



CAM RESEARCH

Designing a polarity therapy protocol: Bridging holistic, cultural, and biomedical models of research [☆]

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Summary One of the methodological challenges of conducting CAM therapies research and in particular, biofield/touch therapies research is the development and use of methods that are compatible with the holistic nature of the therapy. Biomedical scientists claim that the “gold standard” of research must be the randomized clinical trial (RCT), which includes a standardized protocol. Conducting an RCT on a biofield/touch therapy often results in structural and conceptual conflicts with the clinical standards necessary to holistic therapies. This paper discusses a polarity therapy protocol designed as an intervention for the reduction of stress in American Indian family caregivers of patients with dementia. The protocol is designed to maximize efficacy and cultural congruency, adhering to the integrity of the holism, while addressing challenges arising from randomized controlled trial methods. The protocol developed for this study is presented and discussed.

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Introduction

One of the methodological challenges of conducting research into complementary and alternative medicines (CAM) therapies and in particular, biofield/touch therapies is to use methodologically rigorous approaches that are also congruent with the holistic qualities of the therapy. In this paper

we discuss the factors considered in the development of a 2-year Caregiver Study: a study of the feasibility and efficacy of polarity therapy (PT) as a therapeutic intervention to reduce stress among American Indian caregivers of family members suffering from dementia.

Compatibility of research methods with a holistic therapy enhances the likelihood that researchers will capture the range of responses, both gross and subtle, that are commonly observed in clinical practice. Biomedical scientists contend that the “gold standard” of research must be the

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randomized clinical trial (RCT), which includes a standardized protocol (Walker and Anderson, 1999; Berman and Straus, 2004; Miller et al., 2004). Yet carrying out an RCT with a biofield/touch therapy often conflicts with the clinical practices associated with holistic therapies. These practices are often tailored to the specific patient and adjusted from session to session, influenced by therapist technique and intuition. Clinicians consider all of these factors as contributing to synergistic effects that lead to efficacy. Holistic researchers and therapeutic practitioners contend that to accept the methods of RCT's without regard to holistic factors results in reducing the essence of holism by means of separating the constituent parts from the whole. This outcome ruptures effective implementation of the therapeutic philosophy that forms the basis for the therapeutic practice that stresses the restoration of the whole from the parts. This conflict is further amplified when one begins to apply analytic methods to the acquired data. Walach (2004) describes the "efficacy paradox" suggesting that many CAM interventions produce both strong, non-specific effects and weak, specific effects. Faced with this paradox, research scientists may be led to disregard the "absolute effectiveness" of a strong effect, which may be more apparent than in studies with large specific, but weaker overall effects. Like many CAM interventions, Polarity proposes to bring about systemic balance and deep relaxation, thus allowing the innate capacity for self-healing to be restored and re-vitalized. In contrast to prioritizing specific outcomes, balance for each individual is a unique and dynamic process. Hence the adage among polarity practitioners that whatever response results during or following a polarity session, whether it is deep sleep, hunger, memories, tears or joy, all are reflections of the return to equilibrium that balancing the energy fields facilitates. Teasing out specific contributions to efficacy, singular or synergistic while measuring the "whole picture" is thus the developing challenge to clinical research on CAM therapies (Verhoef et al., 1999; Ai et al., 2001). How then can treatment protocols be standardized without jeopardizing the potential for efficacy derived from an individualized approach to therapy? How can we use measures that capture the range of human experience during PT? Finally, how do the cultural attributes and norms of the subject population influence protocol design? These questions led to the design of a uniform PT protocol for a randomized, controlled trial. Achieving a consistent protocol served effectively for the Caregiver Study target sample population while retaining the integrity of the therapy process itself.

In this paper a standardized 21-point PT protocol is presented and the rationale for its design explored for use in the study of the efficacy of PT in the reduction of stress in American Indian family dementia caregivers. The study using the protocol was designed as a single blind, randomized controlled trial designed to respond to racial and ethnic health disparities by addressing the dearth of CAM research with American Indian populations and the paucity of research on PT in particular. The Caregiver Study was designed to assess feasibility and safety and to quantitatively assess outcomes that included a hypothesized decrease in stress, depression, anxiety, and improvement in sleep, health functioning, quality of life and personal growth. Qualitative data collection was designed to provide an opportunity to explore participant narratives across a variety of domains including spirituality.

Note: The 21 point protocol will be described fully in the next issue of JBMT.

