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Research article

Three Arm Pilot Study with Waiting Group Control to Quantify the Effect of Information Field Analysis and Vibration and the Application of Individualized Microcurrent Treatments on Improvement of General Wellbeing and Goal Attainment in Healthy Volunteers

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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 different applications of the Healy device - resonance analysis and vibration of respective results and classical individualized frequency specific microcurrent (FSM) applications - against a wait-list control group in a short-term two-week randomized trial. Method: Healthy volunteers who had given informed consent were randomized to one of the treatment groups using Healy Resonance analysis followed by vibration of analysis results into the participants' information field, or classical Healy individualized frequency specific microcurrent (FSM) applications or had to wait 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: Statistical analysis confirmed that the two active interventions were effective in increasing well-being, whereas the anticipated wellbeing decreases in the control group within the same period. This was confirmed by the MYMOP (Measure Your Medical Outcome Profile) scales. The Healy Resonance intervention shows the same effectiveness for both treatment groups in improving participants decrease in self defined anticipated burdens whereas the decrease in anticipated burdens in the control group was significantly lower. Discussion and Conclusion: The Healy Bioenergy device can improve the wellbeing and anticipated concerns of healthy persons short term by the two investigated modes of action. A testing of these applications for long term improvements would be warranted.

Key words: bioenergetic field analysis, wellbeing, information field, frequency, resonance analysis

Background

Biofield science is an emerging field of study that aims to provide a scientific foundation for understanding the complex homeodynamic regulation of living systems. By furthering our scientific knowledge of the biofield, we arrive at a better understanding of the foundations of biology [1].

The term biofield was proposed in 1992 by an ad hoc committee of Complementary and Alternative Medicine (CAM) practitioners and researchers convened by the newly established Office of Alternative Medicine (OAM) at the US National Institutes of Health (NIH). The committee defined biofield as "a massless field, not necessarily electromagnetic, that surrounds and permeates living bodies and affects the body [2].

Biofield hypothesis implies that complementary therapies act dynamically on bioregulation, rather than on structure function relationships central to the current biomedical paradigm [3].

Recent advances in biofield research have shown that emotional states, intention, stress, and other psychosocial factors can significantly affect biological function. Molecular, cellular, and organismic function and regulation are thus interwoven with and can be influenced by emotion, cognition, and psychosocial factors, suggesting the existence of a "subtle"-i e, low-energy system of biofield—interactions connecting these activities [4].

As a holistic property of the organism and proposed regulator of life functions at multiple levels the biofield could be seen as

conductor regulating the musicians of the ongoing symphony of life.

Based on the theory of biofields, Individualized Microcurrent Frequency (IMF) applications as developed for Healy applications could interact with emotional functions to improve user's status of bioenergetic harmonization.

In 1946, the World Health Organization (WHO) stipulated in its constitution that health was to be understood as a "state of complete physical, mental and social well-being and not just the absence of illness or infirmity" [5]. This understanding of health has become the epitome of an explicitly salute-genetic perspective that was established decades later. For the WHO, well-being becomes the ability to achieve one's own personal, social and economic goals. As a result, critical life events can be mastered, a communal life path can be taken, and the necessary living conditions can be maintained. This includes both subjective and objective parts of health, and at the same time defines a holistic view of bio-psychosocial health [6].

The term implies that an impairment of well-being is always a subjective perception that cannot usually be objectified by diagnostic measures.

In a positive sense, good general condition is usually spoken of even without this differentiation into different areas. In a negative sense, it is referred to as poor general condition for example, as a result of an illness or disability, general defensive reactions of the body occur and/ or the function-al readiness of the entire organism decreases.

All participants should document an assessment of his/her currents status of well-being (WHO-5Q [7,8]) and his /her major concerns (Mymop-Questionnaire [9-11]) before any application of the tested procedures (resonance analysis and vibrating of analysis results respective application of Healy IMF programs) and after 2 weeks of application. Meanwhile, the control group assesses the changes in well-being and the status of their major concerns under normal living conditions and without using the Healy IMF programs.

