Research methodology for studies of prayer and distant healing

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INTRODUCTION

The topic of distant healing or healing intentionality brings some of the most controversial and central questions to the area of complementary medicine. Within the scientific community, the most usual explanation for any beneficial effects of prayer, energy, spiritual or 'psychic' healing efforts is that hope, expectation or the relationship with the healer mobilizes a psychogenic improvement in the patient's health. Such psychogenic effects have been well described in the psychophysiology and psychoimmunology literature and will therefore not be the focus of this chapter. Here we consider research approaches for assessing whether the intentions of one person can benefit the health of another independent of any psychological factors. The term 'distant' when applied to healing intentionality is used to emphasize the removal of ordinary channels of communication between healer and patient, but certainly the modality of healing intention could be present when a healer and patient are in proximity. More than 80% of Americans believe that their 'thoughts can cause healing for another person at a distance' (Yanklovich 1998) and this is a view shared by 75% of family practitioners. Anecdotal reports of healing in a wide variety of conditions have, however, stimulated more than 150 controlled studies dealing with human and/or biological systems. Of these, two-thirds found a statistically significant effect (for review see Benor 1992, Dossey 1993, Targ 1997). The US National Institutes of Health (NIH) now even has a category of studies entitled 'Distant Intentionality on Biological Systems' and yet the concept of distant healing implies a type of consciousness-mediated causality that has never been accepted within the medical sciences.

Few fields of research routinely raise such heartfelt opposition as research in distant healing; as one NIH reviewer wrote to this author, 'healing is intrinsically a matter of faith, and therefore cannot be studied by science'. Another reviewer from the US Department of Defense felt a study intended to determine whether distant healing could benefit breast cancer patients had 'no translational potential'. These remarks illustrate a popular belief among the scientific community that distant healing, interestingly, has also come from communities of healing practitioners and religious people as well. Some healers have voiced the concern that research cannot test or study the subtle effects of their treatments. Religionists have objected that research in distant healing may dissuade people from prayer for the purpose of strengthening faith and mistakenly focus them on a causal interaction between prayers and physical outcomes (Thomson 1996). Typical concerns are that testing healing is 'testing God' and therefore blasphemous, if not impossible (Dossey 1997).

These concerns, when removed from the heat, do reflect important issues in studying distant healing. Clearly we must consider the limits of our studies. As we interpret results, we must remember that:

- Finding that a change occurs in a biological system in the context of a directed prayer or healing intention neither proves nor disproves the tenets of anyone's religion
- The spiritual, cultural and psychological contexts in which healing efforts are embedded are complex and may have many benefits (or detriments) apart from their efficacy in affecting clinical change through intention alone
- Use of the double-blind randomized clinical trial has multiple inherent constraints that preclude testing of distant healing exactly as it is practised in the community.

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Researchers interested in pursuing studies in this area will take heart from a list of basic research tenets published by the NIH Panel Report on CAM Research Methodology. This report states the underlying assumptions that:

- Research is always feasible – and essential, regardless of the therapy under consideration
- Research rarely provides unequivocal answers
- Good research aims to minimize the effects of bias, chance variation and confounding
- Our priority is research that investigates whether treatments do more good than harm (Vickers et al. 1997).

The methodological questions in research in distant healing necessarily rest on defining a specific intervention and evaluating its impact on a target system. This will be the main focus of this chapter. Questions of mechanisms depend on the successful negotiation of these first tasks and will be discussed more briefly at the end.

DEFINING THE INTERVENTION

There are no established protocols or practice standards for distant healing practitioners as a group. Healer inclusion criteria in published studies have ranged from novice volunteers in many studies (Braud 1989, O'Laoire 1997) to 'people who believe in God' (Harris et al. 1999), to healers of international renown (Grad 1965, Rauscher & Rubik 1983) or with many years of professional experience (Sicher et al. 1998, Snel & Ho1 1983). Each experimenter must carefully choose and document the approach and experience level of healers in a study. The choice may have a theoretical basis, e.g. an attempt to compare one approach to another or to manipulate healing parameters. Or it may be based on a practical issue, e.g. an experimenter may wish to evaluate a method being used in a particular clinic. Documentation of healer approach or experience does not require that healers be identical on all descriptors. For example, one approach might be to require 5 years of experience or a certain score on a test of concentration but not to discriminate on the basis of philosophical approach.

Because the efficacy of distant healing as a modality has not been established, there is no test by which to choose an effective healer to participate in a particular study. In addition, unlike a pharmacological agent or a technical device, distant healing depends specifically on the consciousness of a human being. This raises the important issue that in addition to possible differing efficacy of various approaches, there may be both differing skill levels of practitioners of a particular approach or even of an individual practitioner on a day-to-day basis. In a large study, one runs the risk that certain patients might be treated by an effective healer and others by healers of no ability. One novel approach used by Sicher et al. (1998) has been to have healers that meet certain inclusion criteria work on different patients on a rotating schedule, so that in case some of the healers were effective and others not, all patients would have contact with a range of practitioners. Because a healer might not always be performing at his or her maximum ability, it may also be appropriate to plan several intervention periods, rather than using a one-healer, one-session approach. Another way to think about this is that in studying intentionality as a healing modality, one has to ensure that the intentionality effort is really present and to maximize the potential effects.

