

Conceptualization and Evaluation of an Optimal Healing Environment for Chronic Low-Back Pain in Primary Care

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ABSTRACT

This paper describes what a primary care-based optimal healing environment (OHE) might look like for chronic low-back pain, and presents a research protocol to evaluate the effect of such an environment on a variety of important patient and clinician outcomes. Such an environment may be conceived of as having three major components: (1) the health care environment in which the primary care team works; (2) the cognitive, technical, clinical and organizational skills of the team, and; (3) the “healing” skills of the team members, particularly the primary care physician. A variety of study designs available for evaluating the effects of an OHE on patient and clinical outcomes are described. Decisions about study site and population, appropriate outcome measures, required sample sizes, methods of patient recruitment, treatment protocol and analytic issues would need to be tailored to the specific requirements of the study. Because many elements of an OHE designed for chronic back pain seen in primary care settings would also be relevant for the other 98% of primary care visits, it is preferable to design, implement and evaluate an OHE for primary care practice in general than for only a specific condition.

THE PUBLIC HEALTH AND MEDICAL CHALLENGE OF LOW-BACK PAIN

Low-back pain has represented a major public health problem in developed countries for many years.^{1,2} The large impact of back pain on Western societies results from its high prevalence (between 10% and 18% in the U.S. population with chronic low-back pain [CLBP]³) and high risk of becoming chronic, its impact on worker productivity, the high costs of disability payments and direct medical expenses, and the daily suffering of millions of persons afflicted with back pain. Although the magnitude of the problem of back pain has been recognized for almost two decades, there is little evidence that the situation has improved during this period.¹

One of the major barriers to improvement has been the continued inability of conventional medicine to effectively meet the needs of many persons with CLBP. An astonishing array of conventional treatments is available to treat CLBP. They range from aspirin to spinal fusion, but few of

these treatments have been proven effective.⁴ Studies have consistently found that psychosocial factors (e.g., depression, expectations that the treatment will be helpful, relationships with supervisor and coworkers) are stronger predictors of back pain treatment outcomes than are clinical factors (e.g., range of motion, pain severity, x-ray findings).¹ Physicians have not been successful at eliciting and responding to these psychosocial issues, in large part because of the way in which primary care services are organized and delivered. Thus, for many persons with CLBP, conventional medical practice has failed to provide an optimal healing environment (OHE).

The limitations of conventional medical treatments for CLBP in conjunction with the increasing availability and insurance coverage of alternative forms of treatment (especially chiropractic, massage and acupuncture) over the past decade have resulted in substantial increases in the use of complementary and alternative medicine (CAM) therapies for back pain. Back pain is the number one condition for which Americans seek alternative care.⁵ It is the most com-

mon reason for visits to chiropractors, massage therapists, and acupuncturists.⁶ During 1997, 30% of Americans with back problems visited alternative practitioners for this condition.

Several studies have reported high levels of satisfaction with CAM care (as well as other types of nonphysician care) for back pain.⁷⁻¹¹ The effectiveness of CAM treatments for back pain is less clear. Spinal manipulation has been consistently found to have at least modest beneficial effects, although its benefits may be no greater than those of some conventional medical treatments.^{12,13} The only three published randomized controlled trials evaluating massage for back pain all found it beneficial for subacute and chronic back pain, but two of these trials were small.¹³ The generally poor quality and conflicting findings of the studies evaluating acupuncture make it impossible to judge its value for treating back pain.¹³ Thus, the evidence to date suggests that CAM treatments are more satisfying, and at least as effective as conventional treatments for treating back pain. However, the cost effectiveness of these CAM treatments remains unknown.

The reasons for the higher satisfaction and possibly superior outcomes associated with CAM care for back pain are unclear. Although the evidence is still limited, there appear to be a number of key elements that are important to meeting the needs of persons with CLBP. These include provision by the practitioner of a credible physical examination (which requires touching the patient), patiently listening to the patient's major concerns (even though they may not initially seem relevant to the back pain), providing the patient with an adequate explanation of the cause of their problem (even if it is not known with certainty), legitimizing the patient's problem, providing a variety of therapeutic options in a positive and constructive manner, communicating to the patient a sense of hope and partnership in resolving the problem no matter how long it may take and scheduling follow-up contact to ensure that progress is being made.^{1,8,14-17} Mastery of these healing skills will play a central role in the OHE for CLBP described below.

WHAT MIGHT A PRIMARY CARE-BASED OHE FOR CLBP LOOK LIKE?