Methods

Design

The study was designed as a three-armed, open 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. After signing the online informed consent form, participants were randomly assigned to one of the three study groups:

Application Group (A)

Participants perform an information field analysis on the 1st day and vibrate the resulting optimization list up the next 7 days for 1-2 times per day; on the 8th day an information field analysis is carried out again and the test persons vibrate the results again for 7 days.

Comparison group (B)

Participants of this group are assigned to use classic Healy applications with Bioenergetic Harmony 1 and 2 (1-2 programs of which are freely selectable and apply daily 1-2 x) by means of bracelet electrodes.

Control group (C)

Participants assigned to this group were advised not to use any Healy applications for 14 days (waiting group).

Participants

Participants were volunteers who felt that they would profit from some self-help treatment in their general wellbeing or coping with particular issues, such as sleep problems, low affect, or lack of energy. They gave informed consent to participate.

Volunteers were advised to participate only if they will not violate any restrictions for use as given in the Healy product information (pregnancy, 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).

Treatment device

The Healy's device integrated quantum sensor is detecting bioenergetic imbalances when performing a user specific analysis of the bioenergetic field. The sensor interacts with the participants bioenergetic information field and is detecting any imbalances. These imbalance patterns are sent to the digitalized databases to identify the most suitable information to reduce respective to resolve these imbalances. The corresponding information is transferred via vibration into the participants information field, resulting in imbalance repair.

For application of individualized frequency modulated microcurrent applications the Healy bioenergetic device is to be attached to the body via electrodes and cables on various places depending on the program and the aim. The electrodes were exclusively placed as conductive wrist bands at the wrists, so that the microcurrent would flow through the upper part of the body.

Healy uses frequencies from 0.1 Hz to 1 MHz. Healy applies an electrical current between 200 µA and 1000 µA. The maximum applied voltage is 10 V.

Treatment application

Prior to performing resonance analyses of their bioenergetic information field, group A participants indicated two digitalized databases. For each of these databases a resonance analysis was performed by starting the corresponding module available in the HealAdvisor Analyze App. This procedure is detecting the most suitable information available in the corresponding database to resolve the detected imbalance. The corresponding digital information is stored in the participant's optimization list. Each participant vibrated the information of his/her optimization list into his/her personal information field by using the Healy's vibration capability 2-3 times per day for the first 7 study days. On day eight the resonance analysis was performed again, and the updated results were vibrated 2-3 times per day during the second study week.

Participants of group B are assigned to use classic Healy applications with Bioenergetic Harmony 1 and 2 (1-2 programs of which are freely selectable and apply daily 1-2 x) by means of bracelet electrodes. The Healy applications of the Bioenergetic harmony are especially developed to harmonize the participants

bioenergetic field. Participants of group C do not apply any Healy applications for the total study duration of 14 days.

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 [7-8], 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 [9-11]. This is an individually defined measurement system following the generic approach of goal attainment scaling [12]. 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 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 a 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.

Statistics

The statistical analysis was performed hierarchically in a 3 steps procedure:

1.A pre/post comparisons of the different study groups concerning the WHO5-wellbeing scale and the MYMOP respectively to confirm the efficacy of treatments by used of t-tests for paired samples. H0: no difference between baseline and study completion: Baseline Score = Completion Score. H1: increase in wellbeing score respective decrease in symptom burden score in the course of the study: Baseline Score > Completion Score (for wellbeing) respective Baseline Score < Completion Score (for Mymop Symptom Load)

2.Covariance analytic methods to confirm overall group differences with baseline values as covariate. H0: No differences between the study groups. H1: At least one study group differs from both others

3.Post hoc pair-wise comparisons of the different groups

4.All data sets were inspected for violation of the required assumptions to perform parametric tests. In case of any violation of these requirements non-parametric test would be performed, but all datasets conformed well to normal distribution, homogeneity of variances and no outliers could be detected.

As there was no predecessor study on which to gauge effect size and it could not be predefined how many potential participants will give their informed consent, no sample size calculation was conducted.

For the wellbeing score 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 and if not more than one single datapoint of a dataset was missing. In all other cases (if more than on data-point per set was missing), the respective dataset was excluded from the analysis.

