DJ Benjamin, H Bilz, G Fischer, J Burke, S Alexander, S Penny(Australien)

Therapy on the cancer process with the Quantron Resonance System

Abstract - A randomised double-blind crossover trial was carried out using 5 pairs of cancer patients treated for 8 weeks with an active pulsating magnetic field (PMF) device and 8 weeks with a placebo. The trial was to test the hypothesis that PMFs of special frequencies, particularly Extremely Low Frequencies (ELF: 3Hz – 300Hz), affect human cells in cancer patients in a way that improves their metabolism, thereby helping to reverse the cancer process or milieu. Several factors claimed to be characteristic of cancer progression were measured before and after the eight weeks of active treatment and before and after the eight weeks of placebo. Results showed that, using one of the four monitoring methods, there were small positive changes observed in two of the three functions measured in the group receiving active treatment relative to their response with the placebo (viz Stage Progression and Lymph System Stress). Using a second method a consistent overall improvement was observed in cell metabolism, heart, allergic response, endocrine system, peripheral and central nervous system, lymph and small intestine. Using a third method no positive benefits were observed but readings suggested that the magnetic field strength might have been too high for optimum effect in some participants. Using the fourth method, a Lymphocyte Viability Test, no benefits were observed. Several of these treatment effects reached significance ($P<0.05$) despite the small numbers in the trial. Most of those that did not reach significance showed a positive effect, suggesting that the effect was real rather than due to chance.

Some carryover effect was observed between the active and placebo treatment periods suggesting that the treatment effect might be understated. A longer washout period should be used in future trials. These results throw some light on the factors that might be important in reversing the cancer process and suggest ways of improving protocols and monitoring changes for future trials.

Introduction

For many years controversy has surrounded the hypothesis of what cancer is. The current paradigm sees cancer as a process that starts locally, sometimes recurring locally, later spreads regionally and, in its final stages, metastasises to a remote site. An alternative paradigm sees cancer as a degenerative disease with many contributory factors, including psychological ones, with the tumour seen as a late-stage symptom of the systemic breakdown of the body's cell metabolism and possibly also of the body's immune system[1].

There is therefore a need to shed more light on the cancer process and investigate whether the alternative paradigm is closer to the truth. For this purpose it is necessary to develop methods of measuring the effects, if any, of systemic therapies on the cancer process with a view to identifying what that process might be.

Randomised double-blind placebo controlled trials have demonstrated the efficacy of ELF pulsed electromagnetic fields in reducing pain in osteoarthritis and persistent rotator cuff tendonitis[2-4]. Research (by G Fischer in the Dept of Biology at the University of Graz in Austria, HL Koning in the Dept of Electrophysics at the University of Munich and U Warnke in the Dept of Biomedicine and Biology at the University of Saarbruken in Germany, and SD Jovanic in the Dept of Electrophysics at the University of Belgrade in Yugoslavia) has suggested that the PMF mechanism is systemic and affects cellular metabolism. In particular it suggests that such fields

- help to restore the cell membrane potential[5] that is depressed in people with degenerative disease;
- increase the partial pressure of oxygen and the perfusion of oxygen into cells, thus tending to reverse the anaerobic process whereby cancer cells grow;
- affect the calcium cascade process in cells;
- activate enzymes and free radical scavengers;
- help to regenerate and restructure cells[6].

Each of these factors is claimed to affect the absorption of nutrients into the cell and the elimination of the cell's waste products and possibly also affect the immune system. Such effects are claimed to be observable in the blood of cancer patients immediately after PMF treatment. Tens of thousands of people have been treated with ELF PMFs for a wide variety of conditions with many anecdotal reports of positive results[7]. Similarly many practitioners have used such devices on cancer patients and have reported positive results, even with terminal cancer patients[8] although again these are only anecdotal.

The purpose of the present trial is to test the hypothesis that pulsating magnetic fields affect cells, identify the organs affected and, if possible, identify the mechanism for the action of the fields.

Four factors were measured to identify the types of change involved:

1. Immune response, measured by means of the Lymphocyte Viability Count[9];
2. Disease progression as shown by the Bolan's Clot Retraction Test[10-12]. This test identifies systemic effects of metabolic dysfunction caused mainly by Reactive Oxygen Toxic Species (ROTS) which include the free radicals and hydrogen peroxide. The test measures Oxidative Stress overall as a measure of stage of cancer progression; and includes a measurement of acute stress to the lymph system and central organs (particularly the gastro-intestinal tract).
3. Blood circulation efficiency. This was in the form of monitoring changes in the blood volume being pumped, blood pressure in peripheral circulation, blood viscosity and the amount of oxygen being transferred from the blood to the peripheral tissues. These four factors were measured by means of **N**ear-**I**nfrared **R**ed **P**hotoplethysmography (NIRP) using a **C**omputerised diagnostic device for measuring **M**icro- and **M**acrovascular **D**ynamic perfusion (CMMD)[13-14].
4. Skin resistance at selected acupuncture points. This was Electro-Dermal Screening Testing (EDST) in the form of a **L**ife **I**nformation **S**ystem **TEN** (LISTEN Machine)[15]. This is based on the hypothesis that various acupuncture points relate to different organs or organ systems. When an organ is unhealthy the skin resistance of the relevant acupuncture point changes, up or down, from the typical value of 100 kilo-ohms.

Method

Ten cancer patients were randomised into two groups, a treatment group and a placebo group. Half were treated with a PMF device for 8 weeks after which there was a 2-3 weeks Crossover during which the treatment and placebo groups were reversed. Lymphocyte Viability and Clot Retraction Tests were carried out and CMMD and LISTEN readings were measured in all participants before and after the first 8-week period and again after the second 8-week period. Both the practitioner and patient recorded symptoms during the eighteen weeks of the trial. Records were kept of any special treatments undergone during the trial.

The protocols

Test protocols were based on those developed by Dr Hannalore Bilz formerly from the QRS Company in Darmstadt, Germany who has treated many cancer patients. The control box for the device has 10 settings with increasing magnetic field intensity. The protocol consisted of three 8-minute sessions each day (morning, mid-day and evening) starting with setting 3 in the morning, 3 at mid-day and 1 in the evening. From the second week they were increased to settings 4,3,1 and in subsequent weeks to 5,4,2; 6,5,2; 7,6,3; 8,7,4; 9,8,5 and finally 10,9,6 for week 8. The same rising settings were used for the second 8 week period after the active and placebo devices were swapped.

The device

The device used was a Quantronic Resonance System (QRS - Salut II) consisting of a control box with 10 settings connected to a "mat" approximately 1m x 2m on which the participant lies. The mat has a single inlaid coil that is bent backwards and forwards around the complete area so as to generate a uniform magnetic field under the body. The patient lies on the mat for the eight minutes. Once the setting is selected and the ON button pushed the control box generates a cycling saw-tooth waveform whose polarity reverses every 2 minutes and switches off at the end of 8 minutes. The magnetic field waveform incorporates a range of frequencies between 0.1Hz and 1000Hz, especially around 3, 23 and 200 Hz at a maximum field intensity from 1.5 microtesla at setting 1 to 15 microtesla at setting 10.

