Presidential Address

ARE ALTERNATIVE TREATMENTS EFFECTIVE? ISSUES & METHODS INVOLVED IN MEASURING EFFECTIVENESS OF ALTERNATIVE TREATMENTS

Carol J. Schneider, Ph.D. & Wayne B. Jonas, M.D.

ABSTRACT

This paper reviews common research methods which have been used in alternative medicine. We focus on a case series method called the before-after treatment experimental design. How this method can be used by practitioners to measure the effectiveness of their treatments is explored in depth. We address what variables should be measured before, during and after treatment. References to commonly used measurement instruments for physical, emotional and spiritually based variables are included.

KEYWORDS: Treatment effectiveness, research methods, alternative treatments, complementary medicine, measurement instruments, before-after treatment experimental design

INTRODUCTION

As claims of treatment success in health care become more and more accountable, all who offer health-related treatments are being asked for proof that they are effective. There are several methods of research which can be used to gather data relevant to energy medicine treatments/outcomes. The focus of this paper is on methods measuring outcomes which can be used involving before—after treatment assessments of symptom frequency and severity, and physiological, psychological and spiritual factors. Variables such as quality of life, length of time the treatment effect lasts, and whether the treatment effects the amount of money spent on other health care resources are all important aspects of assessing these therapies. Assuming changes in these variables occur, how can you tell if the changes are significant and meaningful?

Americans are turning to alternative medicine in large numbers. About 34% of the U.S. population utilized the services of alternative practitioners for an estimated 425 million visits during 1990 at a cost of over 10 billion dollars.[1] The report to the NIH "Expanding Medical Horizons" of March, 1995 has called for the establishment of alternative medicine research centers.[2] Despite the broad use of alternative medicine treatments, there is a paucity of data available to demonstrate convincingly whether these AM practices are efficacious, safe, and/or beneficial. In addition we need to know more about whether alternative medicine practices lead to positive clinical outcomes, improve quality of life, reduce or eliminate adverse symptoms, prevent disease, or promote or enhance health.

In a 1990 report released by the U. S. Office of Technology Assessment, essentially the same conclusion was drawn concerning the evaluation of unconventional cancer treatments.[3] Joel Elkes believes that within 25 years mind-body techniques will permeate medical practice from primary care to specialty care.[4] Arnold Relman, former editor of the New England Journal of Medicine, says that this may be possible but only if we can get more scientific evidence.[4] Marcia Angell, Executive Editor of the New England Journal of Medicine remains skeptical about much of the research in alternative treatments, because many of the studies have been poorly designed and "characterized by exuberant interpretation."[4]

To be fair, the quality of research in conventional medicine is not stellar. The validity of all but about 30% of the claims in conventional medicine is questionable.[5-9] Clearly the fact that there is copious but often faulty research in conventional medicine and scarcer but equally faulty research in alternative medicine doesn't give anyone much of a right to throw stones from their glass houses.

This paper is a review of certain research methods that have been used in both conventional and alternative medicine, and of critiques which have been done suggesting the best ways of using these methods. For practitioners using methods new to the conventional field, a primary way to proceed is to gather more data on the methods by measuring multiple factors before and after treatment on a group of subjects where each subject serves as his or her own control. This is research that any practitioner can do in his or her own office or clinic. Grad pointed out that there is much anecdotal data on the success of healers.[10] He says that hard data is scarce, not because the process itself is that hard to investigate, but because those in the best position to evaluate the results of treatments have little interest in doing so. This paper is an attempt to generate some interest.

SURVEY OF RESEARCH METHODS USEFUL IN ALTERNATIVE MEDICINE EVALUATION.

Isaac and Michael[11] listed models of research methods and we have adapted their list to describe types of methods useful in alternative medicine research:

Descriptive Studies. Both population studies such as Eisenberg, *et. al.*[1] which evaluated the incidence of alternative medicine utilization, and anecdotal case studies are descriptive studies. They simply describe what happened before, during and after the treatment, or present facts as reported by informants.