Many terms have been used to describe interventions which may fall into the category of distant healing. These include: intercessory prayer, non-directed prayer, energy healing, shamanic healing, non-contact therapeutic touch, spiritual healing. Each of these describes a particular theoretical, cultural and pragmatic approach to attempts to mediate a healing or biological change through mental intentions. The following are some operational definitions of modalities which include elements of distant healing.

- *Intercessory prayer*. Any form of requesting God to bring about a specific desired outcome (O'Laoire 1997).
- *Non-directed prayer*. Intercessory prayer in which the person praying wishes only that God's will be done in the life of the subject (O'Laoire 1997). This prayer may typically be worded 'Thy will be done' (Dossey 1997).
- *Energy healing*. This large category describes attempts by a practitioner to send or direct atypical or 'subtle' energy flows either to or within the subject. Examples include attempts to interact with the Asian concept of *chi* (or life energy) through chi gong, jin shin jyutsu or reiki or chakra (human energy centers) energetic manipulations as taught in schools influenced by Ayurvedic teaching (Brennan 1987).
- *Shamanic healing*. This approach is typical of Native American and indigenous Siberian, Tibetan, Central American, Asian and northern European cultures (Halifax 1979). These complex practices involve the healer entering a profound altered state of consciousness in which he or she experiences moving into different 'realms' and interacting with spirits whose aid may be enlisted in healing the patient.

- *Therapeutic touch*. A technique developed by nurse Dolores Krieger (1975) in which the healer uses meditative practice to induce a calm and focused state and moves his or her hands over the patient (without touching) while holding a mental intention for the patient's healing.
- *Spiritual healing*. This very general term has been used to refer to a wide range of techniques including spiritist healing seances (Krippner & Villoldo 1976), as well as meditations focused on visualizing the patient connected with God, a universal force of love or the Absolute. Such healing efforts may be performed in a religious or a non-denominational context.

In a qualitative analysis of what he termed 'transpersonal healers', Cooperstein (1992) found that whatever the cultural or religious orientation of the healer, most typically begin with a period of relaxation, followed by enhanced concentration, culminating in visualization.

Most healing efforts in the community occur within a cultural context either of interaction between the healer and the patient or expectation by the patient that healing is being performed on his or her behalf. This may or may not be the case in a study of distant healing.

WHAT IS THE HEALER DOING?

Healer strategy should be documented before any trial via interview of the healer and healers in extended studies should be asked to write daily logs describing their healing efforts. Healer selection might also involve questions as to level of experience and professional training or other issues of relevance to the study such as healer ability at concentration. At this stage, it has not yet been established whether healer experience or training are significant for outcome but based on claims that certain individuals have extraordinary healing abilities or that certain training programs increase healing ability, this will be an important variable to explore.

FOR HOW LONG IS HEALING ATTEMPTED?

Periods of time for healing interventions in the literature range from a few seconds in experiments attempting to arouse anesthetized mice (Watkins & Watkins 1971) to 60 hours (Sicher et al. 1998). A majority of studies have required healers to perform their healing efforts serially on a daily or weekly basis for a series of treatments. Few, however, have indicated how much time the healer should spend on the healing efforts. For example, in the three major intercessory prayer studies (Byrd 1988, Harris et al. 1999, Walker 1997), in which prayers continued daily for a period of weeks, no indication is given if pray-ers prayed for a few seconds at bedtime or concentrated for minutes or hours. This problem can be addressed as in Sicher et al. (1998) by requiring a set amount of time for the healing effort and providing healers with a log to document the extent of their compliance. In addition, some researchers (Walker 1997, Sicher et al. 1998) have pointed out that it may be important for researchers to stay in communication with and actively encourage their healers during extended studies, for the purpose of motivating their performance and ensuring that healing efforts will in fact be performed.

INDIVIDUAL VERSUS GROUP EFFORTS

Most distant healing interventions have been organized such that one subject is treated by one healer. A variation of this approach described above involves sequential treatment of each subject by a series of different healers. Another variation is seen in the Harris study: the name of each patient was given simultaneously to a 'team of intercessors'. Thus each patient was receiving pooled prayer efforts from a group of people working individually. In the study by Byrd, prayer was performed as a group effort, by preexisting Christian prayer groups. At this point there is no evidence to suggest that individual or group healing efforts are more successful. A logistical concern is the risk that in a group setting, group members may distract one another from the task of focusing on the subject. In addition, studies using healing groups and pooled efforts have tended to use less experienced healers than those studying individual efforts. In order to comment meaningfully on the relative roles of experience versus number of interveners, it will be important that investigators considering one or another of these approaches document the experience and practice level of the healers.