The five placebo devices were normal ones whose control boxes had been modified by the manufacturer so as to generate no current and therefore no magnetic fields in the mats. All lights on the control box were illuminated and fluctuated in the usual way as if the device were active. The 10 devices were provided to the Trial Leader in pairs, one active and one placebo, with the coding withheld until the end of the trial. Thus this was a randomised, double-blind crossover trial.

The 10 participants were divided into five pairs, one to receive the active device for the first 8 weeks and the other the placebo. The first participant in each pair was asked to pick one of the devices. The second device was used by the second member of the pair.

The participants

The 10 participants included 3 with breast cancer, 1 with bowel cancer, 1 with lung cancer, 1 with medullary carcinoma of the neck, 1 with melanoma, 1 with nasopharyngeal cancer, 1 with Non-Hodgkin's Lymphoma and 1 with squamous cell carcinoma of the maxillary sinus.

The tests

The Lymphocyte Viability Test was carried out in the normal way by drawing a blood sample.

The Bolan's Blood Clot Retraction Test involves producing a drop of blood at the fingertip using a pinprick and touching it several times onto a slide. After drying, the slide is viewed under a Brightfield/Phase-contrast Microscope. The appearance of the drop, particularly of the fibrin net, is claimed to give a measure of the progress of degenerative disease, including cancer. If the blood were affected by the ELF PMFs during the 8 weeks of treatment, it would show up on such a test.

The Blood Circulation Test using the CMMD has been claimed to show rapid changes in the blood circulation of patients with degenerative disease, including cancer. However, as mentioned above, the only evidence of longer term effects with cancer patients are anecdotal. Information about characteristics of the vascular system is obtained from the shape of the blood pulse, particularly the relative height and position in time of the dicrote, ie the portion of the pulse wave shape due to the second expansion of the artery. The pulse profile was measured using Near Infrared Red Photoplethysmography. This involved strapping the sensing diodes to the fingertip of the participant. After several minutes of relaxation, and the stability of the temperature and pulse were confirmed, the computerised readings were taken and integrated over a 70 second period, stored if satisfactory and blood characteristics calculated.

Eight different parameters were derived from the pulse shape, in particular the size and position of the dicrote. Four of these relate to the microvascular system and four to the arterial (macrovascular) system. The relative changes in these parameters in relation to the normal range gives some indication of improvement or deterioration of the arterial system or its parts.

For Electro-Dermal Screening Testing (EDST) the ohm meter used to measure the skin resistance is designed to deliver approximately 10-12 microamperes of direct electrical current at 1-1.25 volts. It is calibrated to read from 0 to 100 such that the standard skin resistance of 100 kilo-ohms reads 50. If the reading is below the optimum value of 50 it is claimed to represent degenerative disease; if above the optimum, an acute condition such as inflammation.

There were about 22 readings taken on each person (out of the 54 commonly used), each corresponding to an acupuncture point related to a particular organ or organ system. The 22 points chosen were those considered relevant for people with cancer.

A person in perfect health would measure about 50 on all 22 readings. Efficacy of treatment would be indicated by a reduction in the departure from 50 of the average of the 22 the readings. For large reductions the points that contributed most to the improvement could be identified.

Results

During the course of the trial one patient died (breast cancer) and one (NH Lymphoma) withdrew to travel overseas. For this reason the results of only 8 participants were available. A second participant, (nasopharyngeal cancer) died 5 months after the trial ended, a third (lung cancer) died 12 months after the trial and a fourth (squamous cell carcinoma of the sinus) died 3 months later. The remaining six participants continue in good health.

In the following summary confidence levels and confidence intervals were calculated using two-sample t-tests (two-tailed) with six degrees of freedom. *Significant* means $P \leq 0.05$. *Marginally significant* means $P=0.05$ to 0.1. *Not significant* means $P>0.1$. Actual P values are usually given.

Period effects, to determine if one 8-week period was more propitious for treatment than the other, were measured by comparing the mean of the differences in changes measured between Active and Placebo treatments (A-P) during the first period , $\bar{d}_1$, with the mean of the differences (A-P) during the second period, – $\bar{d}_2$.

Carryover effects, to determine if active treatment during the first period was still having an effect during the second period, were measured by comparing the mean of changes measured on active and placebo (A+P)/2 for the two periods ($\bar{a}_1$ and $\bar{a}_2$).

Treatment effects were measured by comparing the mean of the differences (A-P) during the first period, $\bar{d}_1$, with the mean of the differences (P-A) during the second period, $\bar{d}_2$ (rather than the mean value of A-P for all 8 participants).

1. Lymphocyte Viability (LV) Test

For cancer patients, if the state of the immune system is a measure of the ability of the body to control cancer growth, or if the onset of cancer compromises an already weakened immune system, a gradual fall of a few percentage points might be expected over an 8-week period. A significant increase would be unexpected during such a short period. A slight increase might be expected if a cancer patient were undergoing a therapy that was controlling his/her cancer process or strengthening cell metabolism. As all of the patients were undergoing some long-term alternative cancer therapies at the time, a slight increase, even on a placebo device, would therefore not be unexpected.

In Table 1 increasing LV Count towards 100% represents improved immune status. Changes of more than about 10% over a period of 8 weeks would be unexpected, unless an immune suppressing therapy were undergone during this period. As can be seen from Table 1, patient 4y experienced such an effect (fall of 14%) following surgery to remove a melanoma in the shoulder and patient 5x experienced a similar effect (fall of 14%) following a course of chemotherapy received during weeks 14-18.

Overall Effect

Two of the participants (1 active and 1 placebo) did not have tests at the end of the trial. For purposes of comparison their readings were therefore assumed to be unchanged from those at Crossover.

The average count of the 4 patients receiving active treatment in the first period was about 72% at the beginning of the trial, about 67% halfway through the trial at crossover, and about 77.5% after the placebo. The average count for those on placebo first was about 85% at the beginning of the trial, 79.5% halfway through the trial at Crossover, and about 78% after the active treatment. There was a reduction in the number of those with a deteriorating Lymphocyte Viability Count from 4 to 2. Apart from this there appeared to be no benefit from the active treatment.

The treatment effect was -12%, shown in Table 5b as -0.12. This was partly due to the very large improvement (29%) of 5y on placebo following a slight fall on active. The Treatment effect and Carryover effect were both not significant (P~0.25) but this large change made the Period effect marginally significant (P=0.09) as though the second period had been more propitious (or less detrimental) for treatment. This shows the limitation of the small number of participants where one large effect can distort the outcome.

2. Clot Retraction Test

In the following results several participants had measurements taken both at the beginning and end of the Crossover period. In these cases the mean of the two readings taken is used as the Crossover value.

(a) Progression Stage as measured by Oxidative Stress

Table 2a shows the values of the Progression Stage as measured via the Clot Retraction Test. Values represent the stage of progression from Stage 1, representing an earlier tumour to Stage 4 representing advanced progression. Stage values are one of 8, starting with ½ and progressing in halves to 4. A Stage assessed as being 2-2½ is recorded as 2.25.