Case Studies. The systematic study of whether treatments are effective begins at the level of the systematic case study. Articles by Green and Shellenberger,[12] Benor,[13] and Fahrion[14] contain excellent descriptions of how individual case studies should be done in order to provide evidence of treatment effects. Fahrion's[15] case study of a woman with polycystic kidneys and post cancer

surgery abdominal pain provides an excellent example of the use of EEG measurement techniques comparing the brain waves of the healer and healee and a discussion of the types of data analyses which can legitimately be used in single case studies. There is a book devoted to single case study design authored by Barlow and Herson.[16] In situations where the signs or symptoms being monitored come and go rapidly with an effective treatment and the subject is willing for the investigator to temporarily withdraw treatment or substitute a less effective treatment for the one under study, a true randomized, cross-over, experimental trial can be done. These are called N = 1 randomized controlled trials and can turn what is otherwise only a case study into a trial with more robust design.[17]

In any case, what distinguishes a useless or misleading anecdote from a valuable and interesting case report is the detail and relevance of the information reported. The more specific, detailed, and objective the information, the more useful it will be to those who read it. This information should be such that someone reading it could reproduce the procedure and select a similar patient to the one treated. Sufficient information about other prognostic factors that could possibly influence the outcome need to be provided so that the reader can be confident that the outcome reported was not due to these factors. This requires considerable knowledge about what prognostic factors can influence the outcome. This information usually needs to be collected at the time of the treatment. The National Cancer Institute's "Best Case Series Guidelines" (reprinted and updated in the OAM report)[2] is an example of standards for reporting on cases for cancer therapy. Similar guidelines are needed for other common illnesses.

There is a type of case series study which is more powerfully persuasive than a single case study, uses statistical analysis, and can be feasibly done by the actual practitioner doing the treatments. This is called the before—after treatment experimental design. This method involves a series of before and after treatment measurements on many variables, the analysis of which attempts to show changes in a group of patients all receiving the same type of treatment. This design is essentially a series of single case studies added together to form a group of patients whose data are pooled and statistically analyzed. Although this design avoids the ethical problem of assigning patients to a no treatment control group, there are problems with this design as far as scientific accept-

ability is concerned.[18-22] The main problem with the before—after treatment study is that it can overestimate, commonly by as much as 40%, the true effect of the treatment. It is difficult to be sure that the difference between the before and after treatment measures is due to the treatment alone, rather than to some other intervening variable which could account for the change. For example, if a patient scored high on a depression scale before treatment, fell in love during treatment, and scored low on depression after treatment, it could well be that falling in love was the change agent and not your treatment. Presumably, if you randomized patients to a no treatment control group who scored high on depression, just as many of them would fall in love and truly improve their depression as would those in your treatment group. Thus, the treatment effect is less likely to be over inflated when you compare the changes after treatment with the changes in a control group.

However, since the before-after method remains the most practical one for a practitioner to use to generate data on his or her treatments, and forms the basis for data collection even in trials with control groups, it will be the main subject of this paper. If done properly, before-after studies even without control groups play an important part in the acquisition of scientific knowledge. In addition to using the measurement methods described in this paper, conclusions from these types of studies can be strengthened by having a clear hypothesis, careful planning for the analysis before the data is collected, and articulation of reasonable grounds as to why the results might apply beyond the group studied.[23]

Correlational methods are used in test construction and in factor analytic studies which attempt to shorten existing questionnaires. Perhaps the best examples of such studies in behavioral medicine involve the Hopkins Symptom Checklist, which. when factor analyzed, became the Brief Symptom Inventory,[24] and the General Well Being Scale recently factor analyzed by Levin.[25] Both of these scales are useful instruments for the clinician doing research in alternative medicine. Correlational methods are also used for evaluating associations between variables that may be causal, such as the strong and consistent relationship between smoking and disease and the recently summarized association between religious and spiritual life and health.[26]

Quasi experimental techniques include controlled studies where the control groups are not randomized. Control groups are groups which are as like the

treatment groups as possible, but they receive no treatment, standard treatment, or sham treatment. They may not take all the tests the treatment group takes during the same time span the patients take them. If the control group data is not collected at the same time as the treatment group it is called a historical control group. This type of comparison has considerable limitations and may provide erroneous conclusions.[27]

