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Research Article

Self-Treatment to Improve Mental and Physical Health using Two Bioenergetic Devices: A Randomized Controlled Trial

Harald Walach[1,2*], Peter Marmann[3]

[1]Institut für Grenzgebiete der Psychologie und Psychohygiene e.V., IGPP Freiburg, Germany

[2]Change Health Science Institute, Berlin, Germany

[3]Healy GmbH, Kränzlin, Germany

[*]**Corresponding Author:** Prof. Harald Walach, Schönwalder Str. 17, D – 13347 Berlin, Tel: +49-30-467 97 436

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Abstract

Background: Many healthy people seek to improve their health status, because they feel they lack energy or wellbeing or both. Bioenergy devices are frequently used in this self-help sector. We tested two such devices against a wait-list control group in a short-term two week randomized trial.

Method: Healthy volunteers who gave informed consent were randomized to receive either one of two bioenergetic devices, Healy, or Healy coil, or had to wait to receive one for two weeks. We measured wellbeing using the WHO-5, and individual concerns using the Measure-your-own- outcome-profile (MYMOP) scaling at the beginning and after two weeks.

Results: Linear Models confirmed that the two active interventions were effective over and above waiting (R^2_{adj} = .34; p < .0001). This was confirmed by the MYMOP scales. The novel Healy coil intervention was non-inferior to the Healy system.

Discussion and conclusion: Bioenergy devices can improve the wellbeing and energy of healthy persons short term. A testing of these applications for medical conditions and in patients would be warranted.

Keywords: Health; Wellbeing; Bioenergy; RCT; Frequency

1. Background

Modern life is full of challenging situations. The corona-pandemic 2020/21 added to normal strains some extra challenges, such as economic uncertainty, strain on relationships due to restricted travel options, curfews, prohibition to visit elderly family members, home schooling of children, lockdown of small businesses and loss of income for many freelancers. Short of medically diagnosed illness, many individuals seek self-help options on the third health market of wellness and wellbeing applications to help them with what they feel as a "lack of energy", stress, a high burden on their system, sleep related problems, nervousness, anxiety or feelings of depression and low affective states. Although basically medically "healthy", such individuals often want to boost their mental and physical health.

Over the last few years bioenergy or bio-resonance devices have become popular in this field. Due to the enormously grown capacity and miniaturization of IT-technology, it has become possible to mount exceedingly sophisticated devices with intelligent measurement and feedback loops onto small, handheld devices that can be handled easily by untrained lay persons, but have also become popular with medical practitioners and doctors. A similar system, TimeWaver, is internationally used by around 5.000 practitioners treating patients, and Healy, the system studied here is used mostly via self-treatment by around 250.000 individuals world-wide.

The generic principle of such devices is derived from earlier insights into the bio-physical and bio-electromagnetic processes within the human organism. Popp was one of the first to systematically measure biophoton-radiation. He held that biophotons are not only a waste product of metabolism, as conventionally thought, but also a communication channel within living systems [1-3]. A recent review is in support of this idea [4], and some authors have speculated that this venue might open new ways to treatment [5].

There have been various proprietary systems in use in Germany that implement these principles of bioenergetic treatment. In very general terms, such systems measure one or more bioelectric properties of the organism, for instance resistance or capacitance for different frequencies of the electromagnetic spectrum using alternating currents of low energy, mostly below the threshold of sensation, and often at high frequencies. These measurements are then used, either following an a-priori-framework of empirically derived frequencies as a diagnostic, or following some theoretical ideas and fed back in slightly altered modes to the organism, using electrodes of various kinds and of different applicatory modes, for instance hand-held electrodes, or electrodes attached to certain locations on the body. The empirical database is preliminary, but positive, demonstrating that in many cases even refractory problems such as chronic pain can be treated [6]. Although some scientific studies have been published [7-13], bioenergetic therapy has not been accepted by conventional medical science, both due to the complex theoretical rationale, and a lack of a robust randomized evidence base.

