of alcohol and is largely preventable. According to expert forecasts, if current trends continue, by 2030 the NCD epidemic will claim 52 million human lives annually [1–3]. This situation poses a threat not only to human health, but also to development and economic growth. NCDs cost billions of dollars in national income, and rising health care costs push millions of people into poverty every year. For all countries, the cost of inaction significantly exceeds the costs of action, but developing countries suffer the most [2–4].

Considering the prevalence of NCDs among patients, in particular those diagnosed with coronary heart disease and type 2 diabetes mellitus, issues of continuity in the management of such patients are currently relevant. Namely: timely provision of assistance at the outpatient stage, avoidance of duplication of measures, early, effective rehabilitation, which begins already at the inpatient stage of patient treatment. The main goal of rehabilitation is to adapt disabled people and people who have temporarily lost their ability to work to normal life through a series of special measures. Secondary prevention of coronary heart disease and type 2 diabetes mellitus has a significant

impact on the long-term outcome of patients, helps reduce disability, reduce temporary disability, reduces the risk of repeated exacerbations and improves quality of life and level of health [5].

Continuity is one of the basic principles of the work of medical institutions. Continuity in healthcare means the implementation of uniform tactics in the treatment of people, medical care of the population in various medical institutions in order to achieve a single strategic goal — restoration (preservation) of health, especially for patients with chronic non-infectious diseases, such as coronary heart disease and type 2 diabetes mellitus. The significance of the problem of continuity between polyclinics and hospitals in the examination, diagnosis and treatment of patients increases in the conditions of restructuring of medical and preventive care, increasing the role of its primary care, prospects for the development of general medical (family) practice, giving polyclinics the status of centers of diagnostic, consultative and specialized care, development of a network intensive care units in outpatient settings [6–8].

As we know, for patients, continued treatment in an outpatient setting after discharge from hospital is essential. At the same time, in our opinion, the discharge summary from the medical history should describe in more detail issues related to diet, physical activity and disease prevention, as well as possible complications and risks of readmission. In this regard, in 2021, we developed a standard form of the «Algorithm» for patient care after inpatient treatment (including stages of observation, periods of clinical examination and mechanisms for organizing rehabilitation services, including diet, exercise therapy and sanatorium treatment). After a discussion with specialists at the Tashkent City Main Directorate of Health Care, an appeal was sent to the Republican Specialized Medical Centers so that they could help develop «Algorithms for patient care in outpatient clinics», according to their profile of patients and the approximate form we presented for the main and most common diseases. Over the next 3 months, algorithms were received from republican specialized medical centers for 11 major diseases (Table 1).

Algorithm of the Outpatient Follow-Up of Patients after the Inpatient Treatment Diagnosed with Coronary Heart Disease

I. General Definition of the Disease

Coronary heart disease is a common disease of the cardiovascular system; is accompanied by myocardial ischemia and coronary circulation disorders. Coronary heart disease (CHD) is mainly caused by the lack of blood circulation in the heart muscles as a result of atherosclerosis of the coronary (coronary) arteries, and because of this, the heart does not receive blood. Coronary heart disease includes angina pectoris (initial, stable, unstable), myocardial infarction, post-infarction cardiosclerosis, arrhythmic type and heart failure. Coronary heart disease is a serious heart disease that develops regularly. As a person grows older, the incidence of disease increases. CHD is clinically variable, intermittent and intermittent. Often, the ischemic heart disease goes away, and the patient does not know that he has such a dangerous disease and does not consult a doctor. Usually, one of the first clinical signs of the ischemic heart disease is an attack of angina pectoris, which occurs during physical work or a mental stress. Later, the disease can last a long time, even years. Its severe manifestations include an acute coronary syndrome, an acute myocardial infarction and a sudden death.