True experimental studies are those which have random assignment of subjects to control and treatment groups. This type of study has been used in a number of alternative and complementary practices. These types of studies often include blinding to control for expectation effects and observer bias. The utility of blinding has been useful primarily in studies of the effectiveness of homeopathic dilutions.[28-30] and herbalism.[31] It has also been used in evaluating acupuncture,[30] although the issue of the appropriateness of some types of blinding and control groups when studying acupuncture treatments has been addressed by de La Torre.[22] Benor's book[18] contains a review of the controlled studies of healing, including randomized controlled studies. Oleson and Flocco[32] described a randomized controlled study of PMS with a reflexology based treatment which was successful in alleviating PMS symptoms. The use of the term "true experimental studies" by Isaacs[11] in describing this type of research reflects the paradigm bias typical of conventional medicine researchers. This type of design is most useful for simple and well defined diseases where short term treatment and outcomes are the main interest. It is less useful for making definitive conclusions about treatment for chronic illness. Many thought provoking papers exist questioning whether the old paradigm is actually a "true" one for evaluating some alternative medicine approaches.[18-22] The utility of "true experimental studies" is especially questionable when intentionality and expectation effects are used as a prime component of therapy and individualization, learning, and choice are considered necessary for maximum benefit.

Meta Analysis Research. A type of research not discussed by Isaacs, but nonetheless important is meta-analysis. This approach frames the integration of research data from comparable studies as a research effort in its own right.[33,34] Meta analysis makes it possible to estimate the overall strength of a treatment's effectiveness across many experimental studies. The most comprehensive meta analysis of psychological, educational and behavioral treatments is that of Lipsey and Wilson.[35] It includes some studies in biofeedback, medita-

tion and relaxation techniques, which are often considered alternative treatments. Sacks[7] provides an excellent analysis of how to do good research in meta analysis of randomized controlled studies in medicine, while concluding that only 30% of published meta analyses in medicine address all necessary issues for good research. Lipsey and Wilson[35] conclude that any study which has a control group is an eligible study for meta analysis whether it is randomized or not. However, they looked only at behavioral and psychological treatments.

There are a few meta analyses to date in alternative medicine. Some of them examine the effects of transcendental meditation, one on physiology,[36] another on self actualization and psychological health,[37] and one on trait anxiety.[38] Recently, Linde,[39] looking at laboratory studies and Reilly,[40] looking at clinical studies of immunotherapy have conducted meta analyses in homeopathic areas. Meta-analyses of manipulative therapy for low back pain,[41] acupuncture for pain[42,43] and addiction[44] and the effectiveness of several herbal and nutritional therapies have also been done.[45-47] Finally, there have been a number of meta analyses of experiments in parapsychology that, presumably, form the theoretical foundation of therapies involving consciousness and subtle energies.[48-50] The main reason that there are so few meta analyses of research in alternative medicine is that there are so few studies which are comparable enough with one another that their subjects can be, in effect, added together.

Qualitative Research. Many methodologist and researchers have discussed the problems in the old paradigm which have been used to evaluate both conventional medicine and alternative medicine.[19-21,30,51-53] Researchers in the field of nursing and primary medical care are using new paradigms combining quantitative and qualitative methods of gathering data, using grounded theory research methods and hermeneutic analyses. Perhaps the best introduction to these important new paradigm shifting methodologies is Nursing Practice Research, a volume of the journal Advances in Nursing Science.[54] Although qualitative methods have traditionally been used in anthropology and during the definition phase of a developing clinical research agenda, recent efforts have focused on the importance of grounding even long accepted outcomes by using qualitative methods, especially when conducting research in new populations.[55,56]

CONDUCTING PRACTICE BASED RESEARCH

For the practitioner in his or her own office, however, the most practical way to demonstrate treatment effectiveness on a group of patients will be to use existing outcome measures in a before-after treatment design. The remainder of this paper will address variables that need to be measured and some of the existing ways to measure these variables.

We would like to describe examples of how we thought about these and other questions when data was gathered in the biofeedback program at the University of Colorado, Boulder, where Carol Schneider was once director of a biofeedback treatment clinic in the health service. In 1978, all the practitioners in the biofeedback clinic began to collect systematic data on every student who came for biofeedback. All of the instruments we used in the study are contained in the textbook *Foundations of Clinical Biofeedback Practice.*[57] We thought there would be changes in physical and emotional symptoms, feelings of well being, attitudes about self empowerment, and the physiologic parameters of muscle tension, hand temperature and galvanic skin response (a measure of autonomic nervous system arousal). We also thought the symptom changes and feelings about self empowerment would be long lasting. So we measured all those things on all our patients before and after treatment and then also sent a follow-up questionnaire to those we could track down after 6 months.