Background on PT

PT is a syncretic energy medicine, biofield/touch therapy, developed by Randolph Stone, DO, DC during the early 20th century. Polarity evolved from an integration of traditional Ayurvedic medicine and energy meridian therapies with the manipulative therapy traditions of early 20th century "drugless" cranial-osteopathic medical practitioners. There are four integrative aspects to the practice of PT: polarity bodywork, energetic nutrition, stretching postures, and communication/facilitation. The Caregiver Study concentrated on the use of the Polarity Bodywork protocol.

A major principle of PT is that health and healing are attributes of energy that flow in a natural and unobstructed state. Artful touch, focused attention, intention—empathy and love—are the interpersonal foundations of the practice (Association, 1996). Stone described concepts of energetic, myofascial, and structural manipulation based on what he referred to as "wireless energy currents" (Stone, 1986) a concept that is linked to field theory (Korn, 1987) and to hypotheses of energy transduction between cosmic energy, chakras, neural plexi, and the endocrine glands (Tiller, 1997). Thus structural and functional relationships occur within the context of an overarching concept of the five sensory/motor elements (ether, air, fire, water, earth) and the deep energy currents of neural plexi, represented by the image of the caduceus, the ancient icon of the autonomic nervous system.

The goal of PT is to *trace* (by palpation) and *release* (by skilled touch) those energy blockages that manifest as pain or dysfunction. To do this, the practitioner applies three depths of touch depending on whether the energy blockage reflects a hyperactive, hypoactive, or neutral state of activity. The hands (and the consciousness behind them) facilitate polarization of currents by placement on opposing poles (e.g. right hand in negative pole position or left hand in positive pole position) on the body. Elaborate placement charts derived from functional, structural and energetic traditions inform these hand placements. Touch techniques range from very light palpation (5–10 g of pressure similar to methods utilized in cranial–sacral therapy, healing touch, reiki and therapeutic touch), a medium touch where pressure meets tissue resistance, and deep pressure manipulation through the myofascia, similar to the techniques of Rolfing (Neo)-Reichian practitioners and myofascial deep tissue massage applied to break up stagnation, crystalline deposits, and scar tissue. Pressure on energy points, rocking, gentle traction, stretching, and rotation of joints are some of the methods used to help the patient achieve deep relaxation, improve respiratory and digestive function and set the stage for the innate capacity for healing. Polarity posits that the patient will also gain greater self-awareness of behavioral and cognitive influences on their health, and undertake an increasingly responsible role in creating a healthier lifestyle (Table 1).

Evolution of PT

Dr. Randolph Stone was born Rudolph Bautsch in Austria in 1890 and immigrated to the United States of America in 1898. He settled with his family in Wisconsin and then in Minnesota. In the 1920s Dr. Stone completed his primary medical certification as a Doctor of Osteopathic Medicine (DO) and then received his Doctor of Chiropractic (DC) and a

Doctor of Naturopathic Medicine (ND). He maintained his practice in Chicago and in India working with patients considered incurable using techniques learned from many other healing systems. Stone studied yogic meditation in Beas, Punjab, India for personal development and yoga and Ayurvedic medicine deeply influenced his thinking. His theories and techniques suggest that the principles of polarization are universal phenomena and his ideas were influenced by Dr. Albert Einstein's atomic theories of the early 20th century. Thus Polarity is not only a set of techniques but a principle, he proposed, that should guide all therapeutic application including both diagnosis and energy balancing at the physical, emotional, mental, and spiritual levels of existence. While he wrote about the reciprocal effects of emotion on autonomic dysregulation, he did not emphasize the integrative psychosomatic processing that has evolved with Polarity into the fulsome process-oriented bodywork therapies of the early 21st century. Indeed, by all accounts, this deeply spiritual, gifted healer's no-nonsense approach to verbal processing consisted of no more than to give a "Dutch Uncle talk" to his patients and to leave it at that (Stone, 1986). Nevertheless Stone encouraged the extension of his work, by leaving out critical details in his charts, he said, in order to stimulate new thinking and avoid clinical dogma. Among the many contributions that have followed since his death in 1981 at the age of 91 include those made by a small cadre of practitioners who are dually trained in both Polarity and western psychological counseling, who emphasize the use of PT for somato-emotional health (Korn, 1987, 1996, 2000; Kiewe, 1989; Gilchrist, 1993; Axt, 1996).

Research on PT

- Polarity has been evaluated in one randomized study to explore its effects on cancer fatigue and

Table 1 Principles and practice of polarity therapy.

