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Research Article

Efficacy of a Pulsed Electromagnetic Field in Accelerating COVID-19 Clearance: Phase II Clinical Trial Results

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Abstract

The COVID-19 pandemic necessitated innovative approaches for effective treatment and rehabilitation of patients. This study explores the use of pulsed electromagnetic field (PEMF) therapy, traditionally employed in physiotherapy, for clearing the virus from the human oro- and naso-pharynx. This paper reports on a randomized Phase II clinical trial evaluating this approach. In the trial, PEMF therapy was administered for five consecutive days, with a regime of 15-minute exposure followed by 15-minute breaks, totaling at least 4 hours daily. The therapy operated at 50 Hz and 1.5 μT, with peak electrode voltages between 5-6.5 kV and pulse frequencies of 100-150 Hz. The therapy was combined with standard anti-COVID treatment. A total of 236 patients were distributed into three groups: control, PEMF with standard therapy, and deactivated PEMF device with standard therapy. The results were significant: on the 5th day, 87% of patients receiving PEMF tested PCR-negative, compared to 43% in the control group. By day 14, this increased to 99% for the PEMF group, versus 85% in the control group. Notably, no complications or side effects from PEMF exposure were observed. In conclusion, the combination of PEMF therapy with standard COVID-19 treatment significantly accelerated patient recovery, with a high rate of PCR- negative results and no reported side effects. This trial is registered on ClinicalTrials.gov (NCT05220579) and is retrospectively registered.

Keywords: Non-Contact; Remote; Wireless Therapy; Electromagnetic Therapy; Covid-19; Virus; PEMF; EMF

Introduction

The practice of therapeutic electromagnetic radiation has been known since quite long time. Electromagnetic field therapy is used in veterinary medicine to treat osteochondrosis, fractures, neurological diseases, inflammation, swelling and pain, and to stimulate wound healing. Devices with electromagnetic fields are used in physiotherapy to stimulate bone growth and to control the inflammatory process in the postoperative period. *In vitro*, animal and human studies have shown that pulsed electromagnetic field (PEMF) can promote healing in the models of stroke and traumatic brain injury without any side or adverse effects [1-7].

Dominguez-Nicolas S. and *Manjarrez E.* demonstrate a positive effect of PEMF treatment on blood oxygen saturation in Covid-19 patients [2]. At the same time, the use of electromagnetic fields (EMF) in the treatment of infectious diseases has not been sufficiently studied.

Studies aimed at the destruction of virus capsids using electromagnetic radiation *in vitro* are reported in [8,9], where it was shown that the studied viruses can be suppressed under the EMF influence either by increasing the temperature or by means of acoustic oscillations in capsids. However, the described mechanism of electromagnetic action was largely speculative. An idea about potential EMF therapeutic effect without inducing temperature variation was proposed in [10,11] at the initial stage of studies of the EMF influence on biological objects.

A thorough analysis of numerous results available in this field led to develop a remote subnoise technology that is able to suppress pathogens. It was suggested that the mechanisms of action of EMF may be useful during the Covid-19 pandemic as one of the methods to promote rapid clearance from virus and a recovery of patients.

We created a method for suppressing the viral activity by irradiating biological objects with ultra- wide band pulsed EMF with a targeted spatial-temporal structure. Designs of signals with a frequency spectrum covering the range of parts of Kilohertz-Megahertz-Gigahertz were developed, providing the Sars- Cov-2 viruses activity suppression, while not causing metabolic changes in patient bodies. The portable pulsed electromagnetic therapy (PEMT) for non-invasive electromagnetic therapy is designed to eliminate the virus in the human body, which leads to a lower viral load, thus accelerating the recovery of patients with Sars- Cov-2 moderate severity. The patent on the invented PEMT and a method of viral clearance are described in [12-14].

Here, we report the results of a randomized controlled clinical trial on the safety and efficacy of a PEMT for the remote elimination of Sars-Cov-2 from naso- and oro-pharynx of patients.

Materials and Methods Study design

This is a randomized, double-blind, placebo-controlled clinical trial on the safety and efficacy of the PEMT represented in a form of a newly engineered "TOR" device, patented in Russian Federation under "Device for suppression of vital activity of pathogenic microorganisms and viruses by electromagnetic radiation" No2765973 from 07th of February 2022, and a method applied using it as described in a patent "Method of suppression of vital activity of pathogenic microorganisms and viruses by electromagnetic radiation" No2766002 from the 07th of February 2022.