Three years after we first began collecting the data, we decided to pick out 4 different conditions (irritable bowel syndrome, anxiety, hypertension, and muscle contraction headache). We took the data from ten (10) randomly selected patients in each category and analyzed for before and after treatment effects on all the variables we measured. We decided on 10 patients in each group because we expected a large effect size, so we could use a relatively small group to demonstrate an effect. If you anticipate a small, but meaningful, effect, it is necessary to use larger groups. The sample size needed to demonstrate the effect you predict your treatment will have can be calculated mathematically by your research consultant. In order to do this you will need to estimate about how large an effect you expect. We presented our data at a symposium at the annual meeting of the Biofeedback Society of America.[58] The results were very positive in all four groups we studied and the follow up data showed lasting effects. Within a year researchers in other universities got

their graduate students busy doing controlled studies using many of our methods of treatment and measuring instruments. They were studying the same variables we did with comparisons to control groups and getting results which were acceptable in the scientific world. As practicing therapists in a regular clinic setting, routinely gathering data of interest to us, we really made a contribution to research in biofeedback, just by showing that the treatment had a meaningful effect which could be measured by simple measuring instruments in an everyday clinical setting.

BEFORE AND AFTER TREATMENT MEASUREMENTS

An important question to consider when gathering data is what variables will change as a result of the treatment, (e.g., physical, emotional and spiritual variables). The outcomes selected for measurement depend on the goals of treatment. These goals, whether explicit or not, are an agreement between the practitioner and patient. There are basically four categories of outcomes that can be evaluated. One can look for **cure** (elimination of the sign, symptom or disease), **care** (better control or management of the magnitude or consequence of a symptom or illness), **empowerment** (better understanding of the meaning of the experience of illness and increased skills for self care and coping with illness and suffering), or **enlightenment** (realization of the value and purpose of one's life as it is). Those in the mainstream medical community and most patients are usually looking for outcomes in the first two areas. Many alternative and healing practices and increasing numbers of patients are looking for outcomes in the second two areas. These objectives need to be clear at the beginning of any research so that the desired and appropriate data are collected.

Suppose you, as a practitioner, have decided that you want to duplicate what we did and gather data to demonstrate that your treatment is effective.

On Whom Should Data Be Gathered?

If it is useful for your treatment goals, it makes sense to gather data on all patients you treat. For example in our program we routinely discussed the

results of the Brief Symptom Inventory[24] and our Weekly Symptom Chart[57] with every patient we treated. If you gather data on all patients, you can easily study whatever subset of the whole group you wish by selecting various groups, as we did. Of course, if there is no purpose other than research for a specific problem for which you would use the data, you could select your measuring devices and then just administer the measurement instruments to that group you wish to study, (e.g. only tension headache patients). You should gather data on yourself with respect to the treatment of your research patients as well. Cooperstein[59] discussed aspects of transpersonal healers' experiences that contribute to the process of healing and he also suggests some variables of the healers' experience that might be productively studied.

INFORMED CONSENT

You should obtain an informed consent form from your patient before you gather any data which will be used for research purposes. Because a general model for such a form has not been published elsewhere, a model is included here.

WHAT VARIABLES SHOULD I MEASURE?

1. **Belief System.** Benor[13], stressed the importance of measuring the belief system of everyone involved in your study. Ask yourself; "Do I believe my treatment will help this patient? Do I feel a loving connection with this patient?" Data to obtain from the patient include: "Does he or she believe you can help?" Jonas[60] has pointed our that simply asking your patient about the credibility of your treatment may reduce the overall effectiveness considerably. This may be because asking about belief in whether a treatment is effective raises doubts about whether it might be effective or not. Credibility needs to be authentic.

   Other data which are crucial include diagnosis, history of the symptom/disease, prognosis, and baseline data on the symptom/disease and medication before treatment.[13,57]

2. **Physical Symptoms.** The most simple yet often used method of collecting symptoms is a visual analog scale, which is a 10

MODEL FOR INFORMED CONSENT FORM FOR PRIVATE PRACTITIONERS

The questionnaires that you are filling out are part of an ongoing research effort in order to obtain scientific data about your symptoms and their treatment.

