Airedale Local Research Ethics Committee
Project Submission

(10 Copies of form and study protocol required)

Title of Project: A comparison of the effectiveness of Pulsed Electro-Magnetic Energy (P.E.M.E) to Acupuncture (A/E), in a re-recognized shoulder problem where pain and/or stiffness are the cardinal features - A Pilot Study.

Place of Investigation: Paskiewicz Physiotherapy Clinic, Multicentre Y/N NO.
3 Chough Lane, Oakworth, Keighley, West Yorkshire BD22 7HR
Agency or Pharmaceutical company involved: N/A

Payment to be received by investigators: N/A.

Number of patients to be studied: As many as possible within trial period.

Proposed starting date: 1st October 1993.

Length of Study: 6 months.

Finishing Date: 30th April 1994.

For studies involving drug therapy:

a) Name(s) Y/N N/A.

b) Does it/do they have product licence(s) Y/N N/A.

c) Does it/do they have a product licence for the procedure under investigation Y/N N/A.

d) Does it/do they have a clinical trials exemption certificate Y/N N/A.

e) List known serious side effects N/A.

f) List known interactions N/A.

g) For blind/double blind studies, name code holder N/A.

Patient factors:

a) List potential hazards for P.E.M.E. Danger in use near cardiac pacemaker in use - external no known side effects.

b) How will the patient be inconvenienced? For P.E.M.E. In rare cases, who react adversely to A/E may have an increased pain and stiffness for 24/48 hours - as the body energy rebalances itself. There is also the inconvenience of not being able to give blood (a 6% risk). For A/E, all of the above, but especially feeling of relaxation and well-being.

What are the potential or actual benefits for the patient? For P.E.M.E. Reduced pain and stiffness. Improved functional abilities. Increase in range of movement of shoulder and arm. Regaining of strength for A/E, all of the above, but especially feeling of relaxation and well-being.

General reduction of stress.
Acupuncture is part of the Traditional Medicine of China (TCM). Over the last 3000 years it has developed a unique understanding of the workings of the human body. Very fine needles are used to stimulate the body's own healing responses, and it is now becoming increasingly recognised in the West as a safe and effective form of Medicine.

Scientific evidence for the Acupuncture Meridians has recently been published both in the East (1.) and also in the West (2.) using Radioactive Technetium (99mTc) to investigate the pathways. The findings suggest a Neurochemical (Transmembrane Ionic) mechanism of information transmission during Acupuncture along preferential routes, (possibly correlating to the Meridians). Other researchers (3.) indicate an infrared/thermal mechanism, whilst J. Jessel-Kenyon et al. (4.) and Seto et al. (5.) consider it a possible Biomagnetic phenomenon. Nelson in his Advanced Treatise in Quantum Biology suggest an even more fundamental energy process where photonic/virtual photonic principles exist albeit for a short period of time! (6.). Experimental work by F.A. Popp and others (7.) supporting this.

Whilst noting such advances in our theoretical knowledge it remains imperative that clinically we must keep apace and continually evaluate our therapeutic practice as Lewith (8.) and others (9.) have done. Their conclusions that there was positive evidence of a limited efficacy for the use of Acupuncture for pain relief. Other clinicians (10,
have been trying to establish the parameters and protocols for Acupuncture use in several other fields, again with mixed success.

But there remains at present no clear cut therapeutic or clinical guidelines for the inclusion of Acupuncture into the established format of treatment of definable western conditions, where pain/stiffness are the main features. This paucity and difficulty of research is due in part to the complexity of the TCM model, and also due in part to the problems encountered designing ideal Western trials as the late Professor Dundee (12.) and others(13.) have pointed out. It is for these reasons that I have tried to design the trial to consider such factors as Spontaneous Recovery, Placebo and the Standardisation of Pain Medication, in order to begin to sort out these variables first and foremost, before considering which specific features of the PEME and Acupuncture produce which effects.