An OHE for CLBP in primary care may be conceived of as having three major components: (1) the health care environment in which the primary care team works; (2) the cognitive, technical, clinical, and organizational skills of the team; and (3) the "healing" skills (and abilities) of the team members, particularly the primary care physician (PCP).

Health care environment

The physical attributes of the healing space in which the patient-provider encounter occurs (e.g., light, air, color, décor)

have been discussed elsewhere in this issue (pp. S-1-S-6). Additional aspects of the health care environment that may affect the healing experience involve access to health care. An OHE would logically include: easy and responsive access to requests for information or appointments to see the PCP (who is the leader of the primary care team and is assumed here to be the primary healer in this context), friendly staff and efficient procedures for checking in upon arrival at the doctor's office, timely access to services perceived as useful (through adequate insurance coverage and ready availability of services) and ensuring that the primary providers have adequate time to effectively address their patients' needs. However, the relationship between visit duration and quality of care is complex, and it may be that how the time is spent is a more important determinant of outcome than the actual duration.¹⁸

Cognitive, technical, clinical, and organizational skills of the PCP

In an OHE for CLBP, the PCP would understand the relevant literature regarding care of patients with CLBP so he/she could confidently and effectively address patients' questions about the cause, prognosis and treatment alternatives for their problem. One study found that patients of family physicians who were more confident of their abilities to manage low-back pain effectively were more satisfied with the information they received about their back problem than patients of less confident physicians.¹⁹ To rule out the "red flags" (e.g., tumors, infections, fractures, substance abuse), the PCP would elicit the relevant medical history including information about the effectiveness of the treatments the patient has used in the past for their back pain. The PCP would then conduct an appropriate physical examination, not only to identify possible red flags, but also to reassure the patient that their back has been adequately examined.²⁰ In addition, the PCP would attempt to identify "yellow flags" that are risk factors for chronicity (e.g., patient is applying for or receiving compensation, psychologic distress) because this information might influence clinical decisions.²¹

For the great majority of patients with CLBP lacking evidence of serious spinal pathology, the PCP would then determine if the patient has a clear preference for particular treatments. If there were no good reasons to deny the patient a preferred treatment, the physician would accommodate the patient's wishes, knowing that allowing the patient to receive the preferred treatment might enhance the likelihood that the treatment will be effective.²² However, there might be circumstances where providing patients with preferred treatments would be inadvisable or impossible. For example, there might be medical contraindications for a particular patient, the treatment might have substantial risks, the treatment might not be available or covered by the patient's health insurance, or there might be compelling evi-

dence that the treatment is not effective or cost effective. In such circumstances, the PCP would carefully and respectfully explain the reasons why the preferred treatment would be inadvisable or unavailable, and then offer alternatives that seem most compatible with the patient's beliefs about what would be helpful.

Given the paucity of clearly effective treatments for low-back pain, however, accommodating patients' preferences, where feasible, seems a reasonable strategy. The PCP would work with the patient to develop a specific treatment plan, and identify specific methods of jointly monitoring the success of the plan as it unfolds. The treatment plan might include:

- Physical treatments to break the cycle of chronic pain, at least temporarily (e.g., spinal manipulation, massage, acupuncture, physical therapy, specific exercise program);
- Strategies to increase body awareness and efficiencies of movement (e.g., Alexander technique, bodywork/massage education, yoga classes)
- Self-care strategies to maintain back health or enhance self-awareness and coping (e.g., exercise, relaxation, mindfulness training, yoga, stress reduction, psychotherapy, and writing therapy as described by Pennebaker²³)
- Recommendation of high-quality educational resources (e.g., books, videotapes, Web sites) to help the patient understand how to take appropriate advantage of social and family support without being a burden on family and friends.

The PCP would be familiar with the various treatment options and would provide the patient with the information and/or referrals necessary to facilitate the patient's access to the treatment selected. Thus, the PCP would initiate, facilitate, coordinate and integrate care provided by any other providers (both conventional and CAM) involved in the treatment plan. However, the PCP would also consistently encourage learning self-care strategies that can help the patient better cope with back pain as well as with other problems that might be caused or exacerbated by life's stresses.

The visit would conclude with the PCP and patient understanding and agreeing to the plans for follow-up contact (visit, phone, or email) to evaluate the patient's progress.

During this contact, the PCP and the patient might conclude that a different approach would offer more promise and that the treatment plan needed to be modified. This follow-up would provide another opportunity for the physician to reassure the patient that they have not reached a dead end in their search for relief of their back pain and that they have not been abandoned by their physician.