If your responses are ever used for any presentation, the data will be presented as averages over a group of people having similar symptoms and treatments. There is no possible way that anyone could identify you as one of the group, so that the confidentiality of your answers will be preserved. Nothing about your individual treatment will ever be presented anywhere in any form without an additional permission signed by you for that purpose.

If you have any questions about this study, please feel free to ask. You have a right to be fully informed.

You have a right to refuse to participate in this study. If you do participate, you will be contributing to a scientific knowledge base for the field of alternative medical treatments. Your voluntary contribution is valuable.

If you wish a copy of any papers using group data which result from this study, they will be sent to you upon request.

Signature_____
Date_____

Witnessed by: *(witness can be the research clinician)*

_____
Date_____

centimeter line used especially for measuring the intensity of a symptom before and after treatment.

For example,

PAIN:

0_____10
no pain — most intense pain experienced

The difference in the number of centimeters before and after treatment is considered a measurement of change in pain levels. A more complex symptom rating method which gives an average daily pain rating and can be plotted on a daily or weekly basis throughout treatment was used in the study mentioned above.[57] Since feelings of well being are not always correlated with symptom frequency and intensity, we added a 5 point well being scale and asked patients to rate both symptoms and well being every day.

Whatever symptom measurement scale is used, the patient should rate the presence and severity of the symptom(s) for each of the 7 days before treatment begins, even if done retrospectively. This is called baseline data and is a before treatment measurement.

3. **Emotional States.** If you think your treatments will produce an emotional effect as well as a physical one, you need to measure mood states before and after treatment.

   The most simple measurement device for emotional states is called the mood thermometer. A five item mood thermometer scale is discussed in *Measures for Clinical Practice.*[61] This book contains over 300 clinical measuring scales presented by problem area and in their entirety along with one page profiles. Two other books which give profiles of tests in general use are guides from the Educational Testing Service[62] and the Test Corporation of America.[63]

   Four more complex emotional scales which are in common use in current research done by clinical practitioners are the Brief Symptom Inventory,[24,62,63] the Profile of Mood States,[62-65] the Beck Depression Scale,[62,63] and the General Well Being Scale.[25]

   There are several books which discuss the concepts and tests used specifically to measure health and/or well being.[66-71] These texts include information on many scales and techniques not discussed in this paper. The Bush Quality of Well Being Scale, formerly the Index of Well Being is widely used in nursing research and is worth investigation.[72]

4. **Quality of Life.** Like well being, some aspects of quality of life can improve even if symptoms do not. Included in quality of life

measurements are such factors as symptom improvement, pain management and stabilization, ability to take care of oneself independently, lowered emotional distress, higher satisfaction with life, lowered alienation and enhanced social adjustment, improved coping with stress, increased activity levels, better ability to work productively, and enhanced self-efficacy and empowerment. Patrick has discussed the concept of quality of life in detail,[73] as have Walker and Rosser,[70] who include a very simple thermometer-like scale for measuring the different factors involved.[70] (p.472)

Developing reliable and valid outcome measures can be a complex task and it is probably best for a practitioner interested in research to use measures that are already established and extensively used for the areas of interest. One of the most extensively validated and easily used global measures of outcome is the SF 36, developed from work done by the RAND corporation. It involves 36 questions in 7 domains of health and function. It can be filled out by the patient, usually in less than 10 minutes before a visit. Including a properly developed and widely used outcome measure such as the SF 36 may allow for comparison of your outcomes with complementary or conventional treatments in other settings.[74] Wilkin and colleagues have written a clear and comprehensive description of common validated outcome measures, both global and condition specific and outlined their development, use and sources.[75]

5. **Severity of Illness.** While measuring outcomes in practice can provide data on the effectiveness of your treatments, comparison with other practices requires not only standardized outcomes but comparable populations being treated. If the patients that you treat are either more or less ill than those you may want to compare them with, the outcomes may be different because of this difference in starting points. While direct comparisons of balanced groups of patients is the best way to make judgements about the relative effects of therapies, one can make some assessments of comparability if information on the severity of illness groups is available. While responses on some outcome measures (such as the SF 36 mentioned above) may indicate severity of impairment, a separate severity of illness assessment at the first visit may be useful.[76] If this is not possible, consider measuring the patients baseline more than once before treatment starts (separated by a reasonable period) to document the stability of his or her condition.