Integrates bodywork, exercise, nutrition and self-awareness Energy and biofield balancing uses three depths of touch: Satvic, (light); Rajasic, (moderate); Tamasic, (deep) Hands are placed at two poles, energy flows between these contacts Right hand is positive, left hand negative Practitioner enters into focused, relaxed state of awareness; facilitates deep relaxation, energy flow, self-awareness Balance of the elements: ether, air, fire, water, earth Two dimensions of efficacy: release of energy blockages and flow of electromagnetic and wireless currents; and increased self awareness and appropriate healing relationship with practitioner Principle of engagement: <i>practitioner heal thyself</i>
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health quality of life. This study found a statistically significant reduction in cancer-related fatigue in the Polarity treatment group compared to the controls (Roscoe et al., 2005).

- Axt (1996) conducted research on PT and cranial–sacral therapy for the treatment of autism and children with special developmental needs, with results suggesting functional improvement in behavior.
- In an unpublished hospital-based study undertaken with patients in the critical care unit, Clifford (1997) reports administering PT to 70 patients with a range of acute and chronic illnesses, 20 staff members and one physician to assess the degree of relaxation as a result of treatments. A feeling of peace, rest, or deep relaxation was noted in 194 sessions.
- Benford et al. (1999) undertook an experimental study of PT that showed statistically significant fluctuation in Gamma radiation during treatment, leading Benford to hypothesize that radiation hormesis might underlie one mechanism of action in PT.

Fields of action

Biofield/touch therapies like Polarity appear to facilitate response associated with a reduction in sympathetic activity (Rowlands, 1984; Cox and Hayes, 1999; Gehlhaart, 2000) by stimulating *vagal* response and improved circulatory, lymphatic, and immune response while regulating circadian rhythm and the primary respiratory mechanism (Sills, 2002). Biofield therapies result in a reduction in pain (Sansone and Schmitt, 2000), anxiety (Gagne and Toye, 1994) cancer-related fatigue (Roscoe et al., 2005), quality of life (Metz, 1992) depression (Rowlands, 1984; Field, 2000; Wardell and Engebretson, 2001) and improved energy (Lee et al., 2001) mood, and sleep (Smith et al., 1999).

PT has also been referred to as “meditative touch” (Korn, 1987) as it induces somatic empathy (Korn, 1987, 1996)—a state of consciousness that facilitates therapist–patient psychophysiological entrainment (Korn, 1996; Oschman, 2000) and a state of reverie associated with a predominance of *theta* brain waves (Korn, 1987, 1996; Green, 1990). Somatic empathy is also the substrate for dyadic state-specific research. (Tart, 1998) This heuristic method of inquiry engages dual consciousness or the observing self so that both therapist and client may observe and study phenomena from within the altered state engendered by the therapy.

Background on dementia family caregivers

There are 45 million family caregivers in the United States, 23% of whom report caring for a family member with dementia or Alzheimer’s. Caring for a patient with moderate to severe dementia creates conditions of chronic stress for the caregiver (Teel and Press, 1999; Czaja et al., 2000; Freeman, 2001). Caregivers experience a greater risk of depression, more illness days, more physician visits, increased fatigue and increased risk of mortality than non-caregivers (Schulz and Beach, 1999).

Caregivers have a diminished immune response (Vedhara et al., 1999) that may contribute to their increased incidence of acute illness or exacerbation of preexisting illness, resulting in higher rates of primary care physician utilization (Schulz and Beach, 1999). The dynamic of caregiver stress and burden results in a reciprocal decrement in the quality of life for the patient and often leads to the institutionalization of the patient (George and Gwyther, 1986). Institutionalization results in a more substantial economic burden on the patient’s family and to society. Elder care providers in the study region reflect agreement with other long-term care professionals when they suggest that quality of life for patients is based on their ability to remain in the home. Yet even upon institutionalization, the caregiver most often remains essential to the care of the patient, and even as certain stressors are obviated by departure from the home, the caregiver continues to experience an objective burden (Aneshensel, 1995; Whitlach and Feinberg, 1995; Naleppa, 1996; Levesque et al., 1999) that survives as long as the loved one. The physical and emotional demands on the caregiver are paralleled by the on-going experience of loss of affiliative, shared activities between the caregiver and patient (Lynch-Sauer, 1990; Bradley and Cafferty, 2001). As dementia progresses, the patient loses the cognitive capacities to communicate their needs and feelings, which limits interpersonal communication between the caregiver and patient. The caregiver of a family member with dementia patient experiences “living loss”, during which a primary or important object of attachment disappears, even as s/he remains alive (Doernberg, 1986). Attachment has been defined as: ‘a relationship that develops between two or more organisms as their behavioral and physiological systems become attuned to each other’ (Field, 1985, p. 415). The capacity to provide psychological and physical safety is called psychobiological attunement (Field, 1985) or affect synchrony (Reite and Capitanio,