Healing skills of the PCP

As important as the more technical clinical aspects of the patient-physician encounter for the outcomes of care are the

healing skills that the PCP brings to the visit. Physicians' effectiveness as healers may well depend not only on the healing skills they have developed and continue to hone, but also on their current life circumstances (e.g., happiness with their job, family role, and financial status) and on their underlying personalities. For example, a recent study found that the physician behaviors most strongly associated with patient trust were caring and comfort, technical competency and communication.²⁴ An OHE should include only physicians who are capable of facilitating healing and ensuring that the fundamental physical and emotional needs of the physicians were being met. An unhappy, stressed, and pre-occupied physician is unlikely to be a very effective healer.^{25,26}

Physicians who are effective healers would likely be those who:

- Listen attentively and patiently to patients' descriptions of their concerns and understanding of their problems.
- Elicit information on the "life context" of the current back pain problem to understand both the physical and psychosocial reasons for the most recent flare-up better.
- Touch patients during examinations of the back to reassure them that their problem is being adequately evaluated and to establish a closer personal connection.
- Convey a sense of caring and empathy to their patients.
- Communicate appropriate reassurance and expectations for improvement so patients understand they do not have serious underlying disease and have reason for hope that their problems will improve.
- Validate patients' beliefs that there is a physiologic basis for their pain.
- Explain to patients that chronic back pain involves a complex interplay between the mind and the body (which are intricately connected) and help patients reframe their problem in this new context, thereby opening the door to a variety of new ways of resolving the problem.

RESEARCH PROTOCOL FOR EVALUATING OHE FOR CLBP

A research agenda investigating OHEs and CLBP would involve a number of steps. A variety of study designs are potentially appropriate, depending on the questions to be asked and the current state of knowledge. Thus, decisions about study site and population, appropriate outcome measures, required sample sizes, methods of patient recruitment, treatment protocol, and analytic issues would need to be tailored to the specific requirements of the study.

Basic study designs

There are three basic study designs appropriate for studying various aspects of OHEs designed to improve outcomes

of care for CLBP: qualitative studies, observational studies, and intervention studies. Qualitative studies are most appropriate for initial explorations of complex issues that are not well understood. These methods would be particularly appropriate for studies of the range of factors that patients and providers believe may catalyze or impede healing. Once a comprehensive “roadmap” of these potentially important factors has been identified, quantitative methods such as surveys can be used to examine the relationship among the factors, the relative importance of each factor and how the relative importance is related to characteristics of patients and providers. This type of research can lead to the development of tools for measuring the optimal-ness (or OHE-ness) of specific healing environments.

Once the important dimensions of an OHE have been identified and measures of OHE-ness have been developed, observational studies would be appropriate for evaluating relevant patient outcomes in different healthcare settings with varying levels of OHE-ness. Such studies would determine if settings with specific aspects of an OHE or with higher OHE-ness in fact have superior outcomes. In such studies, the full range of important outcomes include measures of the effect of treatment on outcomes of greatest concern to patients (e.g., social and physical functioning, pain), and future use and costs of health care for back pain. If the OHE includes techniques that may take several months to learn (e.g., stress reduction techniques, yoga), it is necessary to measure outcomes at least 6 to 12 months after initiation of treatment.

Because observational studies can only identify associations between aspects of OHE and outcomes of care and not causal relationships, intervention studies are necessary to truly understand the effect of OHE-ness on outcomes of care. Intervention studies permit comparison of the outcomes of care before and after implementation of an intervention designed to enhance the OHE-ness of a healthcare environment. Because other changes in the health care environment contemporaneous with the implementation of the OHE intervention could be responsible for any changes in outcomes, study designs that simultaneously measure changes in a comparable site that does not receive the intervention would make any positive findings easier to interpret. The ideal design would involve implementing the OHE intervention in a randomly selected half of several sites (e.g., practices) that were willing to participate. Such randomized controlled trials would provide the clearest evidence for (or against) the value of OHEs on outcomes of care.

Selection of clinical study settings

Settings that provide the best opportunities for studying OHEs for CLBP are worksite clinics and primary care clinics with varying degrees of OHE-ness. Worksite clinics have the advantage of focusing on a relatively constrained range of conditions, often emphasizing care for musculoskeletal

conditions, particularly back pain. This focus would facilitate the design, implementation, and adoption of OHE interventions directed at improving outcomes of care for CLBP. However, it is not clear how many worksite clinics would have the organizational commitment and culture necessary for successful implementation of a meaningful OHE program.