The clinical trial was conducted in the period from December 29, 2020 to August 12, 2021 at the Samara State Medical University of the Ministry of Health of the Russian Federation at the clinical base of the Faculty Therapy Department.

Study population

Men and women aged 18 and over, diagnosed with coronavirus infection Covid-19 after PCR testing were included into the study. Overall 236 patients were participants in the study, where 14 died, and hence the analysis was conducted on 222 patients. The average age of patients was 54 years, 55.5% were females, 44.5% were males. Males ranged from 19 to 78 years old, females ranged from 24 to 85 years old. All participants were Caucasians.

The inclusion criteria for involvement into the study were

- Patients hospitalized with Covid-19 disease. Positive result of a PCR test (biomaterial - a swab from the naso-pharynx and/or oro-pharynx) for infection with the Sars-Cov-2 virus within 72 hours on the day of screening.
- Patients with characteristic computed tomographic signs of the "ground-glass opacity" (one or two-sided spread) in combination with local foci of consolidation or without them;

- Oxygen therapy is not required, or oxygen therapy is required using a face mask or nasal cannulas;
- The duration of the disease from the first symptoms to the day of screening is not more than 7 days;
- Signed consent to participate in a trial;
- The ability to understand the requirements for participants, including the use and transfer of information about the health of patients, relevant to the research, and to follow the procedures specified in the protocol.

The exclusion criteria for involvement into the study were

- The patient's desire to discontinue participation in the study (withdrawal of informed consent).
- The decision of the investigating physician that the patient should be excluded for the benefit of the patient him/herself;
- The patient refuses to cooperate with the investigator or is not disciplined;
- Death of the patient;
- Progressing of the disease to a severe degree.

Randomization and masking

According the clinical trials design, three cohorts were formed, patients were randomized into control group A (standard therapy), study therapy group B (exposure to the pulsed electromagnetic therapy plus standard therapy), and placebo group C (imitation of exposure to the pulsed electromagnetic therapy plus standard therapy). Patients were randomized at visit 0 (1 day) in a ratio of 1:1. Group A consisted of 84 people (during the clinical trials, 73 patients remained due to the death of 11 patients), group B - 77 people (75 patients remained due to the death of 2 patients), group C - 75 people (74 patients remained due to death of 1 patient). Study participants were assigned unique randomization numbers that remained the same throughout the clinical trial. Quadruple masking: Participant, Care Provider, Investigator, Outcomes Assessor was used.

Pulsed electromagnetic therapy

Patients of the test group were exposed to the pulsed electromagnetic therapy for at least 5 consecutive days for at least 4 hours daily in the 15 + 15 mode (15 minutes exposure + 15 minutes break) in combination with standard therapy. The periodic magnetic field strength is applied at 50 Hz and 1.5 μT during treatment procedures. Peak voltage between the electrodes of the exciter is within 5-6.5 kV, the frequency of high-voltage pulses applied to the electrodes of the exciter is within 100-150 Hz. Patients of the placebo group were exposed to the switched off pulsed electromagnetic therapy in combination with standard therapy. The simulation of the electromagnetic effect consisted in turning on the instrument lights on the device and the noise effect that emanated from it. These parameters created the appearance of a working device in the absence of generation of electromagnetic waves. Patients in the control group received standard therapy. Standard therapy was prescribed in accordance with the recommended treatment regimens presented in the current version of the Interim Guidelines of the Ministry of Health of Russian Federation "Prevention, diagnosis and treatment of coronavirus infection (Covid-19) No. 9 from October 26th, 2020.

Study outcome

Primary performance parameters were

- Dynamics of the Sars-Cov-2 virus replication activity (quantitative measurement of the genetic material of the virus (Sars-Cov-2 RNA) presence by PCR.
- Dynamics of changes in the number of banded neutrophils. Secondary performance parameters were:
- Dynamics of saturation, respiratory rate.
- The dynamics of changes in points on the WHO scale;
- Dynamics of changes in points on the NEWS scale.

Primary outcome measures were PCR on day 5, 14; and banded neutrophils on day 7, 14, 28. Secondary outcome measures were blood oxygen saturation and respiratory rat on day 2, 3, 4, 5; ordinal (WHO) and NEWS-2 scale for clinical improvement on day 2, 3, 4, 5, 7, 14, 28.