Cancer patients would be expected to be progressing slowly through the stages towards Stage 4. Any reversal in this progression during an 8-week period would be unexpected unless the progression were a temporary phenomenon resulting from acute effects of a treatment (in the same way that the TLV count might be suppressed following a harmful treatment) with recovery to the earlier value soon after.

For the 7 participants for whom measurements were available, five (2 active and 3 placebo) showed an increase in stage over the first eight weeks and three (2 active and 1 placebo) showed a decrease.

During the second eight weeks a reduction in stage was observed in all 4 of the participants receiving active treatment and increased staging occurred in all 3 on placebo. This suggests a clear treatment effect. The reduction in staging for 2y stopped and reversed during placebo.

Overall effect

The average stage of the 4 patients receiving active treatment in the first period was about 1.25 at the beginning of the trial, about 1.22 halfway through the trial at crossover, and about 2.4 after the placebo. The average count for those on placebo first was 1.81 at the beginning of the trial, 2.45 halfway through the trial at Crossover, and 1.62 after the active. The treatment effect was found to be significant (P=0.013). The Carryover effect was marginally significant (P=0.06). The period effect was not significant (P>0.3).

(b) Lymph Stress

Table 2b shows the results of acute Lymph-system stress as measured by the Clot Reaction Test. This is claimed to be indicative of a compromised immune system or toxins being inadequately drained from the system.

The test differentiates between the lymph systems on the left and right hand side of the body. The values in the Table are averages of the values assessed for the two sides.

Increasing values in Table 2b represent deterioration (increased stress) of the lymph system. With cancer patients a slow deterioration would be expected due to the inefficiency of the detoxification processes.

Overall Effect

The average lymph stress level of the 4 patients receiving active treatment in the first period was 0.75 at the beginning of the trial, about 0.81 halfway through the trial at Crossover, and 1.56 after the placebo. The average level for those on placebo first was about 1.12 at the beginning of the trial, 1.69 halfway through the trial at Crossover, and about 1.0 after the active. The treatment effect was found to be marginally significant (P=0.075). The Carryover effect and the Period effect were not significant (P=0.16 and P>0.3).

(c) Gastro-Intestinal Tract Stress

Table 2c shows the results of acute oxidative stress of the central organs, particularly the Gastro-Intestinal Tract as measured by the Clot Reaction Test.

As with Lymph-System Stress this test differentiates between the organs on the left and right hand side of the body. The values in the Table are averages of the values assessed for the two sides.

Increasing values in Table 2c represent deterioration of the central organ system. With cancer patients this deterioration would be expected due to the inefficiency of the digestion and detoxification processes.

Overall effect
The average GIT stress value of the 4 patients receiving active treatment in the first period was about 0.88 at the beginning of the trial, about 1.69 halfway through the trial at crossover, and about 1.38 after the placebo. The average value for those on placebo first was 1.5 at the beginning of the trial, 1.88 halfway through the trial at Crossover, and about 1.12 after the active. There was a reduction in the number of those with a deteriorating GIT from 4 to 1. The treatment effect was found to be not significant (P>0.3). The Carryover effect and the Period effect were also not significant (P>0.3 and P=0.13).

3. Blood circulation/vascular system (NIRP/CMMD)

In relation to the eight main parameters derived from the measurements
- There were no abnormal rates observed
- There were differences between readings of those on QRS therapy when compared with those on placebo, but none of the differences were significant.

Some changes were observed in one parameter derived from these, viz fibre stretching, that suggested that the protocols requiring all participants to undergo the same increasing magnetic field intensities over the 8-week schedule limited the efficacy of the treatment.

Fibre stretching (FS) refers to the stretching of elastic fibres of (arterial) blood vessels, including intima (the inner layer of a blood vessel, comprising an endothelial monolayer on the luminal face with a subcellular elastic extracellular matrix containing a few smooth muscle cells) where
- an increase in fibre stretching FS means an increased stretching and therefore an increase in peripheral resistance.
- a reduction in FS is a decrease in blood vessel wall stretching (elastic fibres, intima) which can produce a better "cooperation" of the heart and periphery in the cardiovascular system. Too strong a reduction can lead to a "maladjustment".
- the normal range in FS is 0.94……..1.06

These elastic fibres lie immediately above the vessel endothelium, which decisively influences the vascular function and structure (release of vaso-active substances - eg nitrogen monoxide, and vaso-constrictive opponents - eg thromboxane, free radicals and endotheline)

As a general rule a higher QRS level increases the fibre stretching FS. Figure 3 shows the relationship between fibre stretching FS and vessel tonus (muscle tone) in a 50-year-old trial participant. Levels 2 and 4 show a similar rate within the normal range, whereas Level 6 produced a highly increased fibre stretching. From the measurements it was found that
- Generally the participants had a vascular tonus at the low level of the normal range, as expected for those with cancer
- 45% of measurements reached the normal range, so it can be concluded that the selected QRS level was the correct one
- 33% partly showed an acute increase with the selected QRS level (level selected too high) while
- 22% of rates always stayed in the normal range, even with placebo.

From this is can be concluded that for optimal treatment of cancer patients using PMF therapy the magnetic field settings should be determined on an individual basis to ensure that the fibre stretching remains in the normal range.

The settings chosen for the trial were based on a protocol suggested for cancer patients. It would appear that this should be reviewed.

4. Electro-Dermal Screening Testing (Listen machine)

Table 4a shows the data from this screening test for one of the participants (3x).

The measurements have been processed as follows:
1. All readings of R_n were converted to a value $X_n = (50 - R_n)$ and negative values ignored;
2. The sum of all the values of X_n was obtained, viz $\sum[X_n]$
3. The average of all the difference readings was obtained, viz $\sum[X_n]/n$.

If an overall positive effect is observed (a reduction in the average difference) it is then possible to identify those particular organs or organ systems that contributed most to the improvement.

For participant 3x, the average value of the 22 readings Rn was 42.1 before treatment with pulsed magnetic field therapy and 44.5 afterwards. This is a change of only 6%. However the true measure of change in health status is the change in the differences from 50. The change in the average difference during active treatment was from 8.0 to

5.5, a reduction of 2.5 or 31%. The corresponding change during placebo was from 5.5 to 6.0, an increase of 0.5 or 9%, a gradual worsening expected with a cancer patient.

Table 4a also shows the difference in these effects between active and placebo treatment (A-P). For this single participant the sum of the differences over all 22 readings is 69, an average of 3.14.

The averages of the differences, Ave[Xn], before the trial, at Crossover, and at the end of the trial were then used to calculate changes for the 8 participants for whom readings were taken. Results showing the difference between Active and Placebo treatment (A-P) are shown in Table 4b. Figure 4b shows the individual changes. These are also summarised in Table 4c. In Table 4b an improvement in health status (a reduction in the difference from 50) is shown as a positive value. The sum of the 22 readings of A-P is 21.38, the mean improvement being 0.97.