Possibly more promising settings for evaluating OHEs are the thousands of primary care clinics around the country that vary greatly in their “personalities,” organizational structures, and thus in their OHE-ness. For example, initial studies might identify samples of patients in primary care practices with CLBP and invite them to be interviewed about the aspects of their care that they believe either fostered or hindered resolution of their concerns (i.e., healing). Subsequent studies could examine the actual relationship between the presence or absence of these healing aspects of care and health care outcomes. Then a large number of practices could be randomized to receive or not receive an OHE-enhancing intervention. This would allow changes in patient outcomes to be compared in practices that did and did not receive the intervention.

Patient inclusion and exclusion criteria

Once a study design and research setting have been identified, decisions would need to be made about how to identify patients with CLBP, and which of them will be considered eligible for the study. CLBP is defined in terms of a specific symptom (pain in the lower back) and duration (chronic). A large number of diagnostic codes are compatible with a diagnosis of CLBP, but many of these codes do not specify the region of the back (e.g., backache; none otherwise specified [NOS]), and none indicate the chronicity of the problem.²⁷ There are several methods for identifying potential study participants with CLBP: (1) prospective identification of all persons visiting with CLBP during a specific time period, (2) retrospective review of large numbers of medical charts, or (3) a retrospective computer search of a database that stores information on diagnosis codes that physicians might use for patients with CLBP. This last method would only identify potential cases of CLBP, and would require a further step of reviewing medical charts or contacting patients to determine if the pain was in the lower back, and if it met the criteria for being chronic (usually defined as pain lasting at least 3 months).

Persons with back pain caused by tumors, infections, unstable fractures, or other specific diseases generally should be excluded from studies of mechanical back pain. Depending on the nature of the intervention, care will need to be taken to ensure that persons with special contraindications for specific treatments (e.g., heart pacemaker for acupuncture, eczema for massage, osteoporosis for high velocity spinal manipulation) are not referred for those treatments.

Outcome measures

Primary outcomes. A core set of outcome measures covering five domains (back-related function, pain, general health status, work disability, and patient satisfaction) has been recommended in a recent review of outcomes assessments for evaluating treatments of spinal disorders.²⁸ The outcomes of primary importance to patients with low-back pain are function and pain. Although physiologic or laboratory measures (e.g., range-of-motion measures, spinal fluid endorphin levels, or paraspinous muscle electromyography [EMG] activity) are attractive because of their apparent objectivity, these measures have little inherent value to patients, and it has been repeatedly demonstrated that they are only weakly related to pain symptoms or daily functioning in patients with low back pain.^{29–31} Because patients are primarily concerned with pain and functional ability, these outcomes should be measured directly, rather than with weak proxies.

The Roland-Morris Disability Questionnaire^{32,33} and the Oswestry Low Back Pain Questionnaire³⁴ are the two most popular instruments used by back pain researchers for measuring function. Both instruments have been found to be reliable, valid, and sensitive to clinical changes.²⁸ The Roland instrument is more appropriate for telephone administration and for patients with mild to moderate disability while the Oswestry questionnaire is more appropriate for patients with severe disability.³⁵

Pain is typically measured using an ordinal scale that assesses severity. However, because there are individuals who respond differently to a small amount or moderate amount of pain, a measure of the extent to which participants' lives are affected by whatever level of pain they felt is more relevant to measure than pain severity *per se*. An appealing alternative is use of a 0 to 10 scale of low-back pain "bothersomeness," where 0 represents "not at all bothersome" and 10 "extremely bothersome." This question has worked well in studies with both mailed and telephone interviews^{10,11,36} and appears to have substantial construct validity as it is highly correlated with measures of function and other outcome measures.³⁶ To ensure that patients respond to the question as intended, it is necessary to ask about pain intensity prior to asking about bothersomeness so respondents understand that a distinction is being made between how much pain they feel and how bothered they are by their pain. Visual analogue scales has often been used in pain research but cannot be administered over the phone.