EXTRANEOUS PRAYER

In addition to fully defining the intervention to be tested, it is also important to identify all sources from which the intervention may come. Dossey (1997) has pointed out that in clinical healing studies, especially ones in which the patient is very ill, it is quite likely that patients may be receiving prayer or healing efforts from friends and family members or may be praying

for him or herself. In fact, on a daily basis, hundreds of thousands of people worldwide offer prayers 'for all the sick'.

This observation has been levied as a criticism against an important, large randomized clinical trial of intercessory prayer for patients in the coronary intensive care unit at San Francisco General Hospital (Byrd 1988). Thomson points out that the control group in this study may have been receiving intercessory prayer efforts from friends and family, thereby contaminating the study. This is an important issue to be aware of, although this scenario would suggest that both groups are being prayed for by friends and family and that the study treatment group is additionally receiving prayer from the study healers. This would be more likely to cause a false-negative result, with both groups benefiting from prayer, rather than accounting for the positive findings of the San Francisco General study.

Because of the potential for a false-negative result, or ceiling effect, with 'extraneous prayer', Dossey has suggested that target populations be ones who are less ill (and thus less likely to be receiving community prayer). Another approach would be to recruit large or variable numbers of intercessors to examine possible 'dose' (numbers) effects.

DEFINING THE HEALING INTENTION

The investigator has the responsibility to define parameters of the healing intervention engaged. This may or may not involve defining the specific mental techniques used by the healers. It does, however, require carefully defining the intentions of the treatment. Intentions may be very specifically prescribed such as having healers hold intention for 'lower blood pressure', 'reduced tumor size', 'decreased anxiety' or even 'increased emotional and physical well-being' if the investigator plans to use a broad range of measurement tools. It is *not* appropriate for healers to pray for 'religious conversion' for patients and some studies have specifically directed healers not to do this.

It is also not useful for healers to focus their intentions for change in an area which the investigator cannot measure e.g. 'change in the etheric field' or 'balancing the heart chakra'. If within a healer's theoretical orientation. such an action is believed to also be associated with changes in the target system as defined by the experimenter, this type of focus may be acceptable as part of the healer's working style but a measurable outcome intention should be defined and specified by the investigator.

WORKING WITH HEALERS

Most healers have not worked in a laboratory or experimental setting and many are not comfortable with or sympathetic to the constraints put on their activity in the research setting. This represents a limitation of distant healing as it is performed in the community. It has been our experience that there is a great range of healing practitioners and some are eager to participate, very flexible and appreciative of research efforts. Others have been very angry about not being allowed to, for example, touch experimental Petri dishes or have felt investigators were discourteous because they were questioning the ability of the healers. As with all social and working situations, it is important that the healer – investigator team work toward mutual understanding, respect and consideration. Because of the history of scientists doubting healers, it is especially important to examine unconscious tendencies in the team to be dismissive toward healers. In addition, it is important to respect and understand cultural differences which may be present, such as whether it is important or insulting for a healer to be paid. Likewise, healers who participate in research studies should be fully appraised of the limitations they will experience and should be assessed for their motivation to participate in the study.

TARGET SYSTEMS

Distant healing studies have historically shown significant effects in trials of influence not only on human medical problems but also human physiology in the laboratory, on animals (Grad 1965, Snel & Van der Sidje 1995), bacteria (Ranscher & Rubik 1983) and cells in vitro (Baumann et al. 1986, Braud 1989). Animal and in vitro targets are often chosen for reasons including lower cost, less complexity in running a trial and ease of isolating a particular outcome measure. In addition, in animals and certainly in in vitro systems, it is much easier to eliminate psychological and placebo effects.

POPULATION COMPARABILITY

The same general rules for choosing target populations in any study apply to distant healing, with special emphasis on population homogeneity and the need for thorough baseline assessments of factors which may influence outcome such as social support, levels of depression and anxiety, meditation practice and spiritual beliefs. In smaller samples it may be appropriate to stratify or use pair matching to

ensure balance between comparison groups on these and other relevant medical factors.

PAIR MATCHING

Pair matching is done to control as much as possible for variation in outcomes which might be related to major disease progression. In pair matching two or three baseline variables relevant to outcome are used to form matched subject pairs. First, a normalized z-score is computed for each subject for each variable by subtracting the mean for all subjects and dividing the result by the standard deviation for all subjects. Next all pairwise sums-of-squared differences in z-scores between subjects (over the variables) are computed. For each subject an average difference from all the other subjects is calculated. Starting with the subject with the largest average difference, the closest match is found. The two matched subjects are eliminated from the list and the procedure is iterated until all subjects are paired. A binary random number, generated by computer, is then used to randomly assign one member of each pair to the treatment group and one to control.