These results were complicated by the fact that only 3 (3x, 4x and 5y) of the 8 patients for whom values were available had all three readings taken. Of the other five,

- one (1x) had no final reading taken. This omitted reading was therefore taken to be the same as at Crossover, ie assuming no change during active treatment;
- one (2x) had no readings taken prior to the start of the trial. This omitted reading was therefore taken to be the same as at Crossover, ie assuming no change during placebo treatment;
- three (2y, 4y and 5x) had no readings take at Crossover. Extrapolated readings were therefore recorded for Crossover. For 2y the second reading was taken midway through the second 8-week period, and no reading taken at the end of the trial. The second reading was taken as the final reading, ie assuming no further change during placebo treatment. The delay in the final reading for 5x (and 4x) was ignored.

With these reservations, the average differences from 50 for the 8 participants were as follows (see Table 4c):

- for those on active treatment the average change was from 7.075 to 4.60, a reduction of 35% for the first group during the first 8-week period and remained unchanged at 4.85 for the second group during the second 8-week period; (or from 5.96 to 4.71, an average fall of 20% for all on the active treatment) whereas
- for those on placebo treatment the average change was from 5.55 to 4.85, a reduction of 13% for the first group during the first 8-week period and from 4.60 to 4.78. an increase of 4% for the second group during the second 8-week period; (or from 5.07 to 4.78, an average fall of 6% for all on the placebo treatment)

This set of readings therefore suggests an overall improvement in the group as a whole during the trial, with most of the improvement attributable to the active treatment.

The overall treatment effect for 8 participants was **1.95**, which was significant **(P=0.038)**, see Table 5(a). This represents the difference between the average of the active–placebo effects for the first four participants (2.69) and that of the placebo-active for the second four (0.74). The Carryover effect was not significant (P=0.17) but the Period effect was (P<0.01). This was due to the fact that during the first period all four participants on active experienced large improvements and three of the four on placebo showed some improvement with no change for the fourth. During the second period two on active showed a small improvement, one showed no change and one (2x) showed a significant deterioration. This combination of factors with a single large apparent deterioration on active made it seem as though the first period had been more propitious (or less detrimental) for treatment. This is the opposite to the observation for the LV Test where a single large effect suggested that the second period was more propitious. These apparent anomalies show the limitation of the small number of participants where one large effect can distort the outcome.

Because 22 readings were taken for each participant it is possible to determine if there were changes in specific organs or organ systems that accounted for the most of this improvement.

The data in Table 4b show that the sum of the readings, the net increase (improvement) of 21, is made up from 15 increases with a total of 28 and 7 decreases with a total of 7. (The 15 increases of 1-5 included five>2.5 and another four >1 while the 7 decreases of 1-3 included five<1.0.) Most of the improvement appeared to be concentrated in three participants (3x, 4y and 5y) and 17 of the 28 increase occurred in 5 measurements (shown in bold): These are:

- 4.88 in Cell Metabolism - Right (ORCR) (4.06 on active vs –0.81 on placebo)
- 4.38 in Heart - Right (HTCR) (3.13 on active vs – 1.25 on placebo)
- 3.13 in Allergy - Right (ALCR) (3.25 on active vs 0.13 on placebo)
- 2.88 Endocrine - Triple-Warmer System – Left (THCL) (3.88 on active vs 1.00 on placebo)
- 2.63 in Peripheral and central nervous system – Left (NECL) (2.25 on active vs –0.38 on placebo)

Other apparent improvements were:

- 2.13 in Lymph system - Left (LYCL) (1.94 on active vs –0.19 on placebo)
- 1.75 in Small intestine – Right (SICR) (1.63 on active vs –0.13 on placebo)
- 1.63 in Cell Metabolism – Left (ORCL) (1.25 on active vs –0.38 on placebo)
- 1.50 in Lymph system – Right (LYCR) (0.63 on active vs –0.88 on placebo)

The treatment effects and confidence levels for these organ systems were:
• cell metabolism – Right, **9.75 (P=0.17)**; **–** Left, **3.25 (P>0.3)** Not significant.

• heart – Right, **8.75 (P=0.028)** Significant. For example, one participant's reading changed from 38 to 47 on active so the difference from 50 dropped by 9, and the reading then changed to 44 on placebo, the difference increasing by 3. This gave a total improvement on active compared to placebo of 12.
• allergic response – Right, **6.25 (>0.3)** Not significant
• endocrine system (Triple warmer system - Left), **5.75 (P=0.28)** Not significant
• peripheral & CNS – Left, **5.25 (P=0.068)** Marginally significant.
• lymph –Left, **4.25 (P=0.29)**; **–** Right, **3.00 (P=0.096)** Marginally significant.
• small intestine – Right, **3.50 (P=0.28)** Not significant.

Figure 4b shows that most of the 8 participants showed a distinct downward trend in the differences from 50, ie an improvement. Only one (2x) appeared to get worse on active.

From these results it is clear that pulsed magnetic therapy has had a positive effect.

Treatment Effects and Confidence levels

Table 5a summarises the results after calculating the Treatment Effects, the Confidence Levels and Confidence Intervals for the main measurements and Figure 5b shows these results in a graphical form, together with those for the individual organ systems with the fourth measurement method. Results for the third method (NIRP/CMMD) were not meaningful so are not included. As in Table 4b an improvement in health status is shown as a positive value for all measurement methods.

Although only two of the five main measurements shown (2a and 4) and one of 22 organ systems measured (heart) reached significance at the 95% confidence level, three of the five main treatment effects and 11 of the 22 treatment effects for the organ systems were positive. Also most of the treatment effects that were positive were much larger than the negative effects. This suggests that most of the positive treatment effects that did not reach significance were real rather than due to chance and would probably have reached significance with larger numbers in the trial. Table 5b gives a sample calculation.

This would appear to support at least some of the claims made for pulsed magnetic field therapy.

Discussion

It is possible that the PMF device produces positive effects on the cancer process that are not being measured; or that the positive effects observed on the metabolic or other processes are not affecting the cancer process. The results of this trial therefore cannot demonstrate that PMFs have a positive effect on the cancer process; they can only suggest likely positive effects on body processes that might be involved in the cancer process.

The results of this trial cannot necessarily be extrapolated to cancer patients in general because the particular group of participants was drawn from the membership of a Society that supports the alternative paradigm. Most participants were therefore implementing a wholistic program involving body (vitamins, supplements, etc), mind (meditation and other relaxation techniques) and spirit which could possible have affected the body's ability to respond positively to pulsating magnetic fields.

Since this trial was carried out a later version of the PMF device is being developed that recognises the difficulty of treating
cancer patients with different types of cancer at different stages. It uses feedback from the NIRP/CMMD measurements to identify the optimum setting for the particular patient. This should help to overcome the problem identified in the third measurement (NIRP/CMMD), viz using a common protocol might not have been optimal for all participants.

This crossover trial suffered the usual disadvantage of such trials in that several participants either dropped out or did not have all three sets of measurements taken. This meant that the major advantage of such trials, viz requiring only small numbers, was also jeopardised. The results suggest that future trials of this type would require a minimum of 20 participants to ensure a minimum of 15 complete sets of (A-P) measurements.