Complaints were evaluated for all patients, vital signs were recorded (body temperature, oxygen saturation level, blood pressure and heart rate), clinical and laboratory studies (clinical and biochemical blood tests), urinalysis, and ECG monitoring.

Ethics statement

The clinical trials protocol was approved at the Samara State Medical University of the Ministry of Health of Russian Federation ethics committee meeting (No. 214 dated 03.01.2021). Ethics Council of the Ministry of Health of the Russian Federation approval No. 35 dated July 26, 2021.

Biochemical and laboratory tests

Saturation of blood with oxygen

SpO2 was obtained using oxygen saturation monitor (CMS 50 DL). The finger probe was placed on the index finger of a patient, on the opposite arm from which the arterial sample had been taken.

Blood analysis

K2-EDTA whole blood samples were collected and analysed within 2 hours after collection. Hemoglobin level, hematocrit, erythrocyte count, leukocyte count, leukocyte count, platelet count, ESR were analyzed. Abbott CELL-DYN Ruby blood analyser was used for blood analysis.

Biochemical blood test

Total protein, albumin, glucose, creatinine, urea, ALT, AST, total bilirubin, direct bilirubin, alkaline phosphatase, potassium, sodium, chlorine, C-reactive protein were measured in the blood of patients. Measurements were conducted using Roche Cobas E411 device according to a standard protocol.

Coagulation indices analysis was done using platelet-poor plasma fraction, using Stago STA analyzer according to a standard protocol.

Statistical analysis

Statistical analysis was performed in the population of all randomized patients (groups A, B, C), analysis of safety indicators was performed only among patients who received exposure to the PEMT. Statistical data processing was carried out using the SPSS 25 package (IBM SPSS Statistics, USA, license #5725-A54).

Continuous variables were presented as means and standard deviations (M ± SD) or as medians and interquartile ranges. Figures show the mean values and their 95% confidence intervals (CI) as error bars. Comparisons between groups were performed using one-way ANOVA or Kruskal-Wallis rank sum test and the Mann-Whitney U test according to the distribution of the data. Comparison of related samples was carried out using Wilcoxon Signed Ranks test. Categorical variables were compared by Pearson Chi squared test or by Fisher's exact test. Kaplan-Meier method and the log-rank test was used to assess the differences between times to clinical improvement in different groups. The power of the study was set to 0.8. A two-tailed P-value < 0.05 was considered statistically significant.

Results

Results of a clinical trial

The safety of a treatment with a device was assessed by the presence or absence of adverse events (AEs) and serious adverse events (SAEs) according to: registration of patient complaints, assessment of vital parameters (body temperature, arterial systolic and diastolic pressure, heart rate and respiratory rate), oxygen saturation data, laboratory tests data (clinical and biochemical blood tests and urea analysis), ECG examination data and clinical monitoring data for the patient course of the disease.

The effectiveness of exposure to the PEMT was assessed using primary and secondary criteria. The primary parameter was dynamics of Sars-Cov-2 virus replication activity (presence of the genetic material of the virus (Sars-Cov-2 RNA) by PCR. Secondary parameters were dynamics of saturation, changes in scores according to the WHO and NEWS-2 scales.

According to vital indicators (body temperature, SBP, DBP, heart rate and respiratory rate), laboratory data (clinical and biochemical blood tests and general urinalysis), ECG, patients' complaints and pulse oximeter data, no AEs and SAEs associated with the use of the PEMT were registered during therapy treatment.

Analysis of the frequency of deaths in the studied groups revealed that 86.9% of patients survived in the control group, while 97.4% survived in the test group, and 98.7% in the placebo group (see Table 1). Statistical significance for the contingency table as a whole (p) is given by Pearson chi-squared test. Pairwise intergroup comparisons were made using Fisher's exact method.

Statistically significant differences in the number of deaths were found between groups A (13.1%) and B (2.6%) p=0.019 and groups A (13.1%) and C (1.3%), p = 0.005. There were no statistically significant differences in the number of deaths in groups B (2.6%) and C (1.3%) (p = 1.000).

Outcome	Group a Control n = 84		Group b Exposure to the device N = 77		Group c Placebo n = 75		P (table as a Whole)	P a-b	P a-c
	Abs.	%	Abs.	%	Abs.	%			
survived	73	86.9%	75	97.4%	74	98.7%	0.002	0.019	0.005
dead	11	13.1%	2	2.6%	1	1.3%			

Table 1: The outcomes in the examined group of patients (n=236) enrolled with moderate condition indications.