We report here the results of a two-week randomized trial of two modern bioenergetic devices against a wait-list control group in a group of 260 volunteers who felt that the usage of such devices would help

them cope better with their lives and improve their health.

2. Method

2.1 Design

The study was a three-armed, randomized, parallel design of two weeks treatment duration with a measurement point at the beginning and at the end of the study. A study protocol was finalized before commencement of recruitment. Volunteers were recruited via an existing network of persons interested in this type of treatment. Two active devices were compared with a wait-list control group and participants were randomized in a 1:1:1 ratio to one of the three groups.

Those randomized into the active groups were sent one of two devices (see below) including instructions on usage and were free to use the device following included recommendations for the next two weeks for an application dose of 1 to 2 applications of 45 minutes duration.

2.2 Participants

Participants were healthy volunteers who felt that they would profit from some self-help treatment in their general health. They gave written informed consent to participate.

Volunteers were excluded if they were younger than 18, pregnant, had a pacemaker implanted, or any other electronic or metallic device at or near the place of application on the body, open wounds, scar tissue or insensitivity or radiation therapy near the place of application, or a history of epilepsy.

2.3 Treatment device

Two bioenergetic devices were tested: Healy and HealyCoil. Both devices use basically the same internal proprietary hard- and software. Whereas Healy needs to be attached to the body via electrodes and cables on various places depending on the program and the aim, Healy Coil can be used without connecting cables. The electrodes were exclusively placed as conductive wrist bands at the wrists, so that the mircrocurrent would flow through the upper part of the body.

Healy and Healy Coil both use Frequencis from 0.1 Hz to 1 MHz. Healy applies an electrical current between 200 uA and 1000 uA, whereas the Healy Coil uses a bilfilar coil with a nullified magnetic Field but a non-zero magnetic vector-potential (original magentic field strenghts of each single coil is around 2.0 uT). In each case the maximum applied voltage is 10 V.

HealyCoil applies exactly the same physical parameters of frequencies, duration, amplitude etc. but applies them not by modulation on mircrocurrent but through two opposite coils, whose magnetic fields cancel each other, in order to create a pure magnetic vector potential with a nullified magnetic field. The effect of magnetic vector potentials on charged particles like electrons was described and experiment-tally confirmed and is known as the Bohm-Aharanov effect [14]. In order to have a local effect of the magnetic potential of the HealyCoil it should be placed with a clip very close to the body for example at the collar of the shirt or at the belt.

Those randomized into the waitlist control group received the HealyCoil device after their 2 weeks of waiting was over. Participants received a detailed instruction booklet that helped them with their treatment program of choice and were instructed to use the device 2-3 times a day.

2.4 Randomization

Randomization was conducted by using an online system [15] which produced codes with random numbers according to which registered volunteers were served either with the devices, which were sent to them via mail, or informed that they had to wait for 2 weeks and would receive their device then. Randomization thus was blinded in that neither those who dispatched the Healy devices nor the participants had any knowledge of the sequence.

2.5 Outcome measures

Due to the deliberately heterogeneous volunteer sample, we opted for one very generic and one very individualistic outcome measure. The primary outcome was the WHO5-Wellbeing scale [16-18], a 5 item scale that has been found to be both very parsimonious, reliable and widely applicable to measure wellbeing as a generic scale. The five items of the scale reflect on the state of the last 2 weeks (… cheerful and good spirits, calm and relaxed, active and vigorous, woke up fresh and rested, daily life filled with interesting things) and are rated on a six-point Likert scale ("at no time", "some of the time", "less than half of the time", "more than half of the time", "most of the time", "all of the time"). The items can be summed up to yield a sum score ranging from 0 to 25, or, if standardized on a percentage scale from 0 to 100. Clinically manifest depression is supposed to be present if someone scores less than 50 points, and population means in European countries are around 70 points. We used the standardized sum score as a main outcome and present these standardized scores (sum score multiplied by 4).