PEME has been used for many years in both high and low frequency modes to treat a wide variety of medical problems from circulatory problems to soft tissue injuries. Please see Barclay et all(14.) for a review of its effects and modes of action. However recent experimental work into the underlying mechanisms is providing new and fruitful lines of research in many diverse areas of Biology.(15.) and yielding new insights into biological processes such as cancer, Neural and immune function with significant implications for therapy(16,17,18.). Variable "tuned" Magnetic fields whose magnetic field strength is from 14-19mT is thought to produce the best analgesic and anti inflammatory levels(19.). But we do not know whether it facilitates or interferes with normal function, and is open to conjecture. Indeed information regarding tuning, Modulation and frequency for very weak E/M and Magnetic fields is clearly needed to allow us to understand these basic models and the very subtle therapeutic effects of these fields. Riva Sanseverino E.et
In his research of over 3000 patients concluded that Magnetic Field Therapy was an excellent Physical Therapy in cases of joint diseases. He proposed that the Magnetic Fields influenced the Trans-membrane Ionic activity. A very similar hypothesis advocated by Bjorn Nordenstom of the Karolinska Institute. (see 2. before).

This Research Pilot has been designed to begin the process of investigating these correlations between PEME and Acupuncture.

REFERENCES.

1. Li R. et al. Analysis of the linear migration of the radionuclide along meridians in perfused extremities of monkey. 

2. Dr J-C Darras et al. Nuclear Medicine Investigation of Transmission of Acupuncture Information. 


   Complementary Medical Research: October 1992 Vol 6No3 142-151.

5. Sato et al. Detection of extraordinary large bio-magnetic field strength from human hand during external Qi emission. 

6. Dr William C. Nelson. An Advanced Treatise In Quantum Biology. Enzyme process, lincs PE 11 1DQ.


20/8/93.
Approval for the study to be obtained from the Airedale Ethics Committee, Airedale hospital, Steeton, Keighley.

The PENE equipment to be used in the trial is the Circuplode, developed by Enraf-Nonius connected to a Curapulse 419. This type of adaptor is a pure magnetic field radiator; the electric field component is effectively filtered out by a screen placed in front of the coil. It is hoped to be calibrated by Airedale Medieval Physics department, in order to get an accurate measurement of the very low field magnetic @ 15Hz pulse frequency and No1 LED. intensity indicator setting, and will be checked at monthly intervals during the trial for consistancy. The treatment to be given is Athermal lasting 20 minutes at a time. There are no known contra-indications to this form of treatment, but due to the possibility of developing irregularities, people with pacemakers should not be in the vicinity of the equipment. The procedures will be tuned and checked with the Circuplode Tester during every session to ensure reliability. Please see enclosed sheet.

SELECTION OF PATIENTS.

Referrals for inclusion in the trial are initially made by the patients' Dr or Consultant, who will be asked to fill in a Consent Form with the patient and also give further information regarding medication...
and Diagnosis. Please see enclosed sheet 2. Inclusion/Exclusion criteria checklists will also be distributed. Please see enclosed sheet 4. As can be seen from the lists the main considerations for exclusion is the presence of cervical pathology, where it is a major contributing factor. It is hoped that the Medical attendant will ring if further clarification is needed.

LOCATION OF STUDY.

The study will be held at PARKVIEW PHYSIOTHERAPY CLINIC.

3, CLOUGH LANE, OAKWORTH,
KEIGHLEY, WEST YORKSHIRE. BD22 7HP.

It will be run in the mornings, over a period of 6 months, starting on ONE 1ST OCTOBER 1993 AND RUNNING UNTIL 30TH APRIL 1994.

PROCEDURE.

Details will be taken, an initial assessment for suitability and inclusion and then the Patient Information Leaflet will be read, discussed and duly signed and witnessed. Please see 3.

METHODS.

