Effects of the new energy-medical RIFETECH plasma device on exhaustion in private practice - a prospective application observation

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Synopsis

Type of study: Open-label, prospective, single-arm observational study as a pilot study for a controlled, randomized trial;

Duration of the study: 4 weeks

Target diagnosis ICD: exhaustion, G 93.3; This includes all states of exhaustion, e.g. B. after infections, idiopathic, nervous, psychogenic, cancer related fatigue, etc.

Intervention: Energy medical device with European approval for self-treatment by patients to promote well-being and relaxation: the RIFETECH plasma device, which modulates electromagnetic oscillations onto a light plasma and radiates them into the room (range approx. 2 m);

Number of patients: 100

Number of doctors: approx. 10; each doctor brings in about 10 patients;

Target criterion: fatigue, measured with the German version of the Fatigue Severity Scale, measured before the start of treatment and 4 weeks afterwards;

Inclusion criterion: ICD diagnosis G93.3

Exclusion criteria: Exhaustion, the severity of which makes an initial, visible reaction not conceivable within the first 4 weeks of treatment, systemic treatment that can cause tiredness and exhaustion, e.g. B. Treatment with antihistamines, cytostatic therapy;

Therapy beginning at the same time with another therapist aimed at treating fatigue;

Data collection: Online via “secure link”, sent to the email address provided by the doctor in the declaration of consent;

Evaluation: Purely descriptive using box plot of median and interquartile range in the case of skewed distribution, otherwise of mean and 95% confidence intervals;

Determination of the standardized pre-post mean difference to calculate the statistical power and sample size calculation of a controlled study;

Statistical testing of the difference from before to after using Wilcoxon tests for descriptive orientation;

Publication: The data will be summarized in an evaluation report and, if possible, immediately published in the peer-reviewed literature. At the same time, the evaluation report serves as information material for planning a controlled study and for submission to regulatory authorities.

1. Introduction and background

exhaustion

Exhaustion is now a widespread syndrome. Epidemiological studies in the USA have revealed fatigue as a syndrome in 25 to 35% of all those examined (Billones, Liwang, Butler, Graves, & Saligan, 2021). Rheumatic and inflammatory diseases are very often associated with fatigue, and it is neither known how this connection occurs nor how fatigue should be treated (Davies, Dures, & Ng, 2021). In cancer, fatigue is reported by up to 90% of all those treated, and some complementary medicine treatments such as acupuncture, touch, relaxation, exercise as well as homeopathy and some herbal preparations appear to be treatment options (David, Hausner, & Frenkel, 2021).

Fatigue is also an accompanying symptom of almost all depression, which soon affects 20% of people, sleep disorders, neurological diseases such as multiple sclerosis and chronic pain. There are also an unknown number of people who only suffer from fatigue (Kuppuswamy, 2022). Almost any chronic illness can be associated with fatigue, and it is not clear which disease parameters lead to and contribute to fatigue. In a recently published study by the North Dutch “Lifelines Cohort Study”, of the more than 78,000 people surveyed, 18% reported severe fatigue and 13% reported chronic fatigue. This was more severe and more common in patients with chronic illnesses. The more chronic illnesses occurred, the greater the exhaustion. The odds ratios ranged from 1.61 for one chronic disease to 5.50 for four chronic diseases (Goërtz et al., 2021). Although personality factors such as neuroticism are positively associated with exhaustion and openness and social agreeableness are negatively associated with exhaustion, as a recent meta-analysis showed (Stephan, Sutin, Luchetti, Canada, & Terracciano, 2022), in our view the connections are not strong enough (OR = 1.38 for exhaustion and neuroticism) to justify the widespread tendency to classify exhaustion as a somatoform event and thus in the area of to refer psychotherapeutic treatment. The experiences we had with our own clinical study on 409 chronic fatigue patients showed us that these patients generally feel misunderstood if their symptoms are classified as a psychological problem (Güthlin, Anton, Kruse, & Walach, 2012; Walach et al., 2008).