As secondary outcome we used an individualized score, the Measure Your Own Medical Outcome Profile (MYMOP) Score [19-22]. This is an individually defined measurement system following the generic approach of goal attainment scaling [23]. Individuals are free to define as many – usually up to three – areas of their physical or mental state that they want to see changed. This can be, for instance, sleep, energy, and mood in one patient, and mobility, pain and sexual interest in another. This way, everyone can choose their own areas of change. It is rated initially on a 10-point numerical rating scale. The content area is safely stored and implemented in the follow-up measurement for the participant to score once more. We used three health concerns that participants could mention and rate at the beginning and after 2 weeks treatment or waiting.

Adverse events were elicited by an open question.

Outcomes were measured by presenting the questionnaires as online questionnaires, as soon as informed consent was received, and then again after two weeks, using an email-prompting system that led participants to the online-questionnaire. Since the study was conducted in healthy, well informed volunteers giving informed consent, ethical counsel was not sought and was not necessary according to local legal frameworks.

2.6 Statistics

The protocol defined a hierarchical, two-step testing procedure: Both active treatments were to be tested against the control with a superiority hypothesis, and both active treatments against each other with an equality hypothesis in a second step. This was to be tested using generalized linear models, one for the primary outcome, with appropriate contrasts to test the hypotheses, and one for the secondary outcome, with appropriate contrasts.

As there was no predecessor study on which to gauge effect size and power-analysis, an ad—hoc power analysis was conducted. This assumed a small to medium effect of 8 points difference between the treatment groups and the control groups, which is considered a clinically meaningful difference. For this difference to be statistically proven at a significance level of 5% and with 90% power 100 individuals per group were deemed necessary. A small non-inferiority difference of 2 to 4 points between the two active groups would be able to be statistically ascertained at a power of 76%. We therefore aimed to recruit at least 200 participants into the study and set as an upper limit 300 participants.

Missing data were to be interpolated by a conservative last-value-carried-forward algorithm which assumes no change between baseline and follow-up. This was only employed for the primary outcome. As the secondary outcome might not be fully made use of by some participants and because of its extremely individual nature, it was decided before commencement of the actual analysis to not use any missing-data interpolations for this variable but to use a robust multivariate linear model that can handle missing data.

3. Results

Two hundred and sixty participants fulfilled the inclusion criteria and were randomized into the study. None was lost to follow-up. Ninety participants were randomized to receive the Healy application, 77 to receive the HealydCoil application and 93 were randomized into the wait-list control group. Baseline data are presented in Table 1.

As can be seen from Table 1, the randomization process yielded three quite comparable groups. Due to data-protection concerns age was only collected in rough categories. The majority of the participants, 75%, were female. Two thirds or 172 participants belonged to the middle-aged group between 40 and 60, but nearly 20% were older than 60 years. One hundred and ninety-four participants or 75% said that the reason for use of the device was to improve both mental and physical health. A minority of 18 participants or 7% wanted to improve mental health only and 44 individuals (17%) wanted to improved only their physical health. The majority of participants, 216 (83%) mentioned no other reasons for use. The rest mentioned various reasons from very specific ones like usage in agriculture or with animals, or for hot-flashes treatment to very generic ones like prevention or improving general health (see Table1).

Seven participants were attracted to the study because the Healy Coil would allow them to use the system without cables in a more mobile fashion.

The baseline outcome data were similarly well distributed, with the MYMOP2 variable slightly adrift. Data for the primary outcome, WHO5 were complete, whereas data for the MYMOP scales had some missing values. For the follow-up data of the WHO-sum score 3 data sets were missing and were interpolated with their respected baseline values (last value carried forward).