Note: Statistical significance for the contingency table as a whole (p) is given by Pearson chi-squared test. Pairwise intergroup comparisons were made using Fisher's exact method. Abs.: means absolute. %: means relative in percents.

The quantitative measure of the studied factor (exposure to the PEMT) influence on the outcome (patient's death) is the odds ratio. Thus, the odds ratio for the risk of death for group B, compared with group A, was OR=0.18 (95% CI: 0.038-0.83), p=0.028; and for group C, compared with group A, OR=0.09 (95% CI: 0.01- 0.71), p=0.023 and is a statistically significant value. At the same time, the proportion of patients in the analyzed groups who were admitted in a moderate course and turned into a severe course of the disease occurs to be statistically insignificant.

It is important to emphasize that the placebo or control group had statistically significantly worse results. They were not predictable, but the clinic used all the necessary means in its arsenal to prevent them. Deaths occurred due to the progression of the underlying disease.

When analyzing the deaths in the study groups, it was found that their immediate cause was the development and progression of acute respiratory distress syndrome against the background of viral bilateral polysegmental interstitial pneumonia. It should be noted that the severity of this condition in the experimental group was less than in the rest of the study participants. It is important to note that the treatment of this complication was carried out in the intensive care unit using all standard treatment methods available at the clinic. They included: oxygen therapy, artificial lung ventilation, extracorporeal detoxification methods, correction of hemodynamic disorders, administration of antibiotics, corticosteroid hormones.

PCR

PCR analysis of all 236 patients revealed highly significant differences in the frequency of positive PCR results in the studied groups on the 5th day of hospitalization. Thus, in group B, there were only 13% positive results, while in group A - 57%, in group C - 64% (both p <0.001, the results in groups A and C - control and placebo - are not statistically distinguishable). Differences in the proportion of PCR- positive patients between groups A and B remained on the 14th day of observation.

The assessment of the statistical significance of differences between studied groups was performed by Pearson chi-square test, pairwise comparisons between groups were performed using Fisher's exact method.

After the end of therapy (day 5 of therapy), a clinically significant response to the use of additional therapy with the PEMT in the form of a Sars-Cov-2 negative PCR-test in group B was 87.0% (95% CI: 79.5-94.5) of patients, and in group A (control) in 42.9% (95% CI: 31.8-53.8) of patients. In group C (placebo), the proportion of patients with a negative test was 36.0% (95% CI 25.1-46.0), while in group B, a negative test was observed in 87.0% (95% CI: 79.5-94.5) patients. At the time of discharge, the number of positive patients in group A was 12 (14.8%) patients, in group B - 1 (1.3%) patient and in group C - 6 (8.0%) patients (see Figure 1).

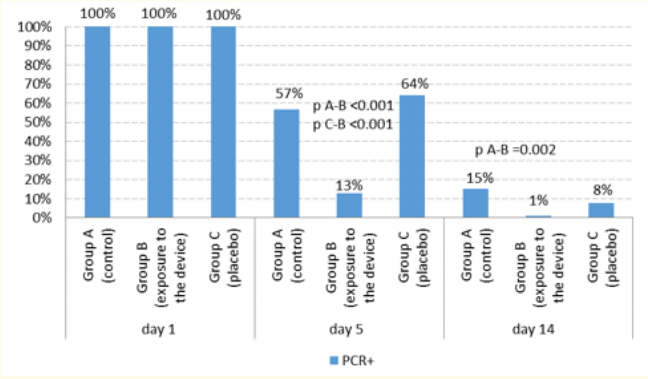
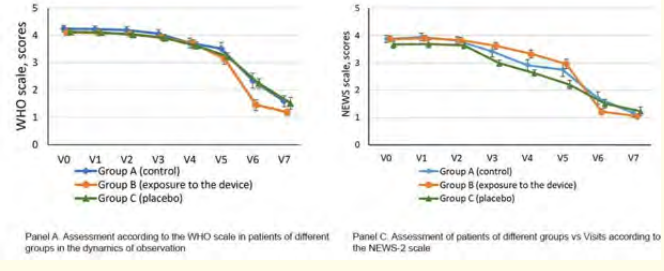


Figure 1: The number of Sars-Cov-2 PCR positive patients in studied groups. The patients were monitored from day 1 to day 14 and the relative number of patients in each group is shown.