The SARS-CoV2 pandemic, in which many patients developed Covid-19, often led to post-Covid syndrome, i.e. symptoms that persist after the acute illness is over (Sykes et al., 2021). A meta-analysis and review of meta-analyses show that 58% of Covid patients subsequently suffered from fatigue (Lopez-Leon et al., 2021). Fatigue has also been observed as an accompanying symptom of other infectious diseases such as mononucleosis (Petersen, Thomas, Hamilton, & White, 2006), and psychoneuroimmunological considerations show that the proinflammatory cytokines released during an acute infection, such as Il-1, TNFalpha, Il-6, etc., lead to an exhaustion syndrome, which in acute cases has the effect of causing a sick person to go to rest (Smith, 2013). However, if the natural back-regulation of the inflammatory reaction is prevented, the behavioral withdrawal reaction, which manifests itself in exhaustion, can persist and lead to the well-known post-infectious exhaustion syndromes.

Finally, chronic fatigue syndrome is a syndrome that is very difficult to treat and, in the eyes of some, is caused by chemical intolerance or environmental medicine toxic stimuli of an as yet unknown nature, or that occurs due to other immunological incorrect reactions (Franssen, Bültmann, Kant, & van Amelsvoort, 2003; Gherardi, Crépeaux, & Authier, 2019; Herrell et al., 2002; Kern et al., 2014; Phelan, Grabowska, & Sepúlveda, 2020; Shapiro & Moller, 2002;

Surprisingly, if you search for clean epidemiological surveys of fatigue (MESH-Heading "fatigue" and MESH-Heading "epidemiology"), you won't find any studies in Pubmed. But the above considerations show that fatigue is a very common syndrome with limited treatment options. Therefore, a complementary medical or alternative treatment option seems to be appropriate (David et al., 2021).

Energy medicine treatment options

Within complementary medicine, which summarizes procedures that are not taught in the canon of university education, energy medicine procedures are playing an increasingly larger role (Bischof & Del Guidice, 2013; Frischknecht, 2018; Galle & Walach, 2018; Oschman, 2006; Schmieke, 2021).

The classic bioresonance methods are the most common (Galle & Walach, 2018). We ignore the non-classical methods that rely on the use of quantum noise and that are derived from radionics because they belong to a different class of methods (Rae, 1977; Schneider & Walach, 2005).

The principle of bioresonance therapy is based on the fact that, to put it simply, electromagnetic vibrations are picked up by an organism and then returned to it in a modified form. The energy with which this happens is so low that it is imperceptible and does not cause any measurable electrical changes. Rather, according to the idea, this will harmonize the electromagnetic coherence of the biological system. The electromagnetic signature is usually picked up via an electrode that measures electromagnetic characteristics, e.g. B. Impedance, resistance, capacity for electromagnetic oscillations of different frequencies. In classic devices, these are compared with large data memories from healthy test subjects, from which modified vibration patterns are then generated that are intended to bring patients back into balance.

There are a number of empirical studies on such procedures that at least demonstrate the principle and clinical usefulness of these procedures; We recently summarized them (Galle & Walach, 2018). A clinically controlled study shows that such a procedure is effective in improving quality of life and reducing stress levels (Walach & Marmann, 2021), and a meta-analysis of a series of such studies shows that this procedure has robust effectiveness with an effect size of g = 0.757 (Walach & Marmann, submitted).

2. The RIFETECH plasma process

The new RIFETECH plasma process to be examined here is named after the American inventor and therapist Royal Raymond Rife (1888-1971). Rife was an inventor who, even before the invention of the electron microscope, found a way to go below the Rayleigh length, i.e. the wavelength of light that is necessary to make the smallest structures visible in the microscope. This enabled him to perform microscopy in the micromillimeter and nanomillimeter range, even before the time of electron microscopy. He examined all pathogens known at the time and measured them using his microscope. He then calculated which specific wavelengths would be used to cause these exciters to oscillate so that they would end up in a resonance catastrophe, i.e. destroy themselves through the energy of the natural oscillation. Rife also treated cancer patients with his method, which he was not allowed to do due to the legal framework. His equipment and records were then confiscated by the FBI on behalf of the FDA. The story is very well presented by Lynes (2011, orig. 1987).