Conclusion

Results showed that, on two of the four monitoring methods (1 and 3), there were no significant changes observed in the group receiving active treatment relative to their response with the placebo. Using the third method (2 - the blood Clot Retraction Test), certain individuals appeared to have received some benefit and there appeared to be a possible slowing down of the cancer process. Using the fourth method, Electro-Dermal Screening Testing (the Listen Machine), a consistent improvement was observed across most participants. These results suggest that pulsed magnetic therapy has had a positive effect on cell metabolism, heart, endocrine system, allergy and peripheral and central nervous system. This throws some light on the factors that might be important in reversing the cancer process and suggests that in future large-scale trials of PMF devices, suitable tests be included for monitoring of these five major organ systems.

It is of interest to note that the measurements taken do not suggest that PMF therapy has a significant effect on the immune system as such (as measured by lymphocyte viability) although it may be affected indirectly, such as via improved cell metabolism or endocrine function. (The Immuno-Augmentative Therapy clinic in the Bahamas produces significant increased survival with cancer patients by boosting particular immune system components, Immunoglobulins IgA, IgG and IgM[16].)

These results throw some light on the factors that might be important in reversing the cancer process. They also suggest ways of improving protocols and monitoring changes for future trials. For example:

- Future crossover trials should have at least 20 participants to allow for some drop-outs and to ensure that most treatment effects reach significance.
- Tests for the effect of the QRS on the immune system should use a different marker such as immunoglobulins rather than lymphocyte viability.
- Settings should not exceed No. 6 for cancer patients because of the potential problem with free radical formation
- It might be possible to use a feedback device to individualize settings to optimize the QRS treatment. This might be possible in a crossover trial where comparisons are made between active and placebo for each individual. It would not be possible in a simple randomized trial where treatment in the two arms must be identical.

REFERENCES

1. Issels, Josef. Cancer: A Second Opinion. Hodder and Stoughton, London, 1975.
2. Binder A., Parr G, Hazleman B & Fitton-Jackson S. Pulsed electromagnetic field therapy of persistent rotator cuff tendinitis. A double-blind controlled assessment. Lancet. Mar 31 1984; **1**(8379): 695-8.
3. Trock DH, Bollet AJ, Dyer RH Jr, Fielding LP, Miner WK, Markoll R: A double blind trial of the clinical effects of pulsed electromagnetic fields in osteoarthritis. J *Rheumatol* 1993; **20** (3):456-460.
4. Trock DH, Bollet AJ and Markoll R. The Effect of Pulsed Electromagnetic Fields in the Treatment of osteoarthritis of the Knee and Cervical Spine. Report of Randomized, Double Blind, Placebo Controlled Trials. Journal of Rheumatology 1994; **21** (10): 1903-1911.
5. Warnke, U. The Possible Role of Pulsating Magnetic Fields in the Reduction of Pain. Elsevier Biomedical Press, Pain Therapy, 1983.
6. Madronero, A. Influence of magnetic fields on calcium salts crystal formation: an explanation of the 'pulsed electromagnetic field' technique for bone healing. J Biomed Eng (Sep) 1990; **12(5)**: 410-414.
7. Bassett, CA. Beneficial effects of electromagnetic fields. J Cell Biochem (Apr) 1993; **51 (4)**: 387-393.
8. Spall DG. Case studies and testimonials. http://www.quantronic.com.
9. Winchester RJ, Ross G. methods of Enumerating Lymphocyte Populations. Manual of Clinical Immunology. American Society of Microbiology, Washington DC, 1976
10. Bolan HL. The Blood Pattern as a Clue to Diagnosis of Malignant Disease. J Lab & Clinical Med 1942.
11. Gruner OC. A Study of the Blood in Cancer. Renouf Publ Co, Montreal, 1942; and Guidebook for Making the Microscope Study of the Blood for the Detection of Cancer. Mitchell-Swift printing Ltd, Montreal, 1950.
12. Bradford RW & Allen HW. The HLB Blood Test as an Indicator of Oxidative Injury and Disseminated Intravascular Coagulation. Townsend Letter for Doctors & Patients, December 1998: 94-103.
13. Krauß M et al. The Determination of Optimum and Normal Values for Heart and Circulatory Parameters of Human Beings and their Recording by the Noninvasive NIRP-Method. Signal and Image Processing (SIP-96). An International Conference Highlighting Recent Developments in Signal and Image Processing, Session 03 (Biomedical SIP). November 11-14 1996, Orlando, USA.
14. Christ, F et al. Time Discrete, near Infrared Photoplethysmography (NIRP) fro Non-Invasive Investigation of the Volume Pulse in Man. Eur J Med Res 1995,96; **1**: 237-243.
15. http://www.healthy.net/aaabem/EAV/eavexplained.htm. Basic Explanation of the Electrodermal Screening Test and the Concepts of Bio-Energetic Medicine.
16. U.S. Congress, Office of Technology Assessment, *Unconventional Cancer Treatments*, OTA-H-405 (Washington, DC: US Government Printing Office, September 1990) pp138-140.

Table 1 Lymphocyte Viability Test

Before		Crossover		After	
2y	67%	Active	71%	Placebo	76%
3x	89%	Active	82%	Placebo	90%
4y	69%	Active	55%	Placebo	(55%)
5y	62%	Active	60%	Placebo	89%
Average	**72%**		**67%**		**77%**
1x	86%	Placebo	75%	Active	(75%)
2x	90%	Placebo	83%	Active	79%
4x	73%	Placebo	68%	Active	79%
5x	90%	Placebo	92%	Active	78%
Average	**85%**		**80%**		**78%**
Average	78%		73%		78%

Clot Retraction Tests

Table 2a Progression Stage

Before		Crossover		After	
2y	2.25	Active	0.75	Placebo	1.87
3x	0.5	Active	1.3	Placebo	2.5
4y	0.75	Active	1.27	Placebo	2.5
5y	1.5	Active	1.38	Placebo	2.75
Average	**1.25**		**1.22**		**2.44**
1x	2.5	Placebo	2.25	Active	1.75
2x	2.5	Placebo	2.92	Active	2.25
4x	0.75	Placebo	1.75	Active	0.75
5x	1.5	Placebo	3.00	Active	1.75
Average	**1.81**		**2.45**		**1.62**
Average	1.39		2.18		2.07

Table 2b Lymph Stress test

2y	0.5	Active	1.0	Placebo	1.0
3x	1.5	Active	0.75	Placebo	2.0
4y	1.0	Active	1.5	Placebo	1.5
5y	0.0	Active	0.0	Placebo	1.5
Average	**0.75**		**0.81**		**1.56**
1x	1.0	Placebo	2.0	Active	
2x	1.5	Placebo	1.25	Active	2.0
4x	1.0	Placebo	2.0	Active	0.0
5x	1.0	Placebo	1.0	Active	0.0
Average	**1.12**		**1.69**		**1.0**

Before Crossover After

Table 2c Gastro-Intestinal Stress

Before		Crossover		After	
2y	1.5	Active	1.5	Placebo	1.5
3x	0.0	Active	1.25	Placebo	2.0
4y	0.5	Active	2.0	Placebo	1.0
5y	1.5	Active	1.5	Placebo	1.0
Average	**0.88**		**1.69**		**1.38**
1x	1.5	Placebo	2.0	Active	1.5
2x	2.0	Placebo	2.5	Active	0.5
4x	1.0	Placebo	2.0	Active	1.0
5x	1.5	Placebo	1.0	Active	1.5
Average	**1.50**		**1.88**		**1.12**
Average	1.14		2.00		1.21