6. **Health Behaviors.** Kaplan[77,78] has made a case that changes in health related behaviors are actually the central variable in whether treatments are effective for making long term contributions to health and well being. Such factors as sleep, alcohol consumption, smoking, diet and social support are important to consider if improved health is a desired treatment outcome.

7. **Self Actualizing Values.** Crumbaugh[79,80] has constructed two interesting tests, based on Viktor Frankl's work and an existential framework. The Purpose in Life Test has 30 items and measures the degree to which a person has found meaning and purpose in life, and the Seeking of Noetic Goals test, has 30 items which indicate how much interest the person has in doing so.[80]

   Shostrim's[81] Personal Orientation Inventory shows the degree to which the respondent's attitudes and values compare with those of self actualizing people. Elmer Green has used this instrument in studying the healers in his Copper Wall Experiment and Patricia Norris uses it in her clinical practice for both teaching and research purposes. Changes in the direction of becoming more self actualizing would be a treatment goal many alternative practitioners might support.

8. **Spirituality.** The 3 Volume set, *The Faith Factor: An Annotated Bibliography of Clinical Research on Spiritual Subjects,* reviews research on spirituality.[82] Levin[83] has described research measuring religiosity and it's correlation with health. Ellison and Paloutzian[84] have designed a questionnaire measuring spiritual well being which is widely used for this purpose.

   Most of the spiritually oriented work is heavily steeped in Judeo-Christian traditional views. Some variables which would be important to consider are awareness of a higher self, experiencing a sense of connection to the ultimate energy source, having a concept of the oneness of all beings, an awareness of the power of the self to heal, belief in the power of prayer to heal, and having the ability to give and receive love. For now, the alternative practitioner could write descriptive statements and scale them in a 7 point Likert type scale from strongly agree to strongly disagree. Until a more general measure is developed for spirituality such a self made measure can

begin to assess this important variable with statements the practitioner considers meaningful. Eventually some researcher will replicate, validate and factor analyze your questionnaire, but meanwhile you would have made a start on measuring the spiritual variables you consider important.

9. **Physiological Measurements.** Three main physiological measurements have been used to demonstrate body-centered effects which are correlated with effective treatments.

   A. **Beta Endorphin levels.** Peniston and Kulkosky,[85] have demonstrated a change in the beta endorphin levels comparing before and after levels using an EEG based biofeedback treatment for drug and alcohol abusers. Beta endorphin is a hormone which is associated with levels of anxiety and agitation .

   B. **Immune Competence.** Hall[86] has reviewed the research in voluntaty immunomodulation through relaxation and imagery therapy and he discusses the most useful immune measures to use. Anderson,[87] reviewed the studies in immune competence improvements with behavioral treatments and Kiecolt-Glaser and Glaser review the methodological issues in such research.[88]

   C. **EEG, EMG, and Temperature Readings Using Biofeedback Instruments.** There is increasing use of before and after physiological measurements in the field of alternative medicine. Fahrion,[15] has been a leader in using EEG in alternative medicine and Ed Wilson received the ISSSEEM annual award for excellence in energy medicine in 1993 primarily for his work with the EEG correspondences between healers and healees and his studies of EEG before and during transcendental states of consciousness.[89] Hall[86] reviewed the work with GSR measurements and Wirth and Cram,[90] have used EMG (muscle) data to measure the physiological effects of distant prayer. For the practicing clinician the least expensive of all physiological measurements are simple hand and foot temperature devices. The hand temperature of most human beings will show an increase when any treatment which purports to

relax its recipient is used. Before and after treatment hand temperature measurements, coupled with self reports of relaxation are important indicators of treatment success in lowering physiological arousal. These devices can be used for home training involving any practice of relaxation between treatments. For less than $20 a digital temperature measuring and training device suitable for office or home training can be obtained (Biofeedback 302 from Human Systems, P. 0. Box 93663, Pasadena, CA 91109). Visual feedback from a liquid crystal strip which costs less than $5 can also be used for home practice (Bio-temp Products, P.O. Box 90050. Indianapolis, IN., 46290). These inexpensive devices can also measure increased blood flow to any body part to which it is attached. Physiological change data before and after treatment is very convincing, as it is more objective than most measurements used in treatment evaluation. Of course, such changes may be only correlates of the treatment, not necessarily the cause of the improvement.