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 but to exclude the corresponding participants from the evaluation.

Results

Two hundred and eighty-three participants consented to the study and completed both questionnaires. 85 (Resonance group A) participants of the study used the Healy Resonance App during the study at least once. 102 Participants were assigned to the Healy group (B) and used at least one Healy application of the bio resonance module.); 96 participants are advised not to use any Healy programs (in the course of the study (Control group C). Baseline and compliance 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, 88%, were female. 70 percent or 199 participants belonged to the middle-aged group between 41 and 60, and nearly 20% were older than 60 years. The majority of participants used the Healy to improve both, mental and physical health. The majority of participants, (79%) mentioned no other reasons for use. The rest mentioned various reasons, in about 4% related to spirituality, in about 3% related to health and in about 2 % related to general wellbeing (Table1).

The baseline outcome data were similarly well distributed, with the WHO-5 scale variable slightly adrift (slightly higher values in the control group).

For the follow-up data of the WHO-sum score when complete datasets or more than one single value were missing, these data were excluded from the evaluation. In case one single datapoint was missing in the follow up set, these data were interpolated and replaced with their respected baseline values (last value car-

Table 1. Gender, Age-Groups, and Reasons for Treatment per Group (Active 1: Healy resonance; Healy; frequency modulated microcurrent Group: Wait-list); absolute frequencies and percentages (per category and group); mean scores for WHO 5 and MYMOP scales, [95% Confidence Intervals];compliance per treatment group as defined as follows: for both treatment groups at least five of the stipulated applications are defined as compliant, less than 5 application were defined as non-compliant; for the waiting group up to 5 Healy application = compliant, more than 5 applications = non-compliant.

	Resonance	Healy	Waiting Group	Total
	(n = 85)	(n = 102)	(n=96)	
Gender				
Female	73 (86%)	90 (88%)	87 (90%)	250 (88%)
Male	12(14%)	11(11%)	9 (10%)	32 (12%)
DNS	0 (0%)	1 (1%)	0 (0%)	1 (0.2%)
Age Groups				
20-40	12 (14%)	7 (7%)	17 (18%)	36 (13%)
41-60	54(64%)	77(75%)	68 (71%)	199 (70%)
61-80	19 (22%)	18 (18%)	10 (10%)	47 (17%)
>80	0 (1%)	0 (1%)	1 (1%)	1 (0.2%)
Reason for Use Improvement of… (multiple answers allowed))				
	168	202	176	546
Mental health	76 (45%)	86(42%)	73 (41%)	235 (43%)
Physical health	75 (44%)	97 (48%)	83 (47%)	255 (46%)
Other	17 (11%)	19 (10%)	20 (13%)	56 (11%)
Outcome Parameters Baseline				
WHO-5 Score	49,41	51.5	59,88	
	[45,70 – 53,12]	[47,88 – 55.10]	[56,28 – 63.46]	
MyMop 1	7.4	7.3	7.1	
	[7.03 -7,77] -	[6,90 – 7.68]	[6,60 – 7.53]	
MyMop 2	6.5	7.2	6.9	
	[6.15 - 6.93]	[6,82 – 7.56]	[6,54 – 7.21]	
MyMop 3	7.0	6,72	6,56	
	[6.52 - 7.33]	[6.32- 7.13]	[6.16- 6.96]	
Compliance				
Compliant	81 (95%)	79 (78%)	88 (92%)	
Non-Compliant	4 (5%)	23 [22%]	8 (8%)	

ried forward).

The testing procedure using t-Test for paired samples yielded for both treatment groups using the resonance application respective the frequency modulated microcurrent application a highly significant increase of the WHO-5 scores during the treatment phase by about 15.0 (Group A), respective 12 (Group B) scoring points ($t = -9,65$, $df = 84$, $p < 0.00001$ for group A; $t = -7,16$, $df = 101$, $p < 0.00001$ for group B), while there was no significant difference between these groups (Figure 1).

In the participants group not using any Healy applications the mean WHO-Score significantly decreases by about 11 scoring points in the course of the study ($t = 5,38$, $df = 95$, p-value < 0.00001), (Figure 1).