1985). The ongoing loss and threat of separation hold profound psychophysiological and spiritual implications for the caregiver (Acton and Miller, 1996; Acton, 1997). In addition to the emotional, physical, and financial burdens of dementia care, the loss of interpersonal, tactile reciprocity between the patient and the caregiver is seldom addressed by conventional interventions. Touch is the original, pre-verbal language that mediates the psychobiological template of attachment throughout the life cycle (Korn, 1996) and may provide a method of communicating that is especially attuned to the needs of the dementia patient and caregiver.

Public health and biofield/touch therapies

There are over 80,000 certified massage therapist and body workers in the USA and over 30,000 nurses practicing some form of touch therapy. There are over 1200 members of the American Polarity Therapy Association (APTA), and numerous PT training programs within technical schools, community colleges and medical schools and tens of thousands of others who practice PT and other biofield/touch therapies under other licensures and certifications. With the growth of CAM education, there is a substantial growth of biofield/touch therapy practitioners, yet with the exception of a few states funding mechanisms have as yet failed to provide payment avenues to ensure widespread delivery of services across the socioeconomic spectrum. In short, there is a large corps of people poised to enter into public health service to address the most pressing needs of elders and their caregivers. One of the goals of this research is to provide evidence that changes public policy in support of the delivery of biofield/touch therapies as a component of public health strategies.

American Indian family dementia caregivers

American Indian tribes number more than 690 (recognized and unrecognized) heterogeneous nations and peoples. American Indian caregivers and elders often attain elder status by their fourth or fifth decade in contrast to non-Indians (Jervis and Manson, 2002) and increasingly many caregivers of elders are in their second and third decade. While constituting a small proportion of the caregiver elderly, between 1980 and 1990 the aging American Indian population grew by 52% (Services, 1997), an increase of 35% over the total older population. The expectation is that the number of Indian elderly

will reach 700,000 (twice as many women as men) by the year 2050 (Jervis and Manson, 2002). Epidemiological data on dementia and caregivers in Indian communities are sparse and among Northwest Indian communities research data and delivery of long-term care support services is either non-existent or at a nascent stage. While research among non-Indians focuses generally on individual or family caregiver burden, caregiving among American Indians may pose a greater strain on the community as a whole, rather than just the individual caregiver. American Indian caregivers experience similar challenges as non-Indians: the competing demands of family and work, distance and relocation, and lack of resources required for providing care (Services, 1997). Barriers such as lower priority service, little appreciation for local needs, and excessive regulations exacerbate these problems. Prejudice and discrimination are the most frequently cited service barriers for primary health care (Services, 1997). During the preliminary focus groups to design the study, one elder, a former tribal chairwoman, spoke of her frustration in trying to obtain services for her own family in need saying: *"I would spend all day filling out paperwork, for what? It never came to anything?"*

Caregiver intervention research

Caregiver interventions have focused on helping the caregiver cope with the multi-faceted challenges of caring for someone who may be incontinent, aggressive and unable to eat unassisted during the day and awake, confused and ambulatory in the middle of the night as a result of the disease. A variety of caregiver interventions to reduce stress and enhance coping including psycho-educational, pharmacological therapies, behavioral therapies, and technology-based communications have been studied in non-Indian populations producing conflicting results. Some interventions reduce caregiver psychological morbidity and depression, in particular when they are individualized, intensive and delivered at home (Schulz, 2000; Gitlin et al., 2001). Results from studies of respite care (the delivery of "relief" in the form of another provider or a group day care experience) suggest that respite can be useful to relieve caregiver stress and improve mood (Conlin et al., 1992). Lack of respite care has been identified as one factor contributing to institutionalization (Gaugler et al., 2005). Some studies suggested only modest effects from respite care with the effects linked to receipt of adequate amounts of support. (Zarit et al., 1999;

Strang and Haughey, 1999) or find that efficacy depends upon multidimensional factors such as expectation, meaning, and number of hours provided (Strang and Haughey, 1999). Other research has focused on teaching caregiver skills to manage behavioral problems.