As mentioned in the Proposal, there will be an added emphasis in trying to highlight both the Spontaneous Recovery Phase of the problem and the Placebo Effect aspect. The Standardisation of Pain Medication during the trial has also been taken into consideration in trying to reduce the variables and improve the methodological approach.

There will be 2 people involved in the study. 1: Assessor/Observer of benefit and the 2nd: a separate Assessor/Provider of treatment. It is therefore a proposed SINGLE BLIND STUDY where the observer does not know the treatment given. The assessment of the patients, initially and
serially every day throughout the trial will be performed by both parties. The measurement data will be signed, sealed in envelopes and placed in the patients file for final analysis. Practise in the use of the measuring Devices (Goniometer, Myometer, VAS, etc) will be before hand, ensuring that a very high degree of correlation is achieved and acceptable between the 2 people, and consistency is achieved. Any SelfMeasurement @ home will be fully explained and demonstrated to the patient and/or relative to continue and ensure the regular monitoring of signs and symptoms both during the baseline and treatment phases. The criteria to be assessed will be PAIN (Visual Analogue Scale...VAS), MUSCLE STRENGTH (Myometer), and functional assessment. Please see enclosed sheet 5.

A SINGLE CASE Experimental design originally advocated by Hersen & Barlow (1.) in 1976 and discussed at length by both Jane Riddoch (2.) and Anne Parry (3.) facilitates evaluation of clinical change and to gain a much better understanding about the mechanisms of treatment causing that change. It also allows us to address the issue of clinical versus statistical significance. Please see the enclosed sheet 5. for the overall design of the BASELINE (A)-TREATMENT (B) phases.

SPONTANEOUS RECOVERY.

This has been shown to be maximal in the acute phase of a condition, with or without treatment, therefore the treatment must be shown to steepen the curve or alter what can be presumed to be "Normal" rate of change. So it is important to demonstrate that treatment is having an effect over and above the effect of spontaneous recovery. If performance is recorded over a NO-treatment phase *, some indication may be obtained of the form and rate of spontaneous recovery. Though varying considerably between different individuals (depending on
age, general health, severity of illness, etc] correlation with post
injury, disorder times may be achieved if we have enough patients to
group the studies in the form of Series Trials.

* To be conceived actually as a placebo
period, using the dummy treatment.

PLACEBO EFFECT.

"Every treatment, whether active or Placebo, has a psychological
effect on its recipient and this effect is strongly conditioned by the
behavior of the therapist", as P H Richardson noted in his article on
Pain and the Placebo Effect(4.). With Pain being the central aspect of
the study a host of different variables and mechanisms are addressed by
this effect, from classical conditioning? to excitatory effects and
anxiety reduction. It is for these reasons, that the initial effect of
attention and the excitement effect of a "new" trial be considered. If
our aim is to establish a correct "normal" baseline from which we can
observe a change in constancy, rate or progression, then we must
discriminate as accurately as possible in order to obtain those all
important reliable baseline readings.

I have incorporated a dummy treatment (Detuned Pulsed PEME) as
the 1st therapy and aim to develop a method of assessment/treatment on
the 1st day in order to reduce the overlay and possibly explore this
placebo administration in the single case series. This may reduce some
of the problems encountered in the comparison of results, mentioned by
Kubiena G (5.) in his Placebo considerations.

Though in essence withdrawing treatment from patients, there
is still an Ethical issue to be considered at this stage. But if given
in random order, it should allow us to see if a patient is a Placebo -
responder very quickly and to see if it can be correlated to the
spontaneous recovery period. I feel that with the awareness on the
Methodological process and experimental decisions the patient is still
re
tained as the primary focus of research as Aldridge mentions.(6.)