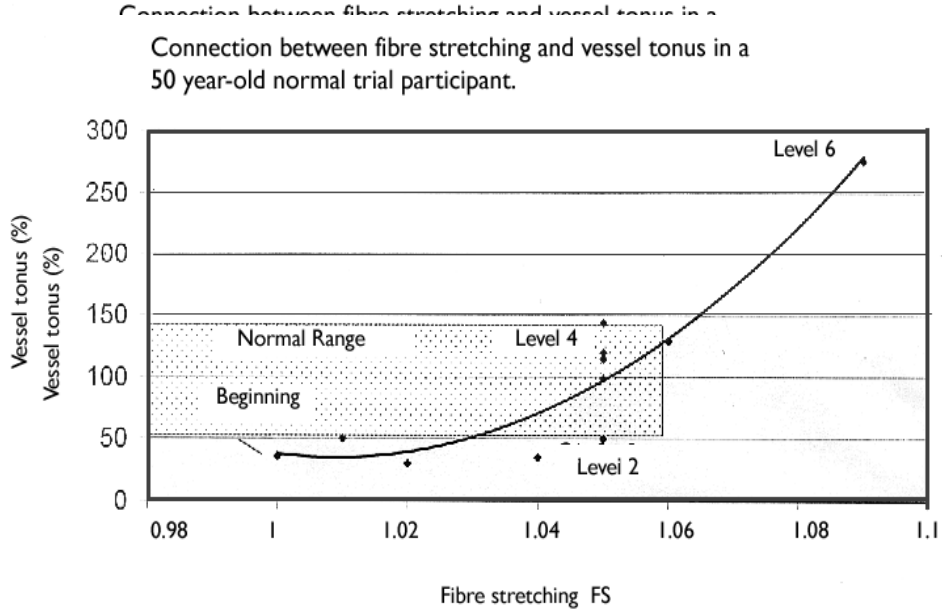


Figure 3 Blood circulation/vascular system Test (NIRP/CMMD)

Table 4a Electro-dermal Screening Testing - Participant 3x

Life Information System Ten (LISTEN) - Point Codes
LYCR = **LY**(Lymph) **C**(CMP) **R**(Right) CMP = Control Measurement
Point R= Right side of body L= left side of body

		Participant 3x									Changes towards 50 during		
		18/11/1999 Before			25/1/2000 Crossover			6/4/2000 After			Active (A)	Placebo (B)	A-P
		Min	Xn	[Xn]	Min	Xn	[Xn]	Min	Xn	[Xn]			
LY1R	Palatino tonsil, with deep cervical lymph nodes - Right	47	3	3	44	6	6	48	2	2	-3	4	-7
LYCR	Lymph - sinuses - Right	44	6	6	47	3	3	48	2	2	3	1	2
LY2R	Drainage of jaw - odontons (teeth) - Right - Not measured												
LUCR	Lung - not pharynx or hypopharynx - Right	43	7	7	45	5	5	49	1	1	2	4	-2
LICR	Large intestine - Right	43	7	7	40	10	10	47	3	3	-3	7	-10
NECR	Peripheral and central nervous system - Right	43	7	7	40	10	10	45	5	5	-3	5	-8
PCCR	Pericardium - circulation - Right	34	16	16	42	8	8	43	7	7	8	1	7
AL1R	Lower body, abdominal organs, chemicals & pesticides - Not measured												
ALCR	Allergy - food or general - Right	33	17	17	49	1	1	40	10	10	16	-9	25
ORCR	Organ - cellular metabolism - Right	32	18	18	49	1	1	47	3	3	17	-2	19
THCR	Endocrine system with pancreas & mammary gland - Right	51	-1	1	45	5	5	44	6	6	-4	-1	-3
HTCR	Heart - Right	39	11	11	46	4	4	44	6	6	7	-2	9
SICR	Small intestine - Right	42	8	8	47	3	3	47	3	3	5	0	5
LY1L	Palate - Left	43	7	7	38	12	12	46	4	4	-5	8	-13
LYCL	Lymph - Left	45	5	5	47	3	3	43	7	7	2	-4	6
LY2L	Drainage of jaw - odontons (teeth) - Left - Not measured												
LUCL	Lung, lower passages - Left	41	9	9	47	3	3	45	5	5	6	-2	8
LICL	Large intestine - Left	46	4	4	45	5	5	41	9	9	-1	-4	3
NECL	Peripheral & central nervous system - Left	33	17	17	43	7	7	44	6	6	10	1	9
PCCL	Pericardium - circulation - Left	42	8	8	44	6	6	39	11	11	2	-5	7
AL1L	Lower body, abdominal organs, chemicals & pesticides - Not measured												
ALCL	Allergy - Left	38	12	12	43	7	7	41	9	9	5	-2	7
ORCL	Organ - cellular metabolism - Left	46	4	4	41	9	9	40	10	10	-5	-1	-4
TH1L	Gonads (ovaries & testicles) and adrenals - Left - Not measured												
THCL	Endocrine (Triple Warmer) system - Left	43	7	7	45	5	5	40	10	10	2	-5	7
HTCL	Heart - Left	48	2	2	48	2	2	47	3	3	0	-1	1
SICL	Small intestine - Left	50	0	0	45	5	5	39	11	11	-5	-6	1
		Sum[Xn]		176	Sum[Xn]		120	Sum[Xn]		133	56,00	-13,00	69,00
		Ave[Xn]		8,0	Ave[Xn]		5,5	Ave[Xn]		6,0	2,55	-0,59	3,14
			Active			Placebo							8,94
	Ave Min	42,1			44,5			44,0					1,91
													1,65
													~0.12

Table 4b – Electrodermal Screening Testing (Listen Machine)

Change during Active - Change during Placebo (A-P)