Formal respite opportunities are rare or rarely used in Indian communities and the availability of formal respite is nascent. There is also significant resistance to respite among many people (regardless of cultural heritage) who state they prefer their privacy and thus decline the offer to have a helper or stranger or even another family member in the home to provide assistance to their family. This reticence may be more pronounced in Indian communities where privacy in response to social service agencies remains strong, and where the cultural imperative is toward the acceptance of responsibility for elder care.

In this study respite care was chosen as the control for two reasons: (a) it is a well-studied standard of care intervention to which we could compare PT and (b) new federally funded caregiver programs were introduced to local tribes and emphasized the delivery of respite care. However as it turned out "respite" or taking time off was a challenging concept to embrace as many participants would say during screening: *"I don't need the help, my mother does!"* This initial conceptual obstacle collided with the practical challenge for caregivers to undertake a rest activity when the primary stressor is indeed the lack of time resulting from multiple responsibilities.

Cultural isomorphism of PT

The feasibility of the study was dependent upon the acceptance of PT as a modality congruent with the target population's health-seeking constructs. The historical focus of American Indian traditional medicine practitioners is on the restoration of balance and alignment with harmonious forces. American Indian elders and their apprentices on, near and distant from Indian reservations continue to practice traditional systems of medicine including healing with touch. In a Tribal Elders Survey conducted in 1992 with elders from eight tribes throughout the United States 35 percent reported using traditional medicine, either by itself (9 percent) or in combination with traditional and conventional medicine (26 percent) (Services, 1997). There is a significant practice of traditional medicine among elders in the Pacific Northwest; it varies in use and application, and a substantial proportion of it remains secret or is derived from

syncretic spiritual practices integrating indigenous traditions with post-colonial religions (Jilek, 1981). Several of the syncretic religions prominent in the Northwest, such as the Shakers, Native American Church and the more traditional Smokehouse, Longhouse, Dreamer and Winter Spirit Dance ways of living include methods of biofield/touch therapy healing. Biofield/touch therapies are a culturally congruent approach for tribal peoples of the Pacific Northwest, having a history of using touch and massage therapies as a traditional form of healing. There is also a small but growing use of CAM services such as Polarity, massage, and Reiki, on and off reservations, with some reservation-based clinics incorporating the use of various forms of bodywork. Yet there is also a powerful reticence, especially among elders (even among themselves or between tribal members) to speak freely of their practices due in large part to their personal experience in boarding schools or in society-at-large where cultural practices were systematically suppressed until recently and during a long period from the late 19th century when the US government imposed legal prohibitions against many cultural and healing rituals (White, 1998; Jonaitis, 1991). Such practices were frequently punished by imprisonment and often with hanging. For these many reasons; the use of touch for healing among some tribal members, the intergenerational memory of touch associated with traditional methods of healing, and a growing acceptance of massage and complementary bodywork therapies provided by tribal clinics or HMOs, that PT appeared to be an acceptable modality to explore with a Salish and Non-Salish urban and rural population (Table 2).

Study hypotheses

This study was designed to address whether PT can reduce stress, depression, and anxiety, and improve the quality of life for caregivers of dementia patients. As an exploratory study, data were also collected on the feasibility of recruitment, the utility and acceptability of the measures and the safety of the protocol.

We proceeded from three hypotheses: that caregivers receiving PT would experience reduced levels of stress, as compared to the control subjects. Stress levels were measured by indices of adrenal stress response (24 h salivary cortisol, DHEA, Circadian rhythm), 24 h heart rate variability (HRV) and the perceived stress scale (PSS). The second hypothesis was that caregivers receiving PT would experience a greater reduction of depression

Table 2 Polarity therapy 21-point protocol for dementia caregivers.