HEALER ATTITUDE

Studies of distant healing, as with many psychosocial interventions, are studies of consciousness either directly or indirectly interacting with another living system. For this reason, it is important to consider issues pertaining to the relationship between the healer and the healing target. At the same time, we must consider the possibility of a target system contribution to the healing effect. Specifically, it may be important for the healing task to be motivating and relevant to the healer. For example, in developing studies in our own laboratory, we interview many healers who state that their preference would be to attempt to heal someone who was very ill, rather than to try and influence a minor problem. Despite staff concerns that healing someone very ill might be too hard, the healers insisted that this would bring forth their better efforts.

Another example of the importance of healer attitude toward the task and the target is a situation in which a chi gong master acting as a healer in our laboratory was asked to attempt to 'kill cancer cells in vitro'. He vehemently objected that as a healer, he was prohibited from killing anything. The situation was resolved when he agreed to 'emit harmonizing chi energy' toward the cells, holding an intention equivalent to 'Thy will be done' with regard to the cells. The cells died significantly faster than controls (Yount et al. 1997). Similarly, in studies at Lawrence Berkeley Laboratories, healer Olga Worrel was not willing to attempt to kill *Salmonella bacteria* in vitro but she was willing (and able) to protect the *Salmonella* from the harmful effects of antibiotics (Rauscher & Rubik 1983).

SUBJECT BELIEFS

Questions have often been raised as to the relevance of subject beliefs about healing, religious orientation and desire for healing. Studies from the literature in parapsychology, for example, have repeatedly found that subjects who believe in clairvoyance or telepathy show higher scores on tests of psychic functioning than do non-believers (Schmeidler 1998). Very few studies have examined the contribution of belief specifically to healing. In studies in our laboratory, we have not found such a correlation. However, the majority of volunteer subjects in our studies have a very high a priori belief in the power of healing such that there may not have been enough variability in our samples to see a difference. In this example, patient self-selection limits the generalizability of results. It is therefore appropriate to assess subject beliefs about healing as well as spiritual or religious issues at study admission. It may be useful to deliberately choose groups of subjects with either high or low levels of belief for the purposes of comparison.

SUBJECT COMFORT WITH HEALING

In addition to differences in belief in distant healing, there may also be differences among patients in their comfort level with being the target of distant healing efforts. For example, in the Byrd study, which used 393 subjects, an additional 57 patients who were invited to participate refused. Byrd (1988) states that some of these refusals were based on religious convictions – a point of view reiterated by a commentator in the *Wall Street Journal* who stated that if any doctor tried to pray for him, 'I would sue him'. We do not know if such opposition would modify the efficacy of distant healing efforts but it emphasizes the importance of documenting patients' attitude as well as obtaining informed consent.

SUBJECT DESIRE FOR HEALING

A potential confounder in healing experiments became clear with the publication of a study by Walker, in which it was found that alcoholic patients remanded to an alcohol treatment facility did worse if they believed family or

friends were praying for them. This emphasizes the complexity of prayer in a social context. Walker speculates that on one hand, alcoholic patients may feel criticized or worked against by the prayers of others and that in some cases their own resistance to recovery may interfere with even unknown prayer efforts by others. In designing a healing study, it would therefore be reasonable to ask subjects to indicate their own level of desire for recovery, as well as their comfort with the possibility of others praying for them.

SUBJECT PARTICIPATION IN HEALING

There has been debate among researchers doing studies in distant healing as to whether it is important for subjects to know they are receiving healing efforts. The primary objection to such trials is that telling subjects they are receiving healing eliminates the blinding and introduces possible placebo or expectation effects. Nevertheless, it would be interesting to compare blinded with open healing trials and assess the magnitude of any added benefit to patients in knowing they were receiving healing efforts.

OUTCOME MEASURES

The choice of a measurable, definable, non-confounded outcome measure is crucial to the development of a meaningful study of distant healing. Ideally, study endpoints should include those that are objective, have adequate variability in the study population and are not modified by the measurement process or study participation. The outcome measurement tools should have been validated in work separate from the study.

CEILING EFFECTS

It is important to choose an outcome measure in which there is adequate room for change. For example, if the subjects are normal healthy volunteers, it will not be appropriate to look for decreased blood pressure or improved mood scores.

MEASUREMENT EFFECTS

Avoid outcome measures that are influenced by the measurement process. For example, if the outcome measure is 'level of depression', this should not be assessed by a series of clinical interviews, as the clinical interview itself may have a therapeutic effect and serve to mask an effect (false negative). Similarly, having patients write daily journal entries over time as a source of information about mood will risk a masking effect because journaling itself is a therapeutic tool.

LIMIT THE NUMBER OF OUTCOME MEASURES

As in all types of studies, hypotheses and measures must be specified before the study is begun. Appropriate statistical correction for multiple testing problems may be done using a variety of statistical methods. When outcomes are believed to be independent, which they rarely are, adjustment can be made by the Bonferroni method which simply multiplies the univariate *P*-values by the number of statistical tests that were used in the analysis. This is a crude method, however, that can lead to severe loss of statistical power.