While the original Rife protocols and devices were lost, the knowledge in the complementary medical community was retained, and some therapists we know work with bioresonance devices and Rife frequencies, even for serious illnesses. Incidentally, the representations that you can find about Rife and complementary medicine methods in general in Wikipedia are grossly distorted. Rife's invention has been reproduced in more recent times. A project financed by the Fetzer-Franklin Fund was able to replicate Rife's arrangement and thus demonstrated that it was actually possible to go below the Rayleigh length with the Rife microscope. This is personal information from Dr. Jan Walleczek, the then project manager of the Fetzer-Franklin Fund, who personally supervised this project and confirmed this fact to us in a personal conversation.

However, the device to be examined here only goes back to Rife in terms of its idea. It is a new development based on an EU-funded project as part of the special call for the treatment of Covid-19 (project no. CZ.011.02/0.0/0.0/20_319/0023173, “Research in the field of a therapeutic facility”). As part of this project, the exact size of the SARS-CoV2 pathogen was precisely measured and oscillated with an appropriately adjusted electro-magnetic frequency so that it is no longer functional and can be broken down by the immune system. The exact principle and the considerations behind it are presented in the appendix to this protocol.

Back in the 1970s and 80s, Fröhlich showed that it was possible to cause organisms to resonate using low-energy electromagnetic oscillations that are not noticeable and not harmful, but which radiate a specific frequency in a highly specific manner. He called this resonant coupling through coherent excitation (Barret & Pohl, 1987; Clegg, 1983; Fröhlich, 1968, 1968a, 1968b, 1970, 1974, 1975, 1980, 1985, 1986a, 1986b, 1988; Fröhlich & Kremer, 1983; Keilman, 1985; Rowlands, 1983).

The principle behind it can be understood if you take musical resonance as an example: When a sound wave of a certain frequency hits a geometrically tuned instrument, the sound is amplified by its own resonance. For example, if you hold down a note "a" on one side of a guitar and place a tuning fork on the guitar, then not only will the note "a" produced by the tuning fork sound, but the side of the guitar itself will begin to vibrate

even though it is not played. Another experiment that illustrates this principle can be carried out in geometric domed rooms, such as those sometimes found in Romanesque crypts or neoclassical buildings. If you position yourself exactly in the middle under the dome and hum very quietly, barely perceptibly, up or down a sliding scale, you will find a tone in which the hummed tone suddenly increases enormously without the volume of the hum having changed. This is the natural resonance of the room, whose geometric properties - the height of the room and the shape of the dome - mean that the standing wave of the sound is now amplified by the natural resonance without introducing more energy into the system. Fröhlich researched the same principle, only with high-frequency electromagnetic waves. If their wavelength resonates with biological structures, e.g. B. with membranes, or even entire biological bodies such as bacteria, viruses or parasites, then these can be set into vibration by the frequency, even if the energy is very low, and this sustained vibration can lead to a resonance catastrophe. This means: they vibrate more and more until they are destroyed or break down in such a way that they become accessible to the immune system.

The phenomenon is known from physics: if a bridge e.g. If, for example, people marching in unison - shown in the famous film "The Bridge on the River Kwai" - or are caused to vibrate by a hurricane, the vibration can continue to build up until the bridge breaks. Bridge engineers therefore try to prevent this phenomenon using different strategies.

In a therapeutic sense, the RIFETECH plasma device now applies exactly this principle (https://rifetech.cz/; see also the more detailed description of the active principle in the appendix of this protocol). It emits very specific electromagnetic frequencies. The frequencies are calculated by dividing the speed of light by the length of DNA/RNA or certain biological structures. These frequencies are modulated onto a plasma that is generated in a cathode tube - a glowing gas like a neon tube - and thereby re-emitted (Fig. 1).

Figure 1 - The Rifetech plasma device in action: the gas in a cathode tube is made to glow by high-frequency voltage; A frequency is modulated onto this pulsating plasma and radiated into space. Since the energy is very low, the radiation is only of short range (see https://rifetech.cz/)

The frequency of this electromagnetic field is very specific and is in the range of low and medium electromagnetic frequencies (approx. 100 Hz to a few 100 kHz). But the energy is so weak that energetically mediated influences are excluded. In addition to the frequencies specific to SARS-CoV2, a host of other frequencies have been implemented for all possible pathogens. These can be used for the specific treatment of infections or their aftermath. In addition, there are now proven frequency bands that are used to increase well-being or to treat exhaustion.