	Participant								
BASE (Organ)	1x	2x	2y	3x	4x	4y	5x*	5y	Average
LY1R	5.0	0.0	0.0	-7.0	1.0	0.0	-8.0	-5.0	-1.75
LYCR	4.0	1.0	4.0	2.0	-2.0	0.0	0.0	3.0	1.50
LUCR	-6.0	1.0	0.0	-2.0	-4.0	0.0	1.0	-7.0	-2.13
LICR	1.0	-3.0	0.0	-10.0	-2.0	2.0	0.0	7.0	-0.63
NECR	-9.0	-2.0	6.0	-8.0	6.0	6.0	0.0	8.0	0.88
PCCR	5.0	-9.0	0.0	7.0	-3.0	0.0	1.0	7.0	1.00
ALCR	-2.0	-3.0	8.0	25.0	-10.0	0.0	-1.0	8.0	**3.13**
ORCR	-1.0	9.0	0.0	19.0	-5.0	0.0	0.0	17.0	**4.88**
THCR	5.0	-3.0	2.0	-3.0	-11.0	0.0	0.0	15.0	0.63
HTCR	-2.0	4.0	0.0	9.0	2.0	10.0	0.0	12.0	**4.38**
SICR	-1.0	-3.0	4.0	5.0	-1.0	2.0	0.0	8.0	1.75
LY1L	2.0	-5.0	0.0	-13.0	15.0	6.0	1.0	-4.0	0.25
LYCL	-1.0	2.0	0.0	6.0	1.0	10.0	2.0	-3.0	2.13
LUCL	-4.0	1.0	0.0	8.0	0.0	8.0	0.0	-16.0	-0.38
LICL	1.0	-1.0	0.0	3.0	-10.0	0.0	0.0	1.0	-0.75
NECL	-2.0	-2.0	0.0	9.0	0.0	10.0	0.0	6.0	**2.63**
PCCL	-2.0	-4.0	0.0	7.0	3.0	0.0	1.0	-1.0	0.50
ALCL	-4.0	-6.0	0.0	7.0	-9.0	0.0	1.0	6.0	-0.63
ORCL	-2.0	-7.0	0.0	-4.0	22.0	0.0	1.0	3.0	1.63
THCL	-3.0	-5.0	0.0	7.0	12.0	0.0	1.0	11.0	**2.88**
HTCL	1.0	-1.0	0.0	1.0	-6.0	8.0	-6.0	-2.0	-0.63
SICL	-5.0	-3.0	0.0	1.0	0.0	2.0	0.0	6.0	0.13
Sum	-20.00	-39.00	24.00	69.00	-1.00	64.00	-6.00	80.00	21.38
Mean	-0.9	-1.8	1.1	3.1	0.0	2.9	-0.3	3.6	0.97

***Note:**
Although readings for Crossover were extrapolated for participant 5x, so that the total change was assumed to be shared equally between placebo and active, LY1R and HTCL had "Before" readings of 54 and 56 and "After" readings of 46 producing extrapolated values of about 51. This would normally have shown as no net benefit since the difference from 50 (~5) was unchanged after treatment. However the change from ~55 to 50 on placebo is considered an improvement, whereas the change from 50 to 46 on active is considered as a deterioration.

Thus changes of this type produce relatively large apparent effects, in this case –8 and –6.

Figure 4b **Electro-Dermal Screening Testing (Listen Machine)**

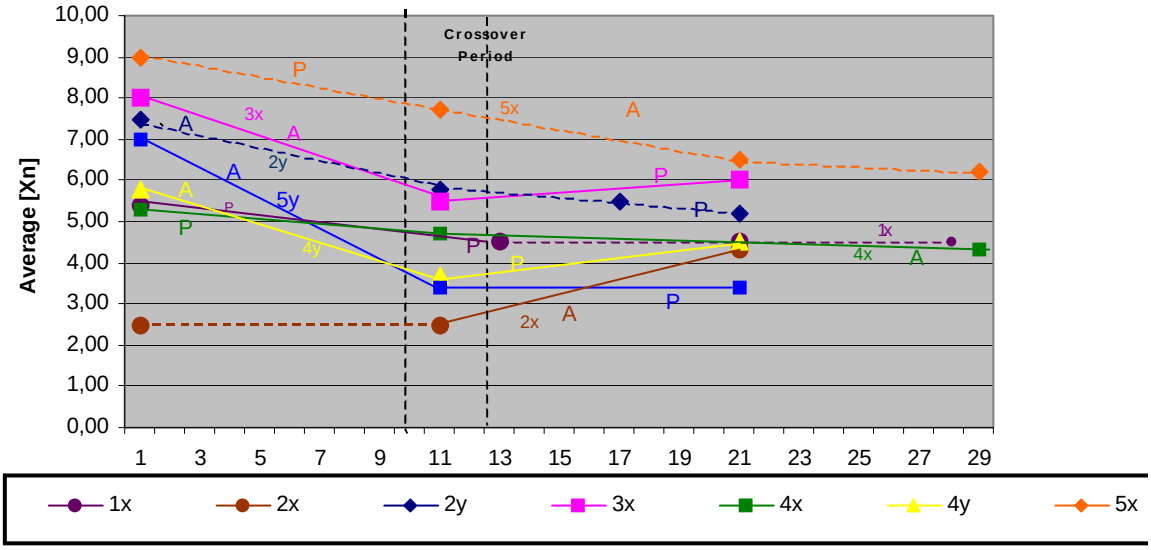


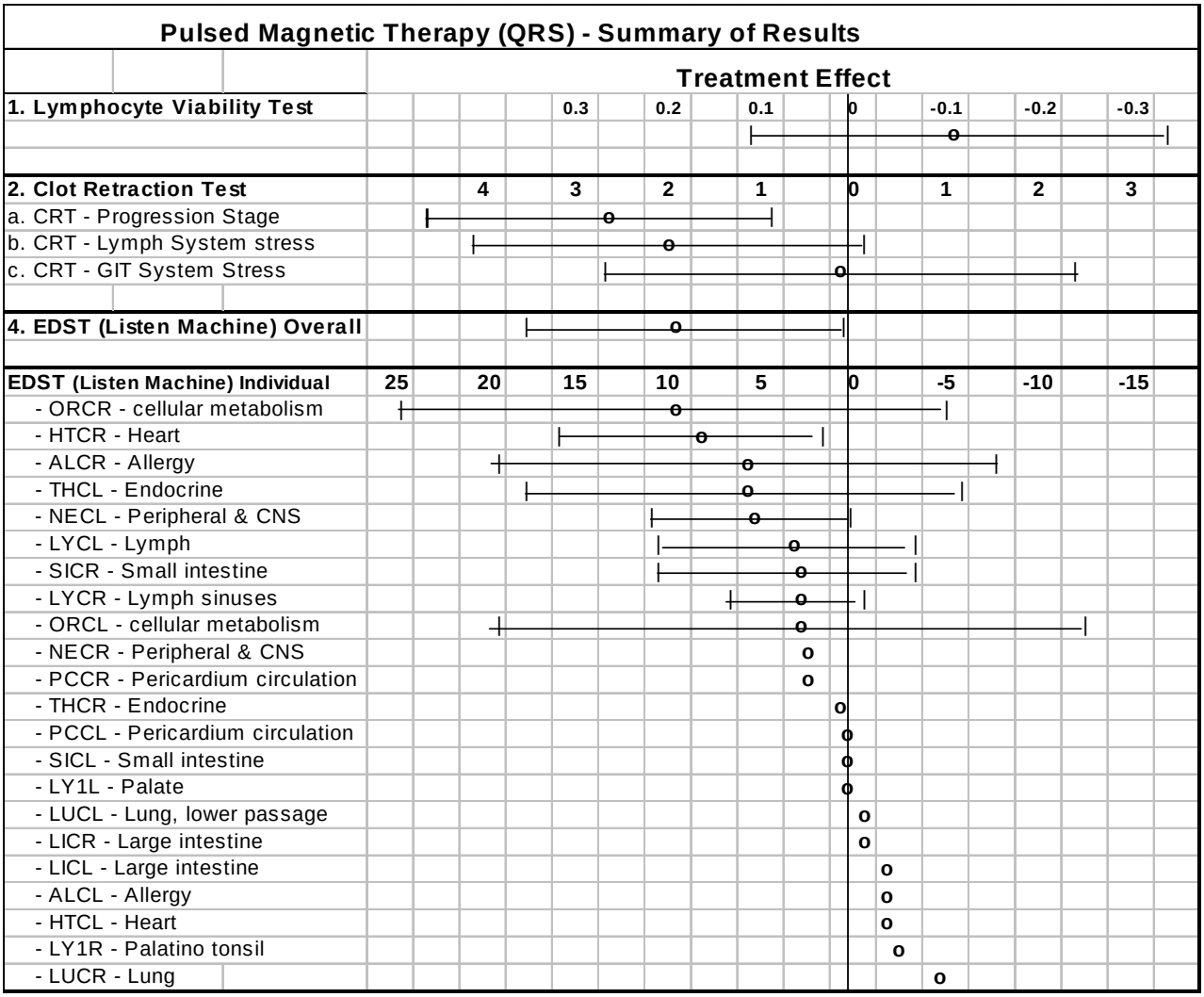
Table 4c – Electro-Dermal Screening Testing (Listen Machine)