The clinically significant response (effect) from the use of exposure with the PEMT (negative PCR-test) was 44.1% between groups A and B and 51.0% between groups B and C.

WHO scale

At the time of hospitalization, all three groups were comparable, no statistical differences were found (p = 0.093), the WHO score ranged from 3 to 6 points. From 1 to 3 days, no one had less than 3 points. At the same time, patients in the control group had more diversity in scores, both for the better and for the worse. By the 4th day of observation, the groups became statistically insignificant. From V4-V5, some patients had values of 1-2 points. At the same time, values of 6-7 points remained or appeared. As a rule, they were in those patients who subsequently died. Starting from V6 (14 days in the hospital), an advantage was noted in patients from group B, which manifested itself in a higher frequency of 1 point - 74.7% of cases versus 19.2% in group A and 12% in group C (see Figure 2).



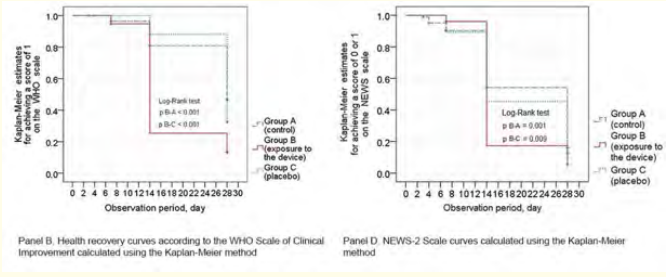


Figure 2: Panel A - Assessment according to the WHO scale in patients of different groups; Panel B – The same using Kaplan-Meyer method; Panel C - Assessment according to the NEWS-2 scale in patients of different groups; Panel D - The same using Kaplan-Meyer method.

Achieving a 1-point score is clearly shown in the graphs with a product-limit survival function estimate. At the beginning of the observation, there was no 1 point in any group (Kaplan-Meier score = 1), with individual patients reaching 1 point at certain times of observation, the curve "descends" downwards. The graph (Figure 2, Panel B) shows that a sharp difference between the groups occurred on the 14th day of observation, when a significant proportion of patients exposed to "TOR" achieved good scores (1 point) on the WHO scale. Differences between the curves were evaluated statistically by log-rank test, and highly significant differences were found between Group B and Groups A and C (both p<0.001). The placebo and control groups did not differ from each other (p = 0.923).

NEWS-2 scale

The general dynamics of changes in the average scores on the NEWS scale is shown in Figure 3, Panels C-D. In the period V0-V2, no positive dynamics was observed. By the 5th visit, a significant decrease in scores on this scale was noted.

No statistically significant differences were found at the time of admission. From the moment of admission for 3 days in the hospital, in patients of all three groups, scores of 3-4 points prevailed on the NEWS scale. Prior to the 2nd visit, none of the examined patients had 0-1 points on the NEWS scale.

On day 14, visit 6, a good result was more often noted in patients of the "TOR" group - B, where the result of 0-1 point was 82.7% of patients, while in group A - 46.2% (p < 0.001), and in group C - 54.7% (p = 0.001). A month later (V7), patients from all groups achieved a score of 0-1 in 85-95% of cases, there were no statistical

differences between the groups. As in the case of WHO scores, not all patients showed a decrease in scores, especially high scores were noted in patients who subsequently died.

Kaplan-Meier "survival" curves were constructed to achieve 0-1 points. Earlier obtaining of good scores - 0 or 1 - in this scale was revealed in group B (exposure to pulsed electromagnetic therapy), compared with groups A - control (p = 0.001 by log-rank test) and C - placebo (p = 0.009). Groups A and B did not differ from each other (p = 0.746) (Figure 3, Panel D).

Saturation of blood with oxygen

Saturation indicators were measured in patients in all groups (Table 2). Upon admission to the hospital, the blood oxygen saturation was comparable in all groups (p = 0.120). The proportion of patients with Sp02 > 94% ranged from 56% to 71%. During the first day in the hospital in all groups, an increase in the proportion of patients with sufficient saturation was noted, there were still no differences between the groups. However, by the fourth day of treatment (V3), the best results were in group B with "TOR" exposure: 92.2% of patients in this group had sufficient saturation, while in group A it was achieved in 85.7% of patients, and in group C in 70.7%. By the 5th day of treatment, saturation increased in group C (where it was the lowest during all previous observation periods) and the groups again became statistically comparable.