	Coil (n = 77)	**Healy (n = 90)**	**Control (n = 93)**	**Total (n = 260)**
Gender				258 (2 missing)
Female	58 (30%)	66 (34%)	70 (36%)	194
Male	18 (28%)	24 (38%)	22 (34%)	64
Age Groups				260
20-40	12 (32%)	12 (32%)	14 (37%)	38
40-60	49 (28%)	60 (35%)	63 (37%)	172
60-80	15 (32%)	17 (36%)	15 (32%)	47
>80	1 (33%)	1 (33%)	1 (33%)	3
Reason for Use Improvement of…				260
Mental and physical health	52 (27%)	77 (40%)	65 (34%)	194
Only mental health	7 (39%)	4 (22%)	7 (39%)	18
Only physical health	15 (34%)	8 (18%)	21 (48%)	44
Other	3 (75%)	1 (25%)	0	4
Additional Reason for Use				260
None	66 (31%)	76 (35%)	74 (34%)	216
Pain treatment	0	3 (60%)	2 (40%)	5
Balance	0	4 (100%)	0	4
Energy	2 (100%)	0	0	2
Skin treatment	2 (50%)	0	2 (50%)	4
No cables	2 (29%)	1 (14%)	4 (57%)	7
Prevention	2 (50%)	1 (25%)	1 (25%)	4
Mental stability	0	0	2 (100%)	2
Immunological	0	0	1 (100%)	1
Fitness	0	2 (100%)	0	2
General health	1 (33%)	1 (33%)	1 (33%)	3
Spiritual	1 (25%)	0	3 (75%)	4
Post surgery treatment	0	0	1 (100%)	1
Hearing, tinnitus	0	1 (50%)	1 (50%)	2
Use in agriculture or with animals	0	1 (50%)	1 (50%)	2
Hot flashes	0	1 (100%)	0	1
Outcome Parameters Baseline				

WHO 5 (0: worst; 100: best)	76,0 (5,3) [74,8; 77,2] n = 77	75,4 (4,3) [74,5; 76,3] n = 90	75,4 (5,0) [74,4; 76,4] n = 93	75,6 (4,8) [75,0; 76,2] n = 260
MYMOP1 (0: best; 10: worst)	6,8 (2,1) [6,3; 7,3] n = 69	6,6 (1,2) [6,2; 7,0] n = 85	7,2 (2,0) [6,8; 7,6] n = 90	6,9 (2,0) [6,6; 7,1] n = 244
MYMOP2 (0: best; 10: worst)	6,7 (2,0) [6,3; 7,2] n = 70	6,2 (2,0) [5,8; 6,6] n = 86	7,0 (1,7) [6,7; 7,4] n = 89	6,7 (1,9) [6,4; 6,9] n = 245
MYMOP3 (0: best; 10: worst)	6,5 (2,2) [6,0; 7,1] n = 64	6,0 (2,0) [5,8; 6,4] n = 81	6,6 (1,8) [6,2; 7,0] n = 86	6,4 (2,0) [6,1; 6,6] n = 231

Table 1: Gender, Age-Groups, and Reasons for Treatment per Group (Active 1: Healy Coil; Active 2: Healy; Control Group: Wait-list); absolute frequencies and percentages (per line); mean scores for WHO 5 and MYMOP scales (standard deviations), [95% Confidence Intervals].