Measures of the healing experience. An OHE for CLBP might benefit patients in ways that may or may not be captured by back pain-specific measures or by conventional general health status measures. Patients who feel listened to, understood and well informed may be more motivated to take increased responsibility for their overall health (e.g., through exercise, meditation training). There are a variety of aspects of the process (e.g., trust of provider, "connection" with provider) and outcomes (e.g., having felt under-

stood by the provider, feeling "balance" has been restored in one's life) of the healing encounter that can be measured, but no set of standardized and validated measures yet exists. This is an important area for further exploration. In addition, we suspect that patient self-efficacy may be an important intervening variable for the success of an OHE. Because patients are at different levels of readiness to take responsibility for their health, we think that asking questions to find out whether they are in the precontemplative, contemplative, action, or maintenance phase of the process may help explain some of the outcomes.³⁷

Costs and possible cost savings. Special efforts to create an OHE intervention will have a variety of costs associated with them (e.g., training time, lost revenues during transition period and possibly beyond). The important question is: are the ultimate benefits worth the initial investment and maintenance costs? Benefits can be measured in terms of the primary and secondary outcome measures described above as well as in terms of possible cost savings due to reductions in health services utilization resulting from the intervention (e.g., reductions in imaging studies, specialty consultations, surgery, medications).

Follow-up assessments. Because the costs of implementing an OHE will undoubtedly outweigh the benefits in the short-term, it is essential for evaluations of OHEs to have a long-term perspective, extending at least 1 to 3 years beyond their implementation. In addition, in a randomized design, it is critical that outcomes data are collected by individuals who are unaware of which patients received OHE care and which did not. Finally, to guarantee the study results are interpretable, adequate resources need to be devoted to ensuring high follow-up rates.

SAMPLE SIZE REQUIREMENTS

Complete grant proposals must always include estimates of the sample size(s) necessary to achieve a prespecified degree of precision. Thus, for example, studies estimating the rate of occurrence of a good outcome (e.g., restoration of function) would need to include enough patients to ensure that the estimate based on the study sample had a high probability of closely reflecting the true rate in the population of interest. Similarly, randomized controlled trials (RCTs) should be designed to include sample sizes that are large enough to be able to have a high likelihood of detecting a meaningful difference between the treatment groups, should such a difference in fact exist. Sample size requirements will depend on a variety of factors including the study design (e.g., randomization of practices versus randomization of patients within a practice), the outcome measure selected, the number of treatment groups being compared, and the size of the difference considered clinically meaningful.

RECRUITMENT

The major challenges of recruitment are to enlist the requisite numbers of participants as quickly as possible, and to ensure that the participants reflect the population of primary interest. Once the population of interest has been identified (e.g., persons receiving care from a specific primary care practice who have CLBP), and the inclusion and exclusion criteria have been determined (see above), potential participants need to be contacted to explain the study and to invite their participation. Depending on the circumstances, this can be done through placement of notices in the media or through direct contact with patients in a particular practice who appear eligible for the study. A person considering participation in a research study needs to be provided with a clearly written consent form that explains the purpose of the study and the potential risks and benefits. They also need to have the opportunity to have their questions about participating in the study answered.

TREATMENT PROTOCOL FOR DELIVERING OHE AND CONTROL TREATMENTS

Evaluations of an OHE must clearly and comprehensively describe both the OHE and the treatment(s) to which it is being compared. This information is essential for designing the OHE, for ensuring that both the OHE and control treatments are implemented as designed and for describing them when the results of the study are published.

Ideally, an OHE for CLBP would incorporate all of the relevant components included in the six dimensions of OHEs described in a report of the Samueli Institute. These components are: healing spaces, collaborative treatments, health promotion, healing relationships, wholeness and energy, intention/awareness (pp. S-1–S-6). However, the practical realities of conducting research in clinical settings (including costs, physical limitations, regulations, and organization–political issues) will likely limit which components of the OHE can be included in a particular setting. It is, therefore, important to design the OHE to include enough of the most critical components of an OHE to ensure that its benefits, if any, will be detected. Furthermore, the more expensive and impractical the OHE being evaluated, the less likely it will be found cost-effective and adopted in other settings even if it is proven effective.

One option for the choice of a control group in a randomized trial design is the usual care that the patient would have received in the absence of the study. Such a control group would answer the question: what effect does the addition of OHE elements to a practice have on patient outcomes and costs of care? The main limitation of a usual care control group is that study participants who agreed to participate in the study because they wanted the OHE intervention, but who were assigned to the control group may

feel disappointed, possibly resulting in poorer outcomes (e.g., lower satisfaction with care) and decreased follow-up rates. An alternative approach would be to randomize clinics or practice teams within clinics to the OHE intervention or control group. This would eliminate some of the problems noted, but would reduce the sample sizes available for analysis, since the clinic or practice team would be the unit of analysis.