Inclusion criteria: ages 27–70, giving care at least 4 h daily to dementia family member, American Indian/Alaska Native
Exclusion criteria: no diabetic neuropathy, no substance abuse, no arrhythmias
Standardized 21-point and body contacts designed to reduce stress
Participants randomized to treatment or control group based on high/low stress levels
Assessments integrate psychological self-reports, biological and physiological measures at baseline, weeks 2, 5, and 9
Biological stress is measured by 24h circadian cortisol and DHEA rhythm
Physiological stress is measured by 24h heart rate variability
5 minutes pre and post treatment interview contributes to qualitative data
Bodywork treatment is 50 min duration each week for 8 weeks

Note: A detailed description of the points used in this protocol will be given in the next issue of JBMT.

and anxiety, as compared to the control group. These measures included the Penn State Worry Questionnaire, the Center for Epidemiological Studies-Depression scale, the Nijmegen scale which measures hyperventilation-anxiety syndrome and the Pittsburgh Sleep Quality Index. Hypothesis three was that caregivers receiving PT would experience an improvement in quality of life, which was measured by Health Status (SF-36) and the caregivers Quality of Life-Alzheimer's Dementia scale (Logsdon et al., 1998). The Stress-Related Growth Scale (Park, 2004) a thematic qualitative analysis of clinical narratives and a clinical exam by a registered nurse blind to group assignment at week 1 and week 9. The stress-related growth scale was used to complement the "negative stress" measures by collecting information on the positive effects of stress on personal growth.

Protocol design

The research team undertook focus group discussions with key informants on and off reservations and among dementia caregiver professionals to collect preparatory information about the perceived problems of caregivers and the potential interest in this study. A tribal consultative group constituted for the study advised about the proposed polarity protocol, measures, the language used to convey the nature and purpose of the intervention and to assist in the process of recruitment.

The use of the term "subject" is pejorative in some research circles and is amplified as a concern among minority populations, especially American Indians, many of whom have experienced or observed "helicopter research" Oberley and Macedo (2004, p. 260) state: 'Helicopter research occurs when researchers swoop in, gather data, and

leave. Helicopter researchers build no capacity recommend no change and invest no funding. They leave behind a community's distrust and regret.' There has been significant research trauma in Indian country and attention to language and meaning (substituting the word participant for subject) and active inclusion in decision making regarding all elements of the project facilitated effective partnerships. A tribal liaison was identified to provide support via bi-directional communication between the research team and the tribal communities and to provide periodic reports to tribal councils and community groups.

The inclusion/exclusion criteria were adapted from the study, *Resources for Enhancing Alzheimer's Caregiver Health* (REACH) criteria, a multi-site study of caregivers and modified to address some of the measures. For example, heart rate variability measures autonomic nervous system function; however, it does not change as a physiological value after the age of 65 or 70; likewise, individuals with diabetic neuropathy were excluded as their HRV is negatively affected. These two exclusions reduced the potential pool for recruitment. The inclusion/exclusion criteria included: The caregiver is between the age of 27 and 70, has been in the caregiver role for at least six months, provides at least four hours of supervision or direct assistance daily, there would be no change in psychoactive medication during the study period, does not have condition associated with severe disability or death and is not participating in any other caregiver intervention study. Exclusion criteria included, no acute inflammation or infection, deep vein thrombosis, cellulitis of the feet or legs, no surgical emergency or psychoses, no conditions that prohibit subject from lying in a supine position, no substance use disorder, arrhythmias, heart failure, Pacemaker devices, or diabetic neuropathy.

The design of the standardized PT (and the study methods in general) had to include three major qualities:

Cultural congruence

The protocol had to be culturally acceptable to a spiritually, socially, economically, and tribally heterogeneous population of Northwest American Indian caregivers. This includes addressing the needs of people who may never have experienced biofield/touch therapies, or for whom religion, belief system or personal or social traumatic history might preclude acceptance and study adherence. Because many principles of polarity therapy are derived from Ayurveda and Hindu imagery, the team eliminated any religious or imaginal references that might cause offense. The decision about protocol development included additional components that were respectful of the diversity of local tribal traditions. For example, treatment would involve wearing light cotton clothes rather than be without clothes, would not involve touching potentially sensitive anatomical areas, such as contact on the coccyx or pubic bone or near the breasts, as touching these areas would not be acceptable for modest individuals. The content and process of polarity therapy is not well known, even among many bodywork professionals, and words such as energy, bodywork, massage, and healing all have different meanings in the explanatory models of diverse tribal (and non-tribal) populations. To explain polarity, we used a variety of words and concepts to explain the principles and methods involved, and tailored language and demonstrations to address the specific needs and reference points of our participants.