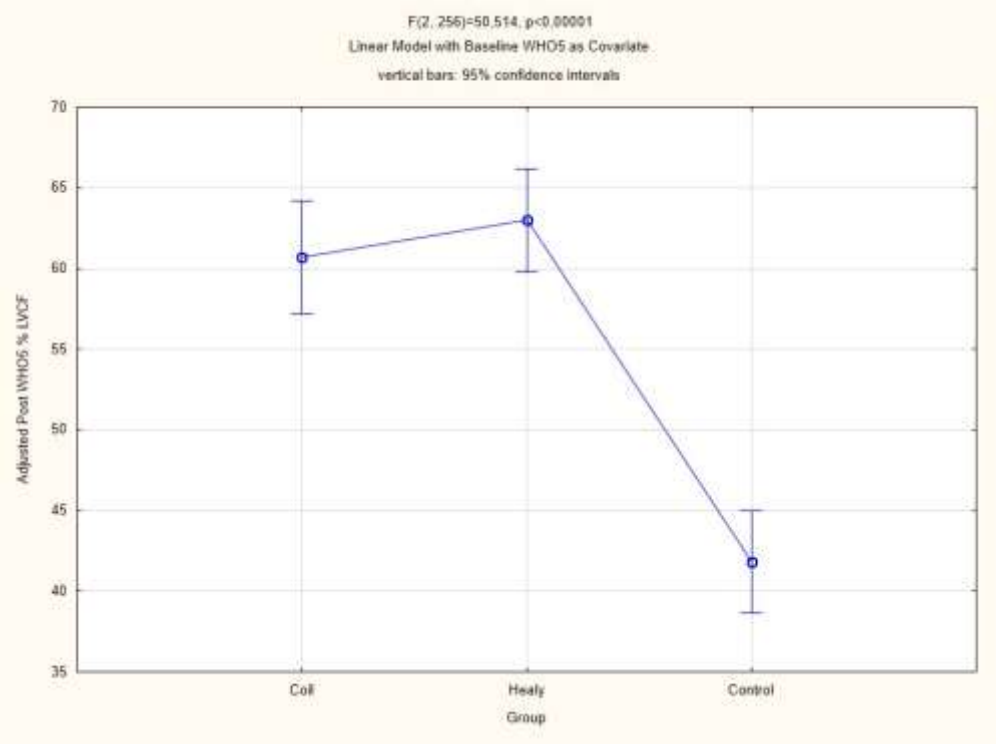

Figure 1: Linear model of main outcome.

The hierarchical testing procedure with linear models and baseline scores as covariates yielded a clear significant effect for the primary outcome (model R^2_{adj} = 0,34; $F_{3/256}$ = 45,68; p < 0.00001). The covariate, Baseline WHO5 was significant ($F_{1/256}$ = 33,35; p < 0.00001; eta^2 = 0,11), as was the group factor ($F_{2/256}$ = 50,5; p < 0.00001; eta^2 = 0,28). The contrast between the two active groups and the control group was significant ($F_{1/256}$ = 99,0; p < 0.00001), while there was no difference between the active groups ($F_{1/256}$ = 0,89; p = 0.34). The difference between the two active groups is 3 percentage points which is well within the no inferiority limit of 2 to 5 points with a standard error of 1,6 to 1,8 points. The confidence limit of non-inferiority would be 3,5 points (1,96* SE) and is not violated by the data. Hence the Healy Coil application can be considered non-inferior to the Healy application, although this non-inferiority is achieved by a small margin. The adjusted post-mean scores are given in Table 2, the analysis is graphically presented in Figure 1.

	Coil	**Healy**	**Control**
Primary Outcome	n = 77	n = 90	n = 93
WHO5 Percent Sum Score	60,7 (1,77) [57,2; 64,2]	63,0 (1,64) [59,7; 66,2]	41,8 (1,61) [38,7; 45,0]
Secondary Outcome	n = 61	n = 79	n = 83
MYMOP1	5,3 (0,34) [4,60; 5,96]	4,6 (0,29) [4,08; 5,21]	6,8 (0,26) [6,24; 7,30]
MYMOP2	5,41 (0,33) [4,74; 6,08]	4,90 (0,28) [4,33; 5,46]	6,37 (0,29) [5,80; 6,95]
MYMOP3	5,80 (0,30) [5,20; 6,40]	4,68 (0,28) [4,12; 5,24]	6,38 (0,28) [5,83; 6,94]
Adverse Events			
No	64 (28%)	84 (36%)	84 (36%)
Yes	12 (46%)	6 (23%)	8 (31%)

Table 2: Outcome Variables - Adjusted Mean Scores (Standard Errors, 95% Confidence Intervals) of Main Outcome (WHO5 Post-score as percentage) and Secondary Outcomes (MYMOP1-3 postscores) and Adverse Events (Frequency, Percent).