Abs.		**Group A Control n = 84**		**Group B exposure to the device N = 77**		**Group C Placebo n = 75**		**P**	**P A-B**	**P A-C**
		%	Abs.	%	Abs.	%				
V0	Sp02 < = 94%	24	28.6%	26	33.8%	33	44.0%	0.120	0.500	0.063
	Sp02 > 94%	60	71.4%	51	66.2%	42	56.0%		0.500	0.063
V1	Sp02 < = 94%	15	17.9%	11	14.3%	16	21.3%	0.525	0.669	0.689
	Sp02 > 94%	69	82.1%	66	85.7%	59	78.7%		0.669	0.689
V2	Sp02 < = 94%	15	17.9%	14	18.2%	22	29.3%	0.144	1.000	0.095
	Sp02 > 94%	69	82.1%	63	81.8%	53	70.7%		1.000	0.095
V3	Sp02 < = 94%	12	14.3%	6	7.8%	22	29.3%	0.001	0.219	0.032
	Sp02 > 94%	72	85.7%	71	92.2%	53	70.7%		0.219	0.032
V4	Sp02 < = 94%	13	15.7%	8	10.4%	11	14.7%	0.592	0.357	1.000
	Sp02 > 94%	70	84.3%	69	89.6%	64	85.3%		0.357	1.000

Table 2: Blood oxygen saturation over time in the studied groups.

Note: At the 4th visit in group A, 1 patient was excluded due to the exclusion criteria. Abs.: means absolute.

%: means relative in percents.

Overall, these results demonstrate that PEMT is effective in the treatment of Covid and its elimination from oro- and nasopharynx of patients, when applied in combination with a standard therapy, promoting faster recovery from a disease.

Discussion

The use of EMF in biology and medicine has a history of more than 50 years and covers a frequency range of at least a few tenths of a Hertz to the frequencies of the visible and even ultraviolet range of the electromagnetic spectrum [7].

Pulsed electromagnetic therapy is based on broadband radiation with special time-frequency properties and a waveform covering a frequency range from hundreds of Hertz to Gigahertz. At the same time, unlike integrated power, the spectral density of this radiation is extremely low and significantly lower than the spectral radiation power of mobile communications.

To modify their further actions, we applied an EMF of a special spectral and space-time structure. The low-frequency part of the spectra is responsible for the activation of the glycocalyx by means of Babston complexes generated by as (see [16,17]) and gigahertz excitations locally generated by the natural frequencies of the acoustic mode in both viral capsids and babstones, which disrupt the effects of interaction between virions (noise). There are many studies devoted to the intrinsic values of the energy states of viruses and their social behavior ([18-22]). Low-frequency electromagnetic radiation affects virion ensembles near cells, thus disrupting viral replication [23].

When developing therapeutic equipment against Sars-Cov-2, we assumed that we were dealing not with individual pathogens, but with a community characterized by adaptive properties, spreading a huge number of virions everywhere, a community that demonstrates collective behavior and traits of supra-organisms [18-20,24,25].

Despite the positive empirical results of using low-frequency electromagnetic radiation in our study, we have to admit that the mechanisms described above and hypotheses of its effect on viruses are currently based on speculative reasoning, with insufficient evidence.

However, the results of a clinical study of the effectiveness of the TOR device in the treatment of Sars-Cov-2 infection and its elimination from the human body led to the conclusion that PET has significant benefits in terms of clinical improvement of patients' condition according to the WHO and NEWS-2 scales, which reduced the risk of increasing the severity of the disease and ensuring a faster recovery. It is worth noting that no life-threatening conditions or adverse events were detected in patients during clinical trials, which indicates the safety of the PEMT.

It should be emphasized that the study did not take into account the area of lung tissue damage. These circumstances could play a significant role in the course of coronavirus infection, the rate of development and severity of respiratory distress syndrome and its immunity to ongoing treatment measures. The second factor that imposed restrictions on the use of the study results was the stratification of risks depending on the existing concomitant pathology and the severity of existing metabolic disorders. These factors force us to continue further research on the therapeutic effect of low-frequency electromagnetic radiation in the new coronavirus infection.

Conclusions

The use of low-frequency electromagnetic radiation as an adjunct to the etiotropic therapy of the new coronavirus infection has demonstrated good clinical results. The mechanisms of the effect of PEMF on the immune system, viral communications, and the behavior of cell membranes can be explored further, and more detailed studies are required, including the interaction with the other pathogens.

Conflict of Interests

The authors declare that there is no conflict of interest.

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