After the baseline measuring period, which is usually from 1 to 7 days, a particular treatment will be randomly selected and introduced into the design either the Pulsed PEME or Acupuncture. The serial measurements are continued by both assessors, blind of each other. In the case of PEME the machine will be tuned at the fixed calibrated level and left on for the specific time of 20 minutes. Alternately Acupuncture will be performed, or even treatment combinations. 32 gauge needles will be inserted into the skin following Assessment and Diagnosis according to TCM (7.). Correct clinical precautions preventing needle stick injury, and practices as laid down in the guidelines for Acupuncture for Chartered Physiotherapists. (8.)

Please see enclosed single copy. If applied properly the patients should feel a slight experience of pain and a dullish ache around the needle-
tip and in the surrounding tissues when the Acupuncture sensation of "De Qi" is achieved. Depending on the specific signs the needles will be manipulated or left in, for 20 minutes. There is often a feeling of relaxation during and after treatment, accompanied by a gradual lessening of the patients signs and symptoms. On the very rare occasion there may be an exacerbation. It is unlikely but is possible. This may last for 24/48 hours as the body energy rebalances itself. This has been explained in the Patient Information Leaflet and should not be unduly worried about. Acupuncture is a relatively very safe and effective form of treatment.

According to Local Authority Health Regulations the person will not be able to give blood for 6 months after having Acupuncture.

After the appropriate time, the active treatment phase will be withdrawn... re-establishing a NO Treatment baseline situation or
altered baseline/treatment phase again. This stage, depending on the patients' progress and whether or not the aims of treatment have or have not been achieved. A further active treatment period, opposite to the first may then be employed. A brief summary of the A.B.A.B. strategies, multiple baseline designs and case series are included. Please see enclosed form 6. Depending on the response to the trial, direct replication in the form of 3 subsequent case studies may be used in order to answer the Generalizability Issue, often leveled at the single case design, and also at the group study approach.

Once all the data has been accumulated the appropriate statistical tests will be used on the data, the correct comparisons sought to see if changes [if apparent] are significant and clinically meaningful.

PERSONS INVOLVED IN THE PILOT STUDY.

Richard J Atkinson, MCSP SRP ASSESSOR/THERAPIST.

Julie Atkinson Registered Midwife, SRN ASSESSOR/OBSERVER.

Simon Mocket, Assistant Principle, Nottingham School of Physiotherapy.

Ron Sharp, Course Tutor, Research Project Coordinator.

References


No 7.


8. Guidelines for the Practice of Acupuncture by Chartered Physiotherapists. Issued jointly by the AACP and CSP.
Figure 1: The AB design

Figure 2: Chart of measurements using AB design

Figure 3: The ABAB design

Figure 4: Chart of ABAB time trials

Figure 5: Multiple baseline design
DISCUSS THE INCLUSION OF ACUPUNCTURE IN THE TREATMENT OF
A PAINFUL SHOULDER.

At present there is NO firm evidence to suggest that acupuncture should
be included NOR that it is indicated to be included in the treatment of
a painful shoulder problem. There have been hints that there maybe a
certain degree of efficacy in its use in a possibly western diagnostic
case (1.), i.e. periarthritis, when 345 cases were used in an organised
trial. However PLACEBO and SPONTANEOUS recovery effects were not fully
standardised nor systematically investigated so make it difficult to
fully clarify and integrate all the variables into the Western research
paradigm which we use as our procedural base for discovering
knowledge.

Indeed a literature search revealed no research done even
comparing an existing standardized treatment, such as SWD, PULSED
SWD, ULTRASOUND, ET COR other modalities to acupuncture. Nor has
acupuncture been included in any trials where a recognised well-defined
diagnostic syndrome such as say frozen shoulder where pain-and
stiffness are cardinal features.

There seems to be unlimited problems facing the investigator
trying to justify the inclusion of the somewhat mystical face and
appearance of eastern acupuncture, and placing it in the rigid
scientific format so necessary for western scientific approval. PAIN
itself is a broad enough category in this case, one common to both
Western and Eastern paradigms, the centrepiece of the whole, namely the
patient under investigation. This undoubtedly represents the central core of the problem and is perhaps the correct starting point for this discussion for its inclusion.