The factors affecting the development of CHD are as follows:

- Overweight, metabolic diseases, endocrine diseases, sedentary lifestyle;
- experiencing regular emotional stress, depression, tragic events, loss of loved ones;
- strong nervous tension due to problems at work;
- genetic predisposition;

Table 1. Algorithms for patient care after inpatient treatment in outpatient clinics

No.	Name of algorithms
1	Algorithm for outpatient observation of patients after hospital treatment with a diagnosis of «Chronic obstructive pulmonary disease»
2	Algorithm for outpatient monitoring of patients after hospital treatment with a diagnosis of bronchial asthma
3	Algorithm for outpatient monitoring of patients after hospital treatment with a diagnosis of Pneumonia
4	Algorithm for outpatient monitoring of patients after hospital treatment with a diagnosis of liver cirrhosis
5	Algorithm for outpatient monitoring of patients after hospital treatment with a diagnosis of «Coronary heart disease»
6	Algorithm for outpatient monitoring of patients after hospital treatment with a diagnosis of hypertension
7	Algorithm for outpatient monitoring of patients after hospital treatment with a diagnosis of «Chronic heart failure»
8	Algorithm for outpatient monitoring of patients after hospital treatment with a diagnosis of «Chronic renal failure»
9	Algorithm for outpatient monitoring of patients after hospital treatment with a diagnosis of «Neurogenic bladder»
10	Algorithm for outpatient monitoring of patients after hospital treatment with a diagnosis of «Prostatic hyperplasia»
11	Algorithm for outpatient monitoring of patients after hospital treatment with a diagnosis of urolithiasis

- age-related changes in blood vessels;
- high level of cholesterol in the blood, as a result of which atherosclerotic plaques and accumulations are formed in the walls of blood vessels;
- harmful habits (smoking, alcohol consumption).

II. The Sequence of Activities Performed in an Outpatient and Polyclinic Facility

In order to prevent attacks and ensure the provision of a quality medical care to the patient, to ensure the performance of the following measures in the ambulatory-polyclinic setting for patients treated in the hospital with this diagnosis:

- taking the patient under «D» control in a timely manner and determining the annual rehabilitation measures;
- monthly cardiologist check-up (ECG, EchoCG, coagulogram, determination of blood lipids every 3 months). If necessary, correction of drugs and their dosages;
- 2 times a year medical examination by specialists in a narrow field;
- organization of active patronage every month;
- formation of a nutritional diet for the patient (increased consumption of foods containing vegetable fiber and dairy products, limiting the consumption of meat and fatty foods, reducing the consumption of bran and additives that stimulate intestinal motility in foods, on average, 1,5-2 per day of the patient drinking a liter of liquid (counting with the first meal), consuming kefir from juices, ginseng tea, dried fruit compotes and dairy products;
- during the treatment of patients with drugs, the prevention and further development of CHD, as well as other symptomatic (if necessary) drug therapy (if the doses and drugs are indicated); (antiaggregants, beta-blockers, statins, ATP inhibitors, if necessary, calcium antagonists, trimetadizine);
- recommend physical therapy physical therapy, dosed walking according to an individual and customized plan to patients with CHD;
- psychotherapy, hyperbaric oxygenation, electric sleep, laser, acupuncture and massage methods should be used;
- to recommend sanatorium treatment according to the profile once a year.

Meals at CHD

First of all, products containing «bad» cholesterol and a large amount of salt should be excluded from the daily diet. To them:

- fatty meat;
- fried foods;
- smoked products;
- includes pickles.

In addition, it is useful to eat bread kept for a day or two, instead of fresh bread taken from the oven. More foods that are rich in vitamins, minerals and help fight disease should be included in a daily diet.

Patients are sent to sanatoria (Turon, Botanika, Boston, Chortoq, Kohinur, Yangier, Khanka, etc.), https://sihatgoh.uz.

After collecting and combining the «Algorithms» into methodological recommendations, in accordance with the letter of the Main Department of Health Care of Tashkent No. 01/1848 dated June 16, 2022, the Yakkasaray District Medical Association of Tashkent was sent to conduct an experiment, putinto practice «Algorithms for patient care after inpatient treatment in outpatient clinics», summarizing the results and conducting a comparative analysis with the control group. Among the workers of outpatient clinics in the Yakkasaray district, explanatory work was carried out on the use of «Algorithms for patient care after inpatient treatment in outpatient clinics», including the «Algorithm for outpatient monitoring of patients after inpatient treatment with a diagnosis of coronary heart disease» during seminar classes. In addition, an instruction was sent that all medical and preventive institutions operating in the territory of Tashkent, regardless of the form of ownership and departmental affiliation, must send discharge summaries of patients from the medical history to outpatient clinics at their place of residence.