A better method is to apply a randomization test to the vector of outcomes. Randomization tests are easy to carry out since all that is required is to repeatedly reassign subjects to treatment and control using random numbers generated by a computer to make the reassignments. The test statistic is recalculated for each computer-generated random reassignment. This process produces an approximation to the 'exact' distribution of the test statistic under the null hypothesis that group assignment made no difference in the study outcomes. The approximation can be made as close as desired to the 'true' distribution by increasing the number of random reassignments. If complete enumeration of all possible outcomes of the test statistic is possible (as is often the case when the number of possible outcomes is small), then an exact *P*-value is obtained. In the simple 2×2 table case, the randomization test is known as Fisher's exact test and has been widely recognized as the most conservative way to statistically analyze binary data. The advantage of this method over the Bonferroni adjustment is that it preserves the correlations among the measurements.

ESTABLISHING CAUSALITY

The biggest outstanding question in the field of distant healing is 'Do distant healing efforts modify biological systems'. Trials exploring this question will be successful only if they avoid the two central research errors: 'false-positive' and 'false-negative' conclusions. Avoidance of the false-positive result has been the chief focus of researchers and critics of distant healing research; however, to the extent that we are trying

to sort one type of consciousness effect (distant healing) from another (hope and expectation), the false negative also presents a significant pitfall.

AVOIDING THE FALSE-POSITIVE RESULT

Hope and expectation are the chief confounders in studies of distant healing. While it is likely that hope and expectation effects would be synergistic with any true non-local healing effects, the focus of distant healing experiments is exploration of the role of healer intentionality in modifying subject outcomes. The gold standard for limiting the role of hope and expectation is the double-blind randomized clinical trial (RCT). It has been well established, for example, that there is a significantly higher likelihood of seeing an improvement with a new therapy in a non-randomized trial than in a randomized one (Colditz et al. 1989) and that blinded studies with inadequate concealment and randomization protocols are also more likely to show positive results (Shulz et al. 1995).

The formula for the double-blind RCT requires that:

- Patients are assigned to treatment group at random
- Patients do not know which treatment they are receiving
- Evaluators of treatment efficacy do not know which treatment the subject is receiving.

In doing research in distant healing the old admonition applies: 'extraordinary claims require extraordinary proof'. The purpose of the double-blind RCT is to eliminate mediators of experimenter bias or subject hope or expectation. Most clinical trials begin with open-label pilot studies and progress step-wise to definitive double-blind methodology. In the field of distant healing, we find the 'open-label' trials to be of limited utility unless the outcome being measured is entirely objective, not susceptible to autonomic effects and not treatable by other means.

DOUBLE-BLIND RCTS

We assume that readers are familiar with standard double-blind RCT methodology. Specific points relevant to trials of distant healing are emphasized below. The purpose of blinding in the RCT is to minimize any elements of hope, expectation or belief that might mediate a differential outcome.

Blinding protocols. Adequate blinding is essential. For a definitive test of efficacy of a distant healing modality, it is required that:

- Patients do not know of their group assignment
- No research staff member may know of subject group assignment
- No outside treating personnel may know of group assignment.

The only person who may know a subject's group assignment is the healer. Ideally, the healer and patient never meet and the healer has insufficient information about the patient to describe or contact him or her (e.g. first name or photo only).

This type of blinding can be accomplished using a series of lists and codes. Randomization should always be performed using a random number generator or randomization table. Use of chart numbers, admission order or patient birthday is not acceptable. In addition, randomization should be performed after the patient is enrolled in the study (i.e. it is not appropriate to randomize a subject and then decide he or she does not meet criteria). The following example describes how this could be done for a study in which subjects are randomly assigned to receive treatment from a healer or to be in a no-treatment group. Investigator 1 is identified as the subject contact person, Investigator 2 is identified as the healer contact person.

1. Subjects are recruited by Investigator 1 (11). Initial assessment is done and subject is enrolled if he or she meets inclusion criteria.
2. 11 assigns non-sequential, randomly chosen enrollment numbers to each subject chart and creates a photocard for each subject with his name. He puts the photocard in an opaque sealed envelope and puts a removable sticky tag on the outside, with each subject's enrollment number. 11 then gives a list of the enrollment numbers, without names, to Investigator 2 (12).
3. 12 uses a random algorithm to assign study numbers to each of the enrollment numbers. He then writes the appropriate study number on each patient envelope and removes the sticky label. The code-key is stored in a sealed envelope. He then uses a random algorithm to assign subjects to either the treatment or the control group. In the event where stratification or pair matching is required, key data such as subject age or CD4 count could be transferred along with the code lists for use by 12. 12 then locks the envelopes assigned to the control group in a drawer and returns the treatment group envelopes (with their new numbers) to 11.

4. 11 then gives the envelopes to the healer according to whatever schedule has been determined. 11 has no further communication with the healer for the duration of the study. Any staff communication with the healer must be handled by 12. If there is a need to interact with a subject during the course of the study, this will be done by 11.
5. Data collection from the subjects is done by I1 who enters data using the enrollment numbers. After all data have been entered, analysis is begun.
6. Ideally, the assignment codes are broken after the main group comparisons have been completed.