We must first and foremost qualify the benefits of acupuncture before its inclusion, comparing it to an recognised treatment, research which may recommend it as an associated accessory therapy, then following that up further with trials designed to prove and utilize it in its own right as an individual specifically-tailored therapy. For as Dundee et al. (2) so eloquently put it, "Is a 10% reduction in Pain scores, as assessed by the VAS adequate or should one look for 100% complete pain-relief". Indeed is 50% sufficient? We must decide at what level these subjective assessment elements become clinically important and statistically significant, beforehand if possible.

With PAIN as the main criteria, the focus of the search of possible underlying mechanisms, by which I mean interrupted QI in the Chinese interpretation, it becomes paramount that we include a means by which the PLACEBO effect, PAIN-RELIEVING medication and SPONTANEOUS recovery effects are all given due consideration in the decisions regarding trial design and necessary analysis of the variables from now on. We need a base on which we can begin to build a firm theoretical construct between the Western and Eastern paradigms of both World view and Medicine.

Reading Benoussans work (3) it becomes imperative to have a thorough understanding of Traditional Chinese Medicine (TCM) in order to know what questions to formulate and what parameters to set for experimental research and DIRECTION in trying to bridge the gap between the two systems. Kubiena G. (4) succinctly considers the true problem in his work, when he tries to understand the placebo problem in acupuncture
From his abstract and analysis of 28 different placebos in 28 different controlled trials, making the comparison of results impossible. The late Professor Dundee encountering scientific problems in the antiemetic Acupuncture evaluation; mentioned in his desirations of an Ideal clinical trial (2) that assessment of benefit should be on either Single OR Double-Blind basis. Kubiena, after reflecting that this cannot be CORRECTLY carried out feels it may all be desirable to replace them with follow up studies.

Research into Acupuncture requires the consideration and integration of ALL significant variables that relate to both THE diagnosis and THE treatment. The researcher must be able to identify and structure them into his research design. So it seems there are further untold problems to be encountered in setting up trials to include acupuncture into the treatment protocols, and then having to test the efficacy of a particular treatment approach. There seems to be an avenue of light, in that the A6 Baseline Single Case study comparisons, advocated by Riddoch J. (5) and Parry A. (6) may lead us towards the end of the tunnel in reducing the scepticism from peer reviewers towards Chinese Medicine. But meanwhile it remains imperative that for acupuncture to be included and finally accepted, the Research should be interpreted in terms of the Western medical model, in terms of TCM and its paradigm, and finally and perhaps most importantly, in equal terms between both camps. The overriding Pain aspect of the problem should be the correlating nucleus in establishing objectivity of any results. It is only after such careful delineation of the results can we then begin to see the real problems underlying the homeostatic mechanisms of how the body works and the patient reacts.

From this hallowed viewpoint, we can then, perhaps, begin to see what conclusions and recommendations can be drawn from our research and
scientific comparisons of incorporating acupuncture into its simplest traditional application, that of pain-relief. Can it be used with other valid modalities? Can it be used alone? If so what aspects of the acupuncture are significant? Do the means of inducing Qi have any effect? Does the needling technique itself, i.e., the methods of insertion, the direction, the depth, the speed, the ways of withdrawing, which are all very important factors that go to determine the so-called PHYSIOLOGICAL action of the specific point, need to be considered? These can then be correctly addressed into the Pain relationship if need be. Moreover, the subject's chronic constitution and even the time of needling may have either a Direct or Indirect effect on the so-called ENERGETIC action of the specific point. We must use Pain and patient sensation as our means of interfacing with the Qi in the form of the sensation propagating along the channel. We then begin to use scientific methods to its best effect and advantage highlighting the salient features. A clear cut pathway and bridge will give us a much fresher understanding, possibly initially following Cheng Shangs work on the nature of the acupuncture point as a Singularity and organizing Centre. (7) Developing his ideas of bifurcation, Separatrices, gap junctions from the Histochemical, biochemical, ionic and molecular viewpoints.