Respective the changes in wellbeing score no significant differences could be detected when comparing group A and group B, whereas both groups were statistically superior to the control group.

The statistical testing of the secondary outcome, the three MYMOP scales, was conducted using a paired t-test for all participants of the different groups separately.

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

	Resonance	Healy	Waiting Group
	(n = 85)	(n = 102)	-96
Outcome Parameters Study Completion			
WHO-5 Final-Score	64.4	63,41	48,13
	[60.61 – 68.13]	[60,27 – 66,55]	[44,38 – 51.86]
MyMop 1	4.6	4.8	6.2
	[4.13 -5.15] -	[4.31 – 5.36]	[5.72 – 6.71]
MyMop 2	4.7	4.9	5.8
	[4.21 – 5.17]	[4.33 – 5.36]	[5,36 – 6.31]
MyMop 3	4.8	5,00	6,02
	[4.28 - 5.28]	[4.53- 5.47]	[5.52- 6.51]
Change from baseline			
WHO-5	15.0	11.9	-11.8
	[11.88 – 18,04]	[8.61 – 15.22]	[-16.08 – -7.42]
MyMop 1	-2.8	-2.5	-0.8
	[-3.34 - -2.31] -	[-3.07 - -1.88]	[-1.23 – -0.35]
MyMop 2	-1.9	-2.4	-0.1
	[-2.42 - -1.33]	[-2.93 - -1.79]	[-1.51 – -0.42]
MyMop 3	2.2	-1.7	-0.5
	[-2.71 --1.61 -]	[-2.27 - -1.16]	[-1.11- 0.08]

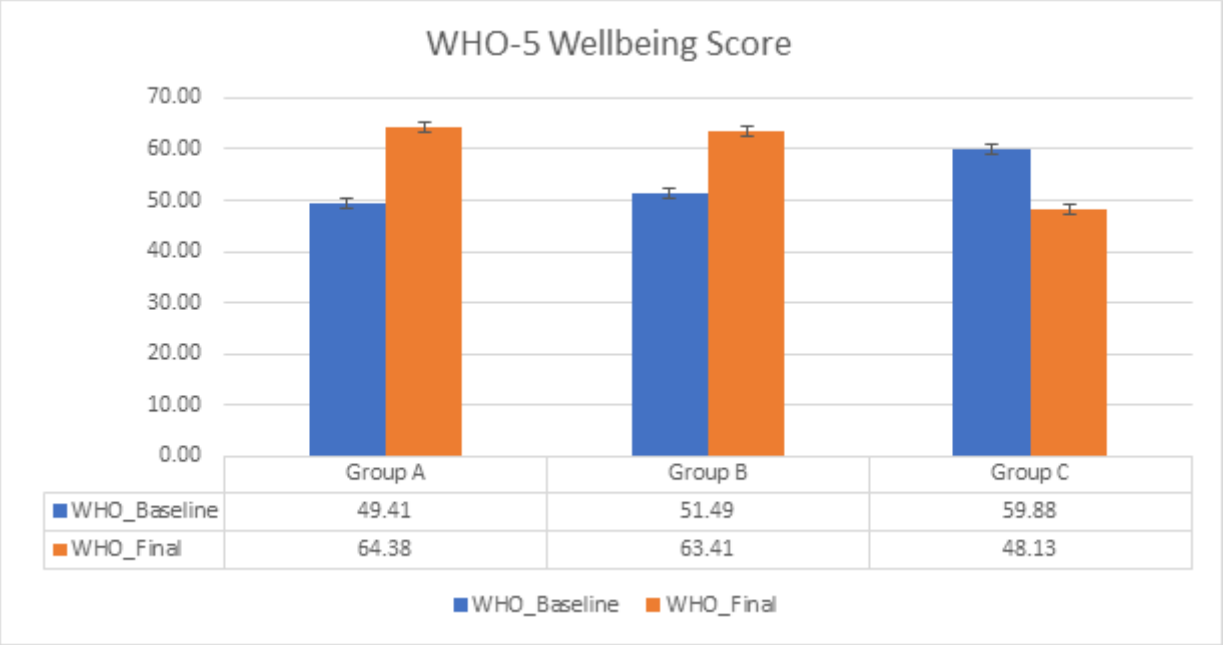

Figure 1. Main Outcome, change in WHO-5 wellbeing score, average and 95% confidence intervals