Analysis plan

The analysis plan will follow directly from the study design. For example, observational studies will permit comparisons between existing groups (e.g., mean improvement in function in high OHE versus low OHE practices), or correlations between OHE-ness and outcomes of care. Randomized controlled trials will require multivariate statistical techniques (e.g., analysis of covariance). Standard statistical computer software is readily available for analyzing these types of data (e.g., SAS, STATA).

APPLICABILITY OF A CHRONIC BACK PAIN OHE TO OTHER HEALTH PROBLEMS

The OHE described above for CLBP as seen in primary care settings should apply equally well to other common nonspecific chronic musculoskeletal conditions (e.g., neck pain, headache, shoulder pain) that collectively comprise a substantial fraction of primary care practice. In fact, most of the OHE design, implementation and evaluation elements are directly applicable to chronic illness care in general, and many elements would also apply to acute and preventive care.

Creation of an OHE in primary care will only succeed with adequate support from a health care organization that is committed to exploring innovative ways of transforming health care. Once such an organization is found, the next major challenge would be to develop a “curriculum” that would fundamentally transform the members of the primary care team and the organizational structures within which they practice. To the extent possible, the curriculum should be at least guided by or preferably based on the relevant evidence that exists in the medical, psychological, organizational, business and other literatures. It is particularly important to provide clinicians with an evidence-based rationale for recommending or withholding specific treatments from their patients (e.g., massage, acupuncture, stress reduction courses).

Preparation for major change might be facilitated by training the entire clinical team in mindfulness and stress-reduction techniques at the beginning of the change process (e.g., the mindfulness-based stress-reduction course).³⁸ In addition to promoting a more open and thoughtful approach to the change process and opportunities for bonding among

team members, such training could provide physicians with a valuable coping skill for use in their own lives and with a profound understanding of the value of a tool that might benefit many of their patients.

Implementation of the "curriculum" might require removing the clinicians from their practices for a period of time (e.g., up to 1 day per week for 3 months), and exposing them to different ways of interacting with patients. This group process might be enhanced by participation of selected CAM practitioners who could model their unique and often more patient-friendly approaches to care. Furthermore, this would expose conventional clinicians to the skills that CAM practitioners have to offer, and would prepare the physicians for more informed and appropriate referrals to CAM practitioners within the context of the new OHE. To benefit from their new awareness of what CAM practitioners and other resources (e.g., stress reduction training, health clubs) can offer their patients, physicians would need the organizations in which they work to permit, support and facilitate such referral options.

Once an OHE has been designed and implemented in a primary care setting, a variety of measures are available for evaluating the effects of implementation of an OHE on both patients and providers. For example, changes in provider satisfaction and stress in their lives and jobs can be measured, as can physicians' perceptions of their ability to substantially help their patients. Measures of the impact on the primary team (e.g., job satisfaction, degree of collaboration) would also be useful. Measurement of effects on patients is more difficult because of the broad range of problems they present with. Nevertheless, there are many examples of measures that might be appropriate such as: (1) general health status scales such as the Short Form (SF)-36,³⁹ (2) common indicator diagnoses that have quality-related measures (e.g., hemoglobin A_{1c} for diabetes and blood pressure for hypertension), (3) measures of patient satisfaction with specific aspects of their care (e.g., information received, clinical competence of physician, physician caring, trust in physician), (4) days of work lost because of common respiratory or musculoskeletal conditions, (5) changes in health care utilization patterns (e.g., more referrals to self-care training opportunities and to appropriate CAM practitioners and fewer expensive tests, specialty referrals, hospitalizations). The ideal study design would involve before versus after comparisons between primary care practices randomized to receive or not receive the OHE intervention. Thus, each practice would serve as its own control while and before-after comparisons in the non-intervention practices would provide estimates of any concurrent changes that were unrelated to the intervention.

We believe that there are enlightened health care organizations that would be interested in partnering with philanthropic organizations to devise, implement and evaluate the development of optimal healing environments in primary care settings. Given the high levels of stress and dissatis-

faction now endemic in the physician community⁴⁰ and the deep chasm between what the American health care system provides and its full potential,⁴¹ forward-looking organizations are hungering for innovative solutions to making fundamental changes in medical practice. The challenge for these organizations is to meld their commitment to change with the skillful, sensitive, and scientifically rigorous development, implementation, and evaluation of a new environment that more fully realizes its potential for facilitating true healing.

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