AIM

To study the practice of applying the organization of continuity and consistency in the provision of medical care for NCDs in Uzbekistan.

MATERIALS AND METHODS

The materials were the results of a study of patients diagnosed with coronary heart disease in 2021 — among 537 patients and in 2022 — 596 patients in the Yakkasaray district of Tashkent. Retrospective, analytical research methods were used for the analysis. Based on outpatient records, patients diagnosed with coronary heart disease were divided into 2 groups, 1 group of patients who submitted a discharge summary and 2 group of patients who did not submit a discharge summary to the family doctor. Analysis and study of outpatient records was carried out to determine clinical examination, follow-up of patie nts and rehabilitation measures according to a specially developed table. Based on the results of the study, the data obtained were grouped and entered into a special program, Microsoft Excel-2021.

RESULTS

To conduct and analyze comparative results, we retrospectively studied the results of organizing medical care for patients after inpatient treatment in outpatient clinics in the Yakkasaray region. According to the data, in 2021, a total of 57, 58, 59, 60 family clinics received inpatient treatment for 537 patients diagnosed with coronary heart disease. Of these, 195 (36 %) brought a discharge summary from hospital treatment, 195 (100 %) patients were taken for D-control, they were consulted with a cardiologist, diagnostic studies were carried out (ECG, EchoCG, coagulogram, lipids), active patronage was established with explaining questions regarding proper nutrition, physical activity, physiotherapeutic treatment, and 12 (6 %) patients were referred to sanatorium and resort institutions (SRI) (Table 2).

At the same time, having studied the results for 2022 in 57, 58, 59, 60 family clinics, we obtained the following results. A total of 596 patients in the Yakkasaray district with a diagnosis of coronary heart disease received inpatient treatment, of which 535 (89 %) brought discharge summaries after inpatient treatment. 535 (100 %) patients were taken for D-control, they were consulted with a cardiologist, diagnostic studies were performed (ECG, EchoCG, coagulogram, lipids), active patronage was established with an explanation of proper nutrition, physical activity, 89 (17 %) received physiotherapy treatment and 84 (16 %) patients were referred for SRI (Table 3).

Table 2. Results of the organization of medical care for patients diagnosed with coronary artery disease after inpatient treatment in outpatient clinics in the Yakkasaray region (data for 2021)

Family clinics	Total treated in inpatient facilities	Including **NOT REPRESENTED** discharge summary (quantity)	Including						Active patronage	The recommendations presented on			Read in sanatorium
			D medical examination	Passed a cardiac examination	Diagnostic and laboratory tests								
					ECG	EchoCG	Coagulogram	Lipids		Proper nutrition	Physical activity	Physiotherapy	
57	74	58	10	10	10	1	0	0	10	10	10		0
58	186	102	24	24	24	2	0	0	24	24	24		1
59	215	134	32	32	32	3	0	0	32	32	32		2
60	62	48	8	8	8	1	0	0	8	8	8		0
Total for Yakkasaray district	**537 (64%)**	**342 (22%)**	**74 (22%)**	**74 (22%)**	**74 (22%)**	**7 (2%)**			**74 (22%)**	**74 (22%)**	**74 (22%)**		**3 (1%)**

Family clinics	Total treated in inpatient facilities	Including **REPRESENTED** discharge summary (quantity)	Including						Active patronage	The recommendations presented on			Read in sanatorium
			D medical examination	Passed a cardiac examination	Diagnostic and laboratory tests								
					ECG	EchoCG	Coagulogram	Lipids		Proper nutrition	Physical activity	Physiotherapy	
57	74	16	16	12	12	2	0	0	16	16	16		2
58	186	84	84	75	75	3	0	0	84	84	84		4
59	215	81	81	76	76	4	0	0	81	81	81		4
60	62	14	14	10	10	1	0	0	14	14	14		2
Total for Yakkasaray district	**537**	**195 (36%)**	**195 (100%)**	**173 (88%)**	**173 (88%)**	**10 (5%)**			**195 (100%)**	**195 (100%)**	**195 (100%)**		**12 (6%)**

Table 3. Results of the organization of medical care for patients diagnosed with coronary artery disease after inpatient treatment in outpatient clinics in the Yakkasaray region (data for 2022)