Broad spectrum efficacy

The primary aims of the specific protocol are to reduce stress and improve health (sleep, depression, anxiety) and the quality of life among caregivers of people with dementia. Thus, the protocol had to, theoretically, reduce stress *in almost anyone*, and maximize the physical, mental, emotional, and spiritual aspects of the therapy. This required that the design at baseline should facilitate the induction of parasympathetic dominance and optimally, allow for the potential for a deep reverie, which might result in creative (hypnagogic) imagery, and spiritual phenomena. The PT developed was designed to maximize efficacy in almost anyone and was informed by the primary author's 30 years of clinical experience

with Polarity. This involved identifying points, holds, and manipulations that could be considered a core set of techniques. It was designed to maximize parasympathetic induction and energy flow, and include a variety of hand placements throughout the whole body, employ a range of techniques, ranging from light to moderate depth of touch for pressure points, rocking, and manipulation of soft tissue and would be considered minimally invasive by a population known for modesty. The design of the protocol included identifying the attribution of qualities associated with the points and manipulations from a perspective of both esoteric and allopathic anatomy and physiology alike (see 21 point tables provided in next issue of JBMT). By identifying the names of energetic anatomical and structural point locations from several culturally determined disciplines we could also understand better the "language" and meaning of the taxonomies of those disciplines. This approach may in the future inform our understanding of mechanisms of action.

Control group acceptability

Randomized controlled trials require a control group that allows for comparison between interventions. During the initial stages of the study we designed a simple respite provision in which alternative care coverage would be provided for the care recipient while the caregiver chose to leave the home for three hours and undertake any stress reduction activity she or he wished. However without a choice of an explicit activity this approach to respite proved to be unacceptable to those randomized into the control group and this in turn challenged adherence to the study. As a result, early on respite was "enhanced" by providing a "choice" of relaxation activities that were not touch related. This fulfilled the option to "choose" how time was spent away from caring for their family member and also responded to the need to be provided "something" that felt equivalent to the polarity treatment. The combination of respite care that provided time away from the family member and included a relaxation opportunity of their choosing (yoga, retreat, music therapy) provided an "equivalent" enhanced respite intervention that emphasized time spent away, "choice" and the relaxation itself. Hence, we would not be comparing to the specific type of respite, but to an individualized, self-chosen approach to stress reduction. The controls received the same "time away" as did the intervention group and the same testing procedures including a

pre- and post-activity qualitative interview structured like the qualitative interviews of the intervention group.

Therapist training

A polarity practitioner is trained in theories and principles as well as numerous protocols and the therapist is encouraged to integrate the needs of the client and the presenting complaints or requests with a sharpened intuitive process that is fueled by observation and understanding the processes of change. However, in this study, the protocol and process was pre-defined, providing eight 50-min sessions of 21 specific points and manipulations, conducted over a period of 8 weeks. A detailed therapist manual was designed to teach the PT and to ensure that all verbal interactions were standardized from the start to finish of each session. The protocol required training the practitioners so their palpation and energy-balancing skills were sufficient and that their interpersonal skills emphasized receptivity rather than directivity. The practitioners were trained to adhere to a set protocol of manipulations, a behavior that as a general rule is intrinsically opposite to a polarity practitioner's normal mode of practice. The PI trained all practitioners and their clinical work was validated for point location, sensitivity of depth of touch, and energy flow. Following group training in the protocol (most of the points and manipulations were generally known to the practitioners) individual practitioners were required to log 10 sessions (including with the other trainees) of the protocol and request a "graduation" session with the PI who conducted a final training session that included "role play" for adherence to language and communication as well as the treatment itself. The therapist "quality" validation process included a "supervisory component" and because senior bodywork practitioners were chosen, training proved to be rapid. Each point has an ideal depth of pressure that along with individual idiosyncrasies, forms a matrix of pressure that is further informed by individual tolerance to pain and sensitivity to pleasure; pressure that too light or too deep can miss the mark that optimizes energy flow and self-awareness. Indeed the quality of the touch itself is the conduit for somatic empathy. PT was conceived for this protocol as a "quiet" type of bodywork where, like the experience of meditation, the phenomenology associated with intensified introspective self-awareness becomes louder as the reciprocity of sensation (for example through movement or pressure) between the dyad becomes quieter.

The natural process of PT encourages discussion between therapist and client before and after a session. This 10-min interview contributed to the content of the qualitative data for both treatment and control and was collected in a manner similar to the process used within the natural clinical setting. The 10-min limit was challenging from a cultural perspective (it is rude to cut off or set limits on discussion among many cultural groups including Northwest Indians) yet was important in order to reduce the potential confounding role of verbal exchange as a major element of efficacy. These methodological choices highlight the paradox inherent in studying a "healing process" where individual needs and variations in the healing dynamic of the clinical setting are artificially limited by the research design seeking standardization.