10. **What are the possible goals my treatment could aim for and which measurements before and after treatment could demonstrate?** To summarize, the following outcomes may be important and should be carefully considered for inclusion in measuring outcomes in your practice.

1. Decrease in physical symptoms
2. Improve pain management[95]
3. Improve health behaviors[77,78,96]
4. Improve compliance with medical treatment[78,91-94]
5. Improve Quality of Life[5,97]
6. Improve General Well-being[25]
7. General Medical Outcomes[74]
8. Improve Spiritual Well Being[83,84]
9. Improve social support and adjustment[98-104]
10. Improve coping with stress[105-111]
11. The development of Hardiness[112,113]
12. Improve attitudes toward coping with the illness.
13. Change in hormonal regulation, immunocompetence or physiological arousal[88,89,100,101,114]
14. Improve Emotional Functioning[115-117]
15. Decrease medical interventions needed for the illness (physician visits, medication, hospitalizations)[118]
16. Increase longevity[64,99]
17. Increase understanding of the meaning of the illness.

11. What if my method requires that I use different treatments on each patient? Since at this point, you are just hoping to demonstrate that your treatments will have any effect, and not trying to demonstrate the mechanism by which these effects occur, you can use your usual treatment even if it's tailored to each patient's needs. If you are seeking to demonstrate mechanisms it is important to standardize what is done. If you limit your goals (and claims) to only showing that an important effect is occurring with your treatment, this approach is sufficient, especially if some corroborating objective physiological measurement is associated with clinical outcomes.

MEASUREMENTS DURING TREATMENT

Symptom/condition data should be gathered on a daily to weekly basis during treatment. Daily or weekly progress ratings can be useful.[57] Many studies stop measuring weekly progress after treatment stops, but healers have noted that changes continue to occur after treatment is finished, so keep on measuring progress as long as you predict it will occur. Compliance with any home training or associated treatment must be monitored.[91-94] If you are teaching any skill as part of your treatment, you must demonstrate that that skill has been learned.

At the conclusion of treatment, readminister all questionnaires given before treatment and measure again all physiological data. If you think your treatment effects will not be maximal until several days have passed after the actual session or sessions are completed, that is the point at which the readministration of all your outcome measuring data should occur.

FOLLOW-UP DATA

All physical, emotional, mental and spiritual measurements should be re administered either at 6 months or 1 year after treatment is finished. You should ask questions concerning any changes which have occurred since the treatment and whether they are related to the treatment, (*e.g.*, changes in health related behaviors or reduction of stress).

ANALYSIS OF YOUR DATA

Research consultants include professors or graduate students at your local universities. The Office of Alternative Medicine is forming research centers where consultation on alternative medicine projects will be available.[2] Two of these have now been funded. One at the Bastyr Naturopathic University focusing on AIDS, and one at the Minnesota Addiction clinic, looking at acupuncture and addiction. Others are being considered. ISSSEEM's publications will keep you updated on the activities of these centers, and provide information to you on where to get help with your project. By the time you have your data collected, help will be at hand.

To repeat, the main problem that this type of before and after treatment data presents is the overestimation of treatment effects. In fact, when control groups are added, the relative effect size will decrease by 40-60%.[60] A discussion of methodological and analysis errors which should be avoided in before-after treatment studies is contained in chapter 9 of Bjorn Andersen's book Methodological Errors in Medical Research.[5] Veney and Kalugney[119] offer a very clear explanation of these before-after designs, their potential problems and simple statistics for evaluation of results. They recommend that these designs be widely used, as they are powerful enough to demonstrate results and to stimulate new controlled research projects. Two excellent books which discuss statistics for health professionals are available for those who wish to become more informed regarding methods of analysis.[120,121]

No doubt there are many areas that you, as alternative and complementary practitioners, will want to consider which haven't been mentioned in this paper. Let us know about your thoughts and concerns about important variables, topics, or anything else related to research. It is only by continued dialogue between researchers and practitioners that real advancement in the evaluation of these treatments will occur.

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CORRESPONDENCE: Carol J. Schneider, Ph.D. Colorado Center for Biobehavioral Health, 939 Pearl Street • Boulder, CO 80302

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