Use of sham control conditions. Under some conditions, for example when the healing treatment requires that the healer be present in the room with the patient, alternative blinding schemes can be used. In studies of non-contact therapeutic touch, Quinn (1989) used a sham condition in which for control patients the healer was present, made hand-passes over the patient's body but did not 'hold a healing intention'. Instead she performed mental arithmetic. This protocol has the advantage of preserving the integrity of the intervention as it is performed in the community but raises concerns, either that the healer may not be able to 'turn off' her healing ability (leading to a false negative) or that the patient might perceive in the healer's affect whether or not healing is being performed (false positive).

In studies in which the principal outcome measure is believed to be objectively stable, e.g. stroke-related paralysis that has been documented stable for years, tests of in-person healing can be done, if subject condition is documented over an initial waiting period of 1 or 2 months, then an intervention or sham intervention is performed and an investigator blind to the condition makes a second assessment. Both these types of protocols allow testing of hands-on healing or healing in which the healer believes he or she must be in the room.

It is not recommended that investigators use a control condition that does not mimic the healing condition, as the expectation effect for prayer and distant healing may be presumed in certain individuals to be the guiding principle of their lives.

In vitro trials. In in vitro trials it is also important to create sham treatment conditions for control samples. Any control sample should travel to the same room on the same schedule as treatment samples, be handled in the same way, and position in test tube racks or incubators should be the same as for treatment samples. To further assess mechanical and environmental factors, in laboratory comparison studies, it is also useful to use systematic negative controls (Walleczeck et al. 1999). In this methodology, some trials compare a treated sample with a sham-treated sample whereas others compare sham treatment with sham treatment. This allows assessment of baseline variability in the treatment system. Many investigators have also used thermistor devices to ensure that healer hand temperatures do not affect treatment samples.

AVOIDING THE FALSE-NEGATIVE RESULT

While most of the attention in distant healing studies is on eliminating the false-positive or type I error, there are a number of ways in which a positive result could be ignored or washed out by the experimental protocol. This mostly applies to situations where subject self-report of symptoms is a primary outcome or where outcomes are known to be modified by a subject's emotional state. This type of potential confounder has been seen in studies of distant healing in blood pressure (Beutler 1988), asthma (Attevelt 1988) and depression (Greyson 1996) in which patients were required to make regular clinic visits for interviews or attend sessions of relaxing in an empty room while blind to a treatment condition.

Subject study-related activity should be minimized, e.g. it is preferable that subjects do not come to the lab or clinic for regular study-related activities, that they do not keep a study-related journal, that they are not instructed to mediate once a day to make them 'more receptive' and that they are not telephoned by staff members to 'see how they are doing'. Any such activity has the potential to alter (usually reduce) symptoms. This symptom reduction will be equally present in both the treatment and control groups and may wash out a possibly more subtle treatment effect. Unless the healing intervention is thought to require the immediate presence of the healer, it is best that, once enrolled in the study subjects, have little or no contact with study personnel and that outcome measurement activities be kept to a minimum.

Effects of social pressure and expectation are well known in the social sciences (e.g. Hawthorn effect). Kiene (1996) has pointed out that such effects may also create type I errors. If subjects in double-blind experiments are overly encouraged to think an effect may occur, if they feel they have to 'please' the experimenter by showing improvement or if they interact with other study subjects who may be receiving the treatments, the effects of psychological pressure may lead to patients either psychophysically self-generating

improved symptoms or simply inflating improvement scores on assessment tools. This 'pleasing' or 'peer pressure' effect is an equal risk among control or treatment subjects. These factors too could wash out a potential distant healing effect. For this reason, it is recommended that subjects do not interact with each other and that at study enrollment, investigators limit their enthusiasm for the treatment.

Treatment outside the study creates an additional potential risk of false-negative results. This was discussed above under the heading of 'extraneous prayer'. Unlike trials of new pharmacological agents, patients have easy access to many forms of distant healing and cannot ethically be discouraged from seeking them out. Therefore, it is important to document patient use of or knowledge of sources of distant healing efforts on their behalf that may be occurring outside the study.

EXPERIMENTER EFFECTS

Experimenter effects have been widely documented and discussed in the literature (Kiene 1996). They can lead to either false-positive or false-negative results. Careful application of the double-blind RCT methodology with additional attention to experimenter equanimity in contact with subjects should minimize such effects. However, research in distant healing presents a special case in which the assumptions underlying the RCT are challenged. The RCT depends on the assumption that the beliefs or desires of the investigator and the subjects will not have unmediated effects. This presumes that the wishes of the investigator will not cause subjects to show improvement and that the wishes of the investigator or subject will not influence random assignments. If distant healing effects are shown to be robust, until it is known how they are mediated, there will always be a risk that the experimenter or the subject may also be in some way influencing the course of the study.