Family clinics	Total treated in inpatient facilities	Including **NOT REPRESENTED** discharge summary (quantity)	Including						Active patronage	The recommendations presented on			Read in sanatorium
			D medical examination	Passed a cardiac examination	Diagnostic and laboratory tests								
					ECG	EchoCG	Coagulogram	Lipids		Proper nutrition	Physical activity	Physiotherapy	
57	97	14	13	9	4	2	4	3	13	13	13	0	2
58	178	13	eleven	3	3	2	0	0	13	13	13	0	0
59	214	10	8	4	4	1	0	0	8	8	8		
60	107	24	21	19	19	9	7	3	21	21	21	2	3
Total for Yakkasaray district	**596**	**61 (10%)**	**53 (87%)**	**35 (57%)**	**35 (57%)**	**14 (23%)**	**11 (18%)**	**6 (10%)**	**55 (90%)**	**55 (90%)**	**55 (90%)**	**2 (3%)**	**3 (5%)**

Family clinics	Total treated in inpatient facilities	Including **REPRESENTED** discharge summary (quantity)	Including						Active patronage	The recommendations presented on			Read in sanatorium
			D medical examination	Passed a cardiac examination	Diagnostic and laboratory tests								
					ECG	EchoCG	Coagulogram	Lipids		Proper nutrition	Physical activity	Physiotherapy	
57	97	83	83	65	65	28	34	thirty	83	83	83	28	22
58	178	165	165	154	154	21	78	78	165	165	165	17	3
59	214	204	204	185	204	15	40	40	204	204	204	42	56
60	107	83	83	39	39	9	7	3	83	83	83	2	3
Total for Yakkasaray district	**596**	**535 (89%)**	**535 (100%)**	**443 (83%)**	**462 (92%)**	**73 (14%)**	**159 (30%)**	**151 (28%)**	**535 (100%)**	**535 (100%)**	**535 (100%)**	**89 (17%)**	**84 (16%)**

In addition, a study was conducted for the control group in outpatient clinics in the Bektemir and Sergeli districts. If in the 69th family clinic in the Bektemir region, 450 patients received inpatient treatment with a diagnosis of «Coronary Heart Disease», 115 (25%) patients received a discharge summary and underwent medical examination, of which 105 (91%) patients underwent control ECG studies, 27 (23 %) EchoCG, 30 (26%) coagulogram, 25 (22%) patients underwent lipid spectrum analysis. Of the 445 people who underwent inpatient treatment, 396 (89%) patients received active patronage, of which 345 (87%) received advice on proper nutrition, 245 (62%) on physical activity, 161 (41%) received physiotherapeutic treatment. In 12 and 13 family clinics of the Sergeli district, 346 patients received inpatient treatment with a diagnosis of «Coronary Heart Disease», 333 (96%) patients submitted discharge summaries to the family doctor, of which 328 (98%) patients underwent control ECG studies, 207 (62 %) EchoCG, 212 (64%) patients underwent a coagulogram and 76 (23%) patients underwent a study of lipid composition. Of the 333 persons who underwent inpatient treatment, 333 (100%) patients received active patronage, received advice on proper nutrition and physical activity, and 161 (41%) received physiotherapeutic treatment.

CONCLUSION

Thus, after carrying out outreach work on the need to collect discharge summaries of patients who received inpatient treatment, conducting outreach work on the implementation of «Algorithms for patient care after inpatient treatment in outpatient clinics» among family doctors on the organization of rehabilitation services for patients with coronary artery disease heart, as well as conducting retrospective data, it was revealed that from 36% (2021) to 89% (2022) the number of people who submitted discharge epicrisis to the family doctor increased, in absolute numbers the number of those registered as «D» increased from 195 (2021) increased to 535 (2022), the number of patients who were examined by a cardiologist from 173 (2021) increased to 443 (2022), cases of ECG increased from 173 (2021) to 462 (2022) and EchoCG from 10 (2021) to 73 (2022), as well as active patronage, consultations on proper nutrition, physical activity from 195 (2021) increased to 535 (2022), and from 12 (6%) in 2021 to 84 (16%) in 2022, patients were sent for sanatorium treatment.

ADDITIONAL INFORMATION

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