	Before		Crossover		After
2y	7.5	Active	5.8	Placebo	5.2
3x	8.0	Active	5.5	Placebo	6.0
4y	5.8	Active	3.7	Placebo	4.5
5y	7.0	Active	3.4	Placebo	3.4
Average	**7.08**		**4.60**		**4.78**
1x	5.4	Placebo	4.5	Active	4.5
2x	2.5	Placebo	2.5	Active	4.3
4x	5.3	Placebo	4.7	Active	4.1
5x	9.0	Placebo	7.7	Active	6.5
Average	**5.55**		**4.85**		**4.85**
Average	6.86		4.72		4.85

Table 5(a) **Pulsed Magnetic Therapy -Summary of Changes** (+ = improvement, - = deterioration)

	Lymphocyte Viabil			CRT - Stage			Lymph Syst Stress			GI System Stress			EDST-Overall		
Participant	Active	Placeb	A-P	Active	Placeb	A-P	Active	Placeb	A-P	Active	Placeb	A-P	Active	Placeb	A-P
2y	0.04	0.05	-0.01	1.50	-1.13	2.63	-0.50	-0.25	-0.25	0.00	0.00	0.00	1.73	0.64	1.09
3x	-0.07	0.08	-0.15	-0.88	-1.13	0.25	0.75	-1.25	2.00	-1.75	-0.25	-1.50	2.55	-0.59	3.14
4y	-0.14	0.00	-0.14	-0.63	-1.13	0.50	-0.50	0.00	-0.50	-1.50	1.00	-2.50	2.11	-0.80	2.91
5y	-0.02	0.29	-0.31	0.13	-1.38	1.50	0.00	-1.50	1.50	0.50	0.00	0.50	3.64	0.00	3.64
Mean (4)	-0.05	0.11	-0.15	0.03	-1.19	1.22	-0.06	-0.75	0.69	-0.69	0.19	-0.88	2.51	-0.19	2.69
Std Devn	0.08	0.13	0.1228	1.07	0.125	1.08	0.59	0.74	1.25	1.11	0.55	1.38	0.82	0.64	1.11
	Placeb	Active	P-A	Placeb	Active	P-A	Placeb	Active	P-A	Placeb	Active	P-A	Placeb	Active	P-A
1x	-0.11	0.00	-0.11	0.25	0.50	-0.25	-1.00	0.00	-1.00	-0.5	0.0	-0.5	0.87	0.00	0.87
2x	-0.07	-0.04	-0.03	-0.38	0.63	-1.00	-0.25	-0.25	0.00	-0.5	2.0	-2.5	0.00	-1.77	1.77
4x	-0.05	0.11	-0.16	-1.00	1.00	-2.00	-1.00	2.00	-3.00	-1.0	1.0	-2.0	0.64	0.59	0.05
5x	0.02	-0.14	0.16	-1.50	1.25	-2.75	0.00	1.00	-1.00	0.5	-0.5	1.0	1.70	0.80	0.91
Mean (4)			-0.04	-0.66	0.84	-1.50	-0.56	0.69	-1.25	-0.38	0.63	-1.00	0.80	-0.10	0.90
Std Devn			0.14	0.76	0.34	1.10	0.52	1.03	1.26	0.63	1.11	1.58	0.70	1.17	0.71
Sum 8 A-P readings		-0.47			10.88			7.75			0.50			7.18	
Mean 8 A-P readings d_1-d_2		-0.06	**-0.12**		1.36	**2.72**		0.97	**1.94**		0.063	**0.13**		0.90	**1.79**
Std Devn		0.16			1.02			1.20			1.70			2.10	
Std error		0.06	0.09		0.36	0.77		0.42	0.89		0.60	1.05		0.74	0.66
t		-1.05	-1.26		3.77	3.53		2.29	2.19		0.10	0.12		1.21	2.73
P		>0.3	**0.25**		<0.01	**0.013**		0.06	**0.075**		>0.3	**>0.3**		>0.25	**0.038**
t for 95 % confid level			2.447			2.447			2.447			2.447			2.447
95% Conf Interval	-0.12	±	0.23	2.72	±	1.89	1.94	±	2.17	0.13	±	2.57	1.79	±	1.61
Carryover effect:	0.03	-0.04		-0.58	0.09		-0.41	0.06		-0.25	0.13		25.50	7.88	
a_1-a_2			0.06			-0.67			-0.47			-0.38			17.63
Std Devn															
Std error			0.05			0.29			0.28			0.35			11.25
t			1.33			-2.34			-1.65			-1.08			1.57
P			0.23			0.06			0.16			>0.3			0.17
Period effect:															
d_1 - (-d_2)			-0.19			-0.28			-0.56			-1.88			3.59
Std Devn															
Std error			0.0934			0.7712			0.8861			1.048			14.471
t			-2.009			-0.3647			-0.6348			-1.789			0.2483
P			0.093			>0.3			>0.3			0.13			0.0012

Figure 5b


Pulsed Magnetic Therapy (QRS) - Summary of Results
Treatment Effect
1. Lymphocyte Viability Test
0.3 0.2 0.1 0 -0.1 -0.2 -0.3
2. Clot Retraction Test
4 3 2 1 0 1 2 3
a. CRT - Progression Stage
b. CRT - Lymph System stress
c. CRT - GIT System Stress
4. EDST (Listen Machine) Overall
EDST (Listen Machine) Individual
25 20 15 10 5 0 -5 -10 -15
- ORCR - cellular metabolism
- HTCR - Heart
- ALCR - Allergy
- THCL - Endocrine
- NECL - Peripheral & CNS
- LYCL - Lymph
- SICR - Small intestine
- LYCR - Lymph sinuses
- ORCL - cellular metabolism
- NECR - Peripheral & CNS
- PCCR - Pericardium circulation
- THCR - Endocrine
- PCCL - Pericardium circulation
- SICL - Small intestine
- LY1L - Palate
- LUCL - Lung, lower passage
- LICR - Large intestine
- LICL - Large intestine
- ALCL - Allergy
- HTCL - Heart
- LY1R - Palatino tonsil
- LUCR - Lung