In fact, this issue was raised in the context of studies of the ability of research volunteers to influence the electrodermal activity of subjects in the next room (Braud & Schlitz 1983). This double-blind randomized study was replicated in numerous laboratories in the United States but failed in the laboratory of a skeptical investigator, Richard Wiseman, in England. After repeated failures of the protocol in his laboratory, Wiseman invited a successful experimenter (Marilyn Schlitz) to replicate the experiment in his laboratory. In alternating trials, when Schlitz functioned as chief investigator the positive results were found, when Wiseman was chief investigator the experiment failed (Wiseman & Schlitz 1999). A first possible explanation for this disparity is that some aspect of the experimenter manner, personality or instructions may have altered subject performance. However, this study also highlights the point that in studies investigating effects of consciousness over distance, all sources of influence must be considered. It does not preclude the possibility of meaningful double-blind RCTs; if an investigator's non-local influence on an experimental population is minimal, neutral or equal then it is possible to determine whether or not the experimental treatment is effective. Theoretically it would be possible for an investigator's non-local influence to wash out an effect, dampen an effect or be responsible for a differential effect. If a difference between the two groups is seen, therefore, it can still be concluded that the effect is non-local but theoretically it is impossible to know whether it was caused by the experimenter or by the healer. These questions suggest, first, the importance of the experimenter's interaction with subjects, especially with regard to whether he or she appears encouraging or discouraging. Second, it may be important in the future to conduct trials comparing outcomes by investigators with different levels of belief.

INTERPRETATION OF DATA

Because the implications of experimental claims for the efficacy of distant healing are so profound, the experimenter is obliged to hold his or her studies up to the most rigorous statistical scrutiny and maintain the highest methodological standards.

EVALUATION OF BASELINE FACTORS

It is especially important when analyzing data from distant healing trials to discover whether there are interactions among relevant baseline variables and outcome measures. It has been our experience that differences which suggest a distant healing effect will be attributed by the scientific community to differences in baseline variables rather than the healing intervention, even when these baseline differences do not achieve statistical significance. Unless these baseline – outcome correlations are measured and understood, the study will be open to criticism that other factors could have led to the observed effect rather than the treatment. It is therefore important to run correlation analyses between all baseline differences and all outcome measures. Appropriate controls for multiple testing can then be used.

Of course, it is impossible to rule out all baseline differences as possibly explaining the

result since it is impossible to think of or test all of them. But the importance of postulating factors that could have an effect on outcomes and measuring them at the start of the study cannot be overemphasized. Specific baseline and independent variables which should be examined include: baseline psychological status, other sources of distant healing, beliefs about distant healing, and the subject's guess as to whether he or she was in the treatment group or the control group.

STATISTICAL POWER

There has been a recent trend in metaanalyses to report data not only in terms of *P*-value but also to calculate an effect size. The reason for this is that in a trial with small numbers of subjects the power to detect treatment effects may be small, even if an effect is present. The use of effect size measurement in addition to standard analysis may assist in evaluation of pilot studies and may allow comparisons between degree of efficacy between treatments that have not yet been evaluated in direct comparison trials.

OTHER RESEARCH APPROACHES

Although the double-blind RCT is the gold standard for establishing causality in clinical trials, qualitative patient and healer interviews (Cooperstein 1992) and descriptive survey studies (Krippner & Villoldo 1976) yield important information which may help define future controlled trials looking at mechanism, comparing interventions and understanding the healing process.

ETHICAL ISSUES

Research in distant healing raises the usual ethical issues involved in testing a treatment with unknown effects. One could argue that scientists have an ethical obligation to study distant healing as it is a modality for which important claims have been made, it is widely available and some people are choosing it over conventional therapies. Others argue that such research is not ethical because of a potential negative impact on subject belief systems as well as concerns as to possible negative uses of information from trials.

INFORMED CONSENT

As for all trials of an untested intervention, it is required that informed consent be obtained under the guidance of a certified human subjects safety review committee. Some investigators have argued (Harris et al. 1999) that because there has not been definitive evidence of harm to patients in distant healing trials, informed consent is not required. We disagree. There is considerable evidence already in the published literature for the modification of biological states via the mechanism of distant healing (see Benor 1992). Some of these data include the possibility of negative effects (Dossey 1993). As with all studies, potential loss of confidentiality should be considered a risk. As evidenced by the 14% refusal rate in the Byrd study, not all subjects wish to participate. As evidenced by the negative outcome for alcoholics who knew they were prayed for by relatives in the Walker study (1997), there is clearly at least some psychological risk. An additional risk includes the possibility of severe anger and disappointment in subjects after they learn they have been in the control group, as occurred in one of our studies. Lastly, in psychiatric populations there may be an additional risk of paranoia or delusions associated with the idea of an unknown person at a distance attempting to influence one's body.

For the protection of the subjects, as well as of the investigators, informed consent should be obtained. Subjects should be told the probability of their being assigned to a treatment or a control group and that it is not known whether the treatment will be beneficial. neutral or harmful. They should be offered psychological or medical consultation if distress occurs as a result of participation in the trial.