The statistical testing of the secondary outcome, the three MYMOP scales, was conducted using a multivariable linear model with baseline-scores as covariates. All covariates were significant. The model itself was also highly significant. The first contrast between the two active groups and the control group was highly significant (Wilk's lambda = 0,90; $F_{3/215}$ = 7,34; p = 0.0001. The second contrast between the two active groups was not significant (Wilk's lamda = 0,972; $F_{3/215}$ = 2,02; p = 0,11). A univariate decomposition of the contrast revealed a significant difference for MYMOP3 (t = 2,11; p = 0.04). As can be seen in Table 2, the actual baseline-adjusted difference is 1,12 points. The confidence limit would

be 0,59 (SE*1,96). This means that in one of the three secondary outcomes the non-inferiority margin is violated. This supports the primary analysis, where the non-inferiority was achieved by a small margin. The secondary outcomes are graphically presented in Figure 2.

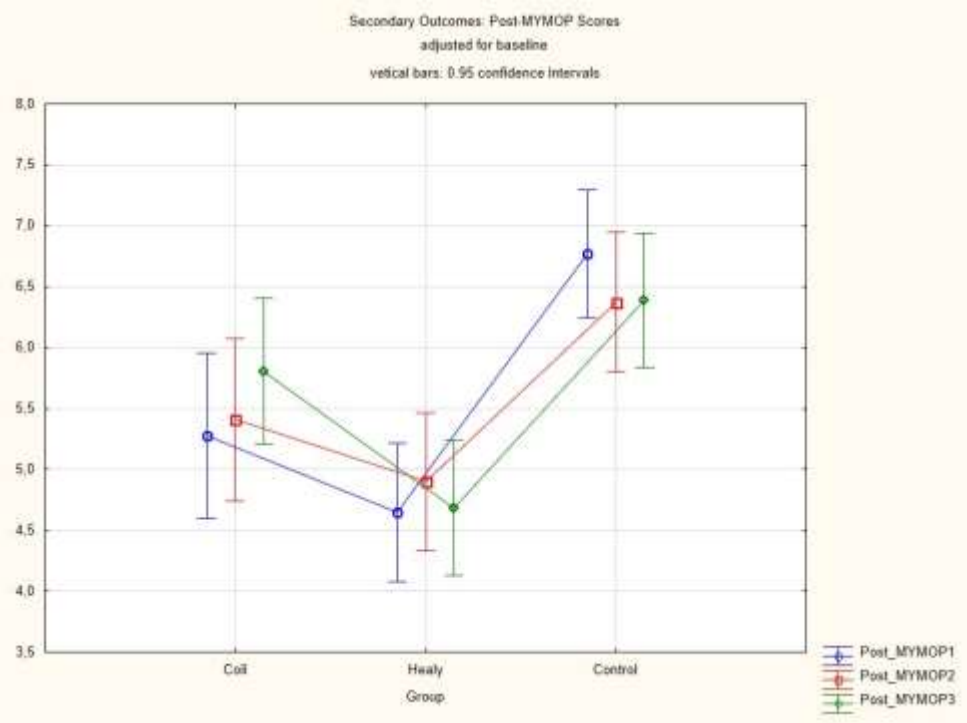

Figure 2: Secondary outcomes MYMOP-scores – postscores adjusted for baseline.

Residuals of both models were inspected for violation of the assumptions. But residuals conformed well to normal distribution, and the plot of cases against residuals revealed no outliers. Altogether 26 individuals reported some kind of adverse issues. Only one person reported an increase in tension and migraine, and this was a person in the control group. Other complaints were by individuals in the control group that they had not yet received their testing equipment.

The other complaints in the active groups referred to some technical issues, loosened cables, faulty or difficult attachments of cables or electrodes or problems with the mailing. None of the reported issues were serious.

4. Discussion

To our knowledge this is the first study testing two bioenergetic devices against a no-treatment wait-list control in a randomized trial in a well-powered study. We find clear evidence for effectiveness of these devices over and against the normal time development in improving general wellbeing and individually chosen health issues (MYMOP). The effects are highly significant and the effect size eta^2 = 0.28 is a

large effect, explaining 28% of the variance, which would equate to an r = .59, which in turn would be equivalent to a standardized mean difference that is larger than one standard deviation [24]. The primary outcome, the WHO-5 Item questionnaire measuring general wellbeing and the secondary outcome, 3 individual goal attainment scales, the MYMOP scales, which measure individually chosen goals of health improvement, are in agreement. The contrast analysis shows that the main effect is between control and both treatments, and both treatments are roughly equivalent, with the more recently developed HealyCoil being somewhat inferior, but not by a statistically clear margin.