The device meets the European standard for electromagnetic compatibility and safety (2014/30/EU and 2014/35/EU) and has the appropriate approval for self-treatment in the wellness area. The company Rifetech s.r.o. Prague is ISO certified (ISO standard 9001:2015). The device can emit frequencies in the range from 10 µHz to 900 kHz. Frequencies can be set to 2 decimal places, the uncertainty is ± 5 * 10-6.

The informal experiences of doctors who have used this device, which is approved for self-treatment and to increase well-being, in off-label applications on patients shows that

it appears to be very effective for fatigue and can significantly alleviate fatigue of various origins with a series of a few treatments.

This question will now be examined in more detail in this prospective application observation. It also serves to explore the effect and its potential size for planning and carrying out a controlled study.

2. methodology

A prospective documentation study is planned as an application observation. 10 resident doctors should each include 10, i.e. a total of 100 patients.

Inclusion criterion: target diagnosis of exhaustion

The inclusion criterion is the target diagnosis “exhaustion”, ICD code G93.3. This is the supercategory “exhaustion”, which occurs as the main symptom in many illnesses, such as after infections (e.g. Long Covid), insomnia, pain syndromes, neurological diseases, diabetes, chronic fatigue syndrome, depression or idiopathic exhaustion with no known cause. It occurs frequently in private practice; according to cooperating practitioners, it occurs in around 50 to 75% of all patients. Whenever fatigue is at the center of the symptom picture and is actively mentioned by the patient as a symptom that needs to be treated, the patient can be considered for the study, provided there are no exclusion criteria.

Exclusion criteria:

The exclusion criteria include:

- Minor, without parental consent (under 18 years old),
- Lack of understanding of the German language, which prevents the study documents and questionnaires from being understood sufficiently well.
- No working email address,
- Life-threatening illness.
- Condition immediately after surgery.
- Systemic treatment that may cause fatigue (e.g. cytostatics or histamine treatment).
- Parallel introduction of another treatment with another therapist, which is intended to exclusively treat exhaustion.
- Characteristics of the patient or his clinical picture that make an initial visible success within the 4-week study period seem unlikely.

Data collection and outcome measures

The usual socio-demographic data (age, gender, socio-economic status, level of education) as well as the duration of exhaustion (months) are recorded.

Self-reported fatigue is measured using the German “Fatigue Severity Scale” (Valko, Bassetti, Bloch, Held, & Baumann, 2008) as the main outcome criterion. This scale measures exhaustion with the following 9 items, which are rated on a 7-point scale (3 negative points, one indifference point and 3 positive points):

1 I'm less motivated when I'm tired.
2 Physical exercise makes me tired.
3 I tire quickly.
4 My fatigue affects my physical performance.
5 My fatigue often causes me problems.
6 My tiredness prevents me from doing prolonged physical activity.

7 My fatigue interferes with my ability to fulfill certain duties and responsibilities.
8 My fatigue is one of the three complaints that hinder me the most.
9 My fatigue interferes with my work, my family or my social life.

In addition, we record general quality of life with the 5-item scale WHO-QuoL 5 (Sischka, Costa, Steffgen, & Schmidt, 2020; Topp, Østergaard, Søndergaard, & Bech, 2015; World Health Organization, 2014).
This scale measures quality of life with 5 items, each of which is rated on a six-point scale (never, occasionally, a little less than half of the time, a little more than half of the time, most of the time, all of the time). The wording is: "In the last two weeks

- I was happy and in a good mood,
- I felt calm and relaxed,
- I felt energetic and active,
- I woke up feeling fresh and rested,
- My everyday life was full of things that interested me."

The survey takes place online and is implemented on Social Science Survey.

Patients receive a personal and protected link (see procedure) and then fill out the questionnaire online, which prevents incorrect information.