Measures and evaluation process

This study was designed to provide an integrative approach to measuring clinical changes in response to PT and to capture effects associated with physical, mental, emotional, and spiritual health. The criteria for measures included that they must be (a) as non-invasive as possible, (b) culturally acceptable and sensitive to the study population, (c) provide meaningful information to the participant at the end of their participation in the study, and (d) represent a spectrum of quantitative and qualitative measures that included psychological, physiological, and biological indices. Very few standardized measures have been used with American Indian populations and even fewer, among tribes in the Pacific Northwest. We chose measures that either had been found valid and reliable (Manson et al., 1990) or reviewed proposed measures with the tribal advisory committee.

Cultural validity of measures

Studies using measures tested on predominantly Euro-American subjects require the evaluation of the cultural validity for use with the American Indian population. The participant population was predominantly Salish, and also included a significantly diverse sample of Indians from many tribes who have settled in the Pacific Northwest. The Salish peoples have substantial exposure to western medicine and have been subject to varying degrees to European acculturation dating back to intensive colonization in the 19th century (Jilek, 1974; Shore and Manson, 1981).

The psychological self-reports included the PSS, the Penn State Worry Questionnaire, the Center for Epidemiological Studies Depression Scale (CES-D), the Pittsburgh Sleep Quality Index, The Health Status Questionnaire (HSQ), the caregivers quality of life—Alzheimers caregivers (Logsdon et al., 1998) and Stress-Related Growth Scale (Park and Fenster, 2004). Physiological measure included 24 h HRV to measure autonomic stress and 24 h cortisol-DHEA circadian rhythm analysis to measure the biological stress response. To our knowledge there have been no studies using either 24 h HRV or 24 h cortisol as measures of stress in American Indian populations. A medical exam conducted by a physician or nurse blinded to group assignment collected basic functional parameters of blood pressure, heart rate, co-morbid conditions, and pharmaceutical and herbal medicine use. We also included questions about trauma history because of the effects of historical and intergenerational trauma on communities and individuals and the chronic effects of stress on the mind/body. We also included the Nijmegen scale, an indicator of hyperventilation syndrome (Chaitow et al., 2002). Because hyperventilation is closely related to anxiety we wanted to assess this affective state via the somatic lens hypothesizing that the inclusion of diaphragmatic points in the protocol might be especially effective at addressing this form of distress.

Phenomenological responses such as spiritual experiences and imagery often occur in response to PT however direct questions about these experiences could be considered intrusive in this population. Hence, open-ended questions about one's experience provided an opportunity to explore these self-reflective moments unobtrusively. These qualitative data were collected immediately before and after the treatment sessions using five questions similar to those used in a regular clinical setting, such as: "Please tell me how you feel" and "Is there anything about your experience you wish to share with me". This provided an opportunity for participants to give voice to their experience and to provide information about the process of making meaning that complements self-reports and bio/physiological data thus allowing for data validation across analytic methods.

Concluding discussion

There are numerous considerations in the design of a biofield/touch therapy clinical research study. The PT protocol was standardized for research with

American Indians of the Pacific northwest in order to: bridge some of the methodological challenges inherent in using the methods of an RCT, to address culture-specific requirements for protocol acceptability and to maximize efficacy while addressing the conceptual conflicts between standardization and the intuition process inherent in biofield/touch therapies. While Dr. Stone never explicitly referred to the influence of American Indian practices on his work, he was an Osteopath and Chiropractor trained in the eclectic tradition of the early 20th century United States when settlers' *materia medica* continued to be profoundly influenced by American Indian healing traditions. Whatever cultural influences may have been in effect, Polarity therapy is a modern CAM modality with links to universal indigenous cultural memories and proved to be acceptable to those recruited. Out of 89 people screened for participation, 44 were eligible based on inclusion/exclusion criteria. Two people declined to participate for 'religious' reasons. Of 42 subjects enrolled, four in the control group dropped out before the 9 weeks concluded, one participant dropped out of the treatment group due to a personal crisis. Paradoxically, the protocol itself was perhaps more acceptable to the participants than to the therapists, for whom sticking to a protocol proved counter-intuitive and challenging at the start. In future papers we will address both clinical outcomes and findings on recruitment and retention.

Note: The next issue of JBMT will carry an illustrated description of the main aspects of the protocol developed for treatment of dementia patient caregivers.

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