These findings have to be seen against the fact that all participants were healthy volunteers and as such a ceiling-effect in the WHO-5 scale could be observed. The baseline scores were well within the margin of population means, but it was still possible to shift them significantly within a two-week treatment. That there was room for improvement can be gleaned from the fact that all participants had some desire for improvement as reflected in the MYMOP scales. Our evaluation concept, using a very generic and well-known scale, the WHO-5, and a highly individualized scoring system, the MYMOP, proved useful. Both showed a similar effect.

As this study was not blinded and participants knew that they were being treated, treatment effects due to the device and treatment effects due to expectation cannot be separated. In a study with partial blinding it could be seen that the effect of expectation can be large [25], and a recent meta-analysis showed that placebo produces strong effects even when presented openly as placebo [26]. However, in our view, for practical purposes this separation is artificial. For in each treatment situation in the real world psychological and genuine treatment effects are mixed and very likely act synergistically to enhance each other [27]. It seems rather interesting that a short-term treatment can elicit such strong and clinically meaningful effects. It would be good to study such effects in clinical patients and see, whether patients suffering from severe symptoms can benefit from such devices. They are easy to apply in a self-help mode and thus can support patients' desire to help themselves. This is a motive frequently cited in surveys of patients' reasons for seeking out alternative treatments [28-30]. Thus, the obvious next step would be a clinical study in patients. From the findings of this study, it is likely that patients with self-reported mild depression, or energy deficits, or fatigue might benefit.

There are various ideas, reviewed by Schmieke [31], how such devices might operate, although none is clearly accepted. There might be stimulatory effects, in that low voltage and high-frequency inputs into the physiological system might non-specifically or in an individual specific manner stimulate cell metabolisms or act at the mitochondrial membrane, bolstering energy supply. It might be also conceivable that such devices regulate bioelectric and electromagnetic properties of the physiological coordination processes within the organisms. But it is a fair assessment, we think, to say that the efficacy of these devices is derived from very generic ideas about the organism's electromagnetic properties and the effects are documented empirically.

The limitations of this study should be borne in mind: although it was well powered the study was only powered to detect a difference between treatments and control and a non-inferiority margin of the treatment. For a more robust assessment, some external and objective measurement in a clinical sample would strengthen the findings. The treatment duration was short, only 2 weeks. A long-term monitoring might be useful to document the stability of improvements.

We conclude that bioenergetic therapy using Healy or HealyCoil is effective in improving general wellbeing and individual health complaints in medically healthy volunteers. The two active interventions are roughly equal in effectiveness, with the traditional Healy being somewhat more effective. But both are clearly superior to no-treatment control. Thus, these devices can be considered useful self-treatment options.

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Authorship Statement

PM organized the study, recruited the participants and collected the data. He also participated in writing and editing of the manuscript. HW developed the design of the study, analyzed the data and wrote the first draft of the manuscript. HW had access to the data and is the guarantor of the study.

Sponsoring

The study was sponsored by Healy GmbH, Kränzlin, Germany.

Role of the Sponsor

The Sponsor provided the bioenergy devices, helped with recruitment by activating his network of users and paid for the analysis. The sponsor suggested some aspects of the design, like the two active devices, non-inferiority of active groups. He paid for the costs of the study and the analysis.

Conflict of Interest

The authors have the following conflict of interests:
PM is an employee of Healy GmbH, the sponsor of the study. HW received consulting fees.

Ethics Statement

As this study was in healthy volunteers who were fully informed and gave written informed consent there was no legal requirement to seek ethical clearance and as the potential benefit – receiving a treatment device and free treatment for free – outweighed the risks, which is non-existent, we felt that ethical clearance is unnecessary.

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