Patients receive such a link immediately after inclusion and 4 weeks after inclusion for the follow-up survey.

During the follow-up survey we also ask:

Compatibility:

"Have you experienced any negative effects that you attribute to Rifetech treatment?" Yes / No, if yes, which ones (free text)

Accompanying treatment:

"During the last 4 weeks, have you used any other treatments for your fatigue?" Yes / No, if yes the following list and free text:

- psychotherapy
- homeopathy
- Vitamins and supplements
- Acupuncture
- Kur/Reha
- Other

At the doctor

The doctor receives a form (case report form) for each patient in which, in addition to the inclusion date and proper patient information, the following data is recorded:

- Presence of the entry criteria (diagnosis G 93.3)
- Failure to meet all exclusion criteria (see above)
- Prescription of other therapeutic measures and medications (list to tick plus free text)

At the end of the treatment, the doctor fills out a short questionnaire about success and safety (see below).

Proceed

Patients who see one of the participating doctors and whose main syndrome is fatigue will be informed about the study by the doctor if there are no exclusion criteria. The doctor fills out a case report form for each patient, which remains with the doctor, gives the patient the patient information and has him sign the consent form and also signs it himself if the patient is willing to take part in the study.

The doctor sends the patient's email address to the study center. This person will then promptly receive an email with the link to the questionnaire that they must fill out. If the patient does not complete the questionnaire within two days, they will receive up to two prompts. If he still does not respond, the patient is removed from observation and the doctor is notified. Failure to answer the question will be viewed by us as a tacit withdrawal of the declaration of consent.

We will record the date the first questionnaire was completed in a file and four weeks after this first questionnaire we will automatically send a link to the follow-up questionnaire. If the patient does not respond to three requests to fill it out, this is considered a protocol violation and the patient is included in an intention-to-treat evaluation with the initial data.

Patient identifier to identify the related questionnaires

So that doctor's questionnaires and patient questionnaires 1 and 2 can be merged, a patient identifier is used, which nevertheless maintains the anonymity of the data. Patients and doctors are encouraged to use the first letter of the first name and the last letter of the last name as well as the first four digits of the birthday in a four-digit format as identifiers.
A patient named Heinrich Bauer, born on May 16, 1974, would then have the ID HR1605. A patient can easily remember this and the doctor can note this identifier in his file.

Treatment and treatment safety

The doctor is free to use the RIFETECH plasma device in the modality he believes is best and documents the number and modality of the treatments as well as the safety at the end of the treatment in his patient file. To make things easier, he receives a documentation form that contains the patient ID as well as fields to document the number, duration and modality of treatment. He also documents other treatments, prescriptions and modalities that he initiates to treat the state of exhaustion or that the patient receives due to other underlying diseases (e.g. maintenance doses of basic medications).

At the end, the doctor fills out the evaluation form. This documents the following variables:

Was the treatment successful?

successful; yes, partly; not very successful; made the condition worse

Have any side effects been noticed? Yes/No,
if yes: which ones

4. Evaluation and statistics

The evaluation is primarily descriptive. We create descriptive parameters, with approximately normal distribution, means, standard deviations and 95% confidence intervals for the two clinical outcome parameters, fatigue and quality of life before and after. The changes are tested for significance using a Wilcoxon test. $P < .005$ is set as the limit below which statistical significance can be assumed. However, since this is only indicative, this test has no further significance.

What is central, however, is the calculation of the effect size. This is done as a standardized mean difference with the average standard deviation of pre- and post as the standardization variable. The modified Ma-Chua algorithm is applied to determine whether the change is due to regression toward the center (Ostermann, Willich, & Lüdtke, 2008).

The data are evaluated according to the intention-to-treat principle, which means that patients who do not provide any data at the second time point are included in the evaluation with their initial values. In addition, a per-protocol analysis is carried out for the existing data sets alone to estimate the effect.

5. Publication

The results of the study will be published, if possible in a recognized peer-reviewed journal. The evaluation report is also used as information material for any applications for approval. The protocol will be published in an English version on the Open Science Foundation platform and the study will be entered into an appropriate study register after approval has been granted by an ethics committee.

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