The use of very modern Electroacupuncture devices and equipment of a medical nature has likewise to undergo scientific acceptance. New protocols of use have to be developed. Research trials and studies are necessary to validate the electrical parameters and satisfy rigorous scientific criteria. If and when they are accepted are the conclusions we draw from its use exact and viable? Can the use of
these methods throw any more light on the diagnosis of the said "Painful
condition". Will they reveal the bridging, common aspects, of the two
paradigmatic models. What are our limits (to be) delineated by the
Acupuncture devices, into understanding the very nature of Acupuncture
and possibly QI itself. They will I feel most definitely bring together
knowledge to improve our Diagnostic criteria and treatment regimes
avoiding Drug and Surgery based alternatives. It will also give us a
computer base providing the solid ground on which to tackle future
theoretical problems and answer some of the miraculous and perhaps quasi
scientific claims of cures that have been so difficult to explain to
date attributed to acupuncture but which are often ridiculed by science,
as unexplainable.

We need clear, Modern Voltametric analysis of individual
Acupuncture points and associated meridians, following on from Motoyama's
AMI readings (8) Omura Y et all (9) and Seto et all (10) If we are to get a
real time picture of the constantly changing and varying energy flow in
the body. We have to follow on from Resistance measures and include
more Capacitance, Inductance, Reactance, Magnetic, Voltage, etc..... In
short a full energetic profile of each individual..... preferably a means
to bodily monitor this profile..... All on computer, to allow us to
manipulate the data..... To initially produce a "Normal" 3D bodily image
and then deviating backwards to incorporate "Sickness" and "Dis-Ease".

With the Acupuncture point as the starting line we need to
Follow up Ron Pethig work on dielectrical and Electrical Properties of
biological materials (11) and his later work as Translation Editor of
Biomagnetism, tying together the Ionic pathways as an Algorithmic means
in to the interior. (12). Indeed Professor E.H. GRANT discussing his many
yearsof theoretical and experimental work (13) showing that
conductivity Decreases with increasing frequency, whilst permittivity
behaves in the opposite manner mentioned that one has to go to frequencies as high as a few THZ before an increase of permittivity with frequency is observed, and this occurs because resonance phenomena are involved. One suspects that this is what may be happening, in that Josephson's ideas of superconductivity may be elicited. Certainly at 10 we are into the infra-red and light end of the spectrum, possible photonic and virtual photonic principles (14) apply certainly at the skin level (15), possibly at the DNA one as well (16).

So our research across the two paradigms, often superficially at odds with one another, comes together at the SQUID biomagnetometer quantum level (17) in our search for the answer to pain and blocked Qi in all its myriad aspects helping to bridge the gap suggesting that the changes in the bodies magnetic, DC, and AC and electric charge bring about meridian flow, blockage and pain. It throws up interesting questions such as those recently in the news regarding over head transmission lines (18) and possibly why the EM spectrum both heals and hurts (19). These ideas through correlation with Tiller's work quoted extensively in Vibrational Medicine (20) & (21), where the mathematical theorizing and analysis produces a very real, albeit negative entropic idea and synthesis of the energy, Qi, and Pain, and perhaps paints a reflection of the incredible complexity and functioning of the human body.

It offers us for the first time, with the acupuncture and meridian system having the central and interfacing role, the key into the door of the interior reflecting the Global-Workspace architecture that Dejan Rakovic Ph.D. mentioned in his thoughtful if esoteric work (22). It also allows everything to be brought down to the level of "dielectrical possibilities", where the Placebo response (23) (24). being Endorphin-mediated & Naloxone-reversible highlights the MULTI-dimensional importance we must strive for in order to understand the
Homeopathic (25), and ultimate Homeostatic (26) balancing Principles of Man and Nature.

References.