MECHANISM OF EFFECT

This chapter has focused on methodology for establishing whether or not an effect is occurring, rather than exploring possible mechanisms of action. One reason for this is that one cannot investigate mechanisms before the effect is known to occur. Nevertheless, investigators who feel they have established replicable protocols may wish to pursue studies of mechanism. These trials can proceed in many ways, probably principally by identifying limits on efficacy, such as studying whether certain techniques or certain individuals show a more reliable effect, or examining potential shielding of targets or looking at a cellular or molecular level to understand what systems are being affected at a microscopic or chemical level.

Theoretical physicists are working on models of consciousness and information transfer that may relate to distant healing, while experimental physicists are attempting to build devices that may detect or replicate energies which some people believe could be associated with distant

healing (Rubik 1995). Clearly the distant healing effect is complex and multifactorial. Even the concept of looking at mechanism will mean different things to different people. At the same time as the embryologist describes the mechanism of human development as beginning with an exchange of DNA, the religious philosopher describes it as caused by the will of God. The discrepancy between these two points of view does not prevent meaningful and useful information from coming out of the work of both of these approaches.

BARRIERS TO RESEARCH

The primary current barriers to research in distant healing are lack of funding and of public acceptability of researching this field. To date, relatively few federal grants have been awarded to support a study of distant healing. This despite the hundreds of thousands of dollars required for a formal clinical trial.

Until recently, a frequent objection to distant healing research was that it simply could not be done. With the recent publication of several large clinical trials, this objection has been tested. More recently, questions have been raised as to the utility of information regarding distant healing. An extremely high scoring distant healing proposal from our laboratory was recently turned down by the Department of Defense with the comment 'it has no translational potential'. Other reviewers have objected that even if healing worked in a particular study, one would be unlikely to find other healers with this type of ability. Obviously, future research will have to determine the prevalence of healers in the population but meanwhile, it is incumbent upon researchers to suggest how healing abilities might be used, if they are in fact shown to have a clinical efficacy.

An additional barrier to research is caused by the existence of a social and academic stigma toward researchers who engage in studies of what many consider to be an implausible or laughable treatment. The only place in the medical literature where paranormal abilities are currently indexed, for example, is within psychiatry under the definitions for psychosis and schizophrenia. It is therefore not surprising that many experimenters feel uncomfortable about expressing an interest in pursuing studies in the area of conscious influence at a distance.

Another, somewhat surprising source of resistance has been religious communities. Some religious people have understandably objected to scientists equating 'intentionality' with prayer. This has led to the concern that testing distant healing is a form of 'testing God' and therefore interfering with the sacred and highly personal relationship of faith.

WHY DO DISTANT HEALING RESEARCH?

Prayer and distant healing have been part of nearly every culture since the dawn of civilization. If research determines that it has a measurable effect, under double-blind conditions, on any group of physical or psychological findings, this might encourage health-care practitioners of all descriptions to include distant healing modalities as part of their treatment plans. If no effects are measured, research should focus on understanding the ways in which the culture around prayer or healing activities serves to lift the spirits and enrich the lives of patients.

Without evidence from rigorous trials, it is not appropriate for physicians to either recommend or discourage distant healing; with such evidence, they will be in an informed position from which to usefully guide their patients.

Future research will help define the conditions (medical, psychological, physical) under which effects are most likely to be measurable, mechanisms by which healing may occur, target systems that are most amenable, the common denominators and necessary factors for distant healing interventions, the relationship between spiritual issues and distant healing outcomes and whether individuals can be trained to improve their distant healing abilities.

SUMMARY

- The double-blind randomized clinical trial is the gold standard for trials of prayer and distant healing.
- Adequate blinding and randomization procedures should be followed and documented.
- The intervention must be well defined (include frequency, amount of time and training and/or experience level of healers).
- Subjects should have risks and benefits of study participation explained to them and sign informed consent before enrollment.
- Populations should be homogeneous. Consider stratification for smaller samples.
- Baseline information, including psychological status, beliefs about prayer and healing and other sources of prayer and healing, should be collected from subjects in clinical trials. This should be examined as part of the final data analysis for contribution to outcomes.

- Objectively measurable outcomes with adequate variability should be chosen.
- Subject study participation activities such as clinical interviews, traveling to special sites, journaling or meditation should be minimized to avoid washing out a small effect.
- In clinical trials subjects should be asked if they *believed* they were in the treatment group and this information should be entered as a co-variate for data analysis.
- Healers/prayers should be treated in a collegial and respectful way. Their healing efforts (time, location, method) should be documented in a log and they should be periodically contacted and encouraged by experimenters if the study is taking place over an extended period of time.
- Observational and outcomes research can add an important dimension to healing research.
- Qualitative studies may also make an important contribution and help guide development of future controlled trials.

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Nature finds a way (urban gardens – Venice) (Danise Rankin-Box).