For both treatment groups a highly significant decrease in concern-load could be observed during the treatment for all concerns by 2,0 up to 3,0 scoring points (Table 2 and Figure 2). In the control group the concern load decreases by 0,5 to 1,0 scoring point only within the same period. Superiority of both treatment groups against the control group could be statistically confirmed, whereas differences between both treatment groups were only marginal and statistically not significant.

Altogether 27 individuals reported some kind of adverse issues (Table 3). In some cases these issues were related to non-medical problems like technical problems (10 cases), job related (2). 14 persons reported in total 15 health related adverse events (Table 3). I most cases these are related the mental condition (8) and pain (2). None of the reported issues were serious.

Table 3. Occurrence of Adverse Events in the course of the study per study group

	Resonance (n = 85)	Healy (n = 102)	Control (N=96)	Total
Mental disorder	1 -	5	2	8
Pain	0	2	0	2
Skin disorder	1	0	0	1
Disk Prolapse	0	1	0	1
Stiffness	0	1	0	1
Sleep disturbance			1	1
General Condition impaired			1	1
Total	2	9	4	15

Discussion

The results of this pilot study are indicating clear evidence for effectiveness of focusing on personally important topics followed by an information field analysis and vibrating of the resulting information against the normal time development in improving general wellbeing and individually chosen health issues (MYMOP). The effects are highly significant and the effect size for group differences regarding improvement of well-being (eta2 = 0.31) is indicating a large effect, explaining 31% of the variance. [13].

The secondary outcome, 3 individual goal attainment scales, the MYMOP scales, which measure individually chosen goals of health improvement, are in agreement (Figure 2), despite the effect sizes are smaller (eta2 = 0.11 for concern 1, 0,04 for concern 2 and 0,06 for concern 3). The contrast analysis shows that the main effect is between control and both treatments, and both treatments are roughly equivalent.

These findings must be seen against the fact that the study was designed as open study. 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. This effect may even be enhanced by the fact, that participants are advised to focus on special items which they strive to improve. In a study with partial blinding it could be seen that the effect of expectation can be large [14], and a recent meta-analysis showed that placebo produces strong effects even when presented openly as placebo [15].

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 [16]. 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 a long-term setting and see, whether these effects are persisting. They are easy to apply in a self-help mode and thus can support subjects' desire to help them. This is a motive frequently cited in surveys of patients' reasons for seeking out alternative treatments [17-19].

There are various ideas how a person's bioenergetic field is acting as sender to transfer information into the information

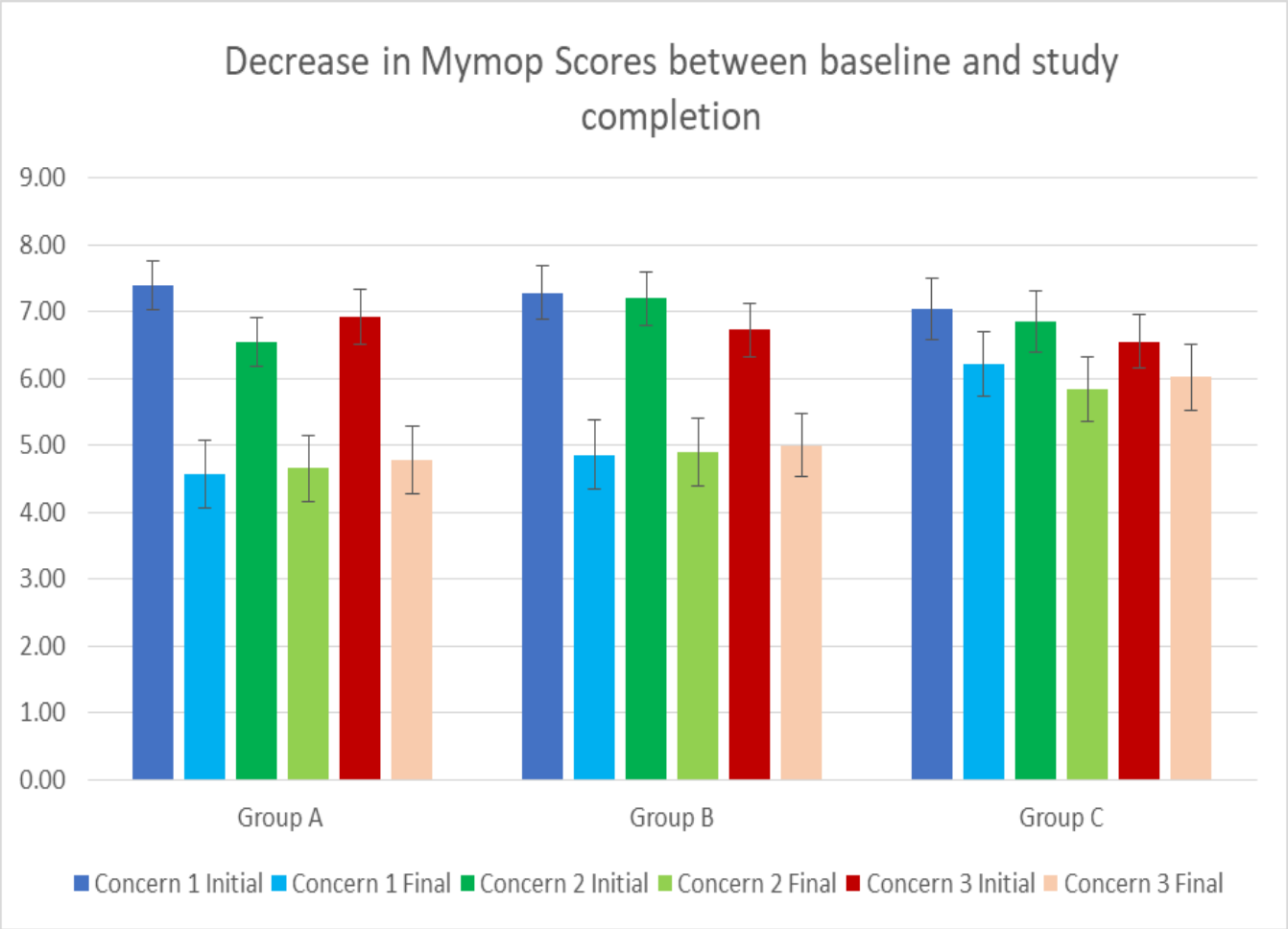

Figure 2. Secondary Outcomes MYMOP-Scores – Pre and Postscore in the different treatment groups

field, and how information from the information field could be transferred into the personal bioenergetic fields [20]. These interactions are far from being understood but it might be conceivable that these interactions may 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.

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. 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 resonance therapy using Healy and Healy conventional FMS is to the same degree effective in improving general wellbeing and individual health complaints in medically healthy volunteers. Both are clearly superior to no-treatment control. These findings agree with previous studies showing also the superiority of Healy applications against a control waiting group [20, 21]. Thus, both approaches tested within this study, can be considered useful self-treatment options.

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We are grateful to the participants that they helped this research by participating without remuneration. PM is an employee of Healy GmbH, the sponsor of the study. MS is co-founder and scientific consultant of this company.

Authorship Statement

PM organized the study, recruited the participants and collected the data. He also analyzed the data and wrote the first draft of the manuscript. MS developed the design of the study and finalized the manuscript.

Sponsoring

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

Role of the Sponsor

The Sponsor 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 modes of action, superiority of both active groups against the untreated control. He paid for the costs of the study and the analysis.

Conflict of Interest

The author has the following conflict of interests: PM is an employee of Healy GmbH, the sponsor of the study.

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 ben-

efit – receiving a treatment device– outweighed the risks, which is non-existent, we felt that ethical clearance is unnecessary.

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