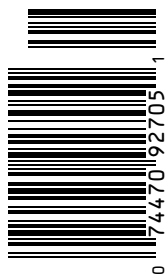


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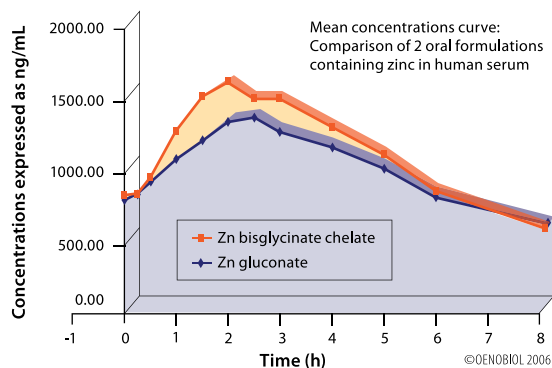
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LETTER TO THE EDITOR: Correction to 2008 Article

In reviewing the data set reported on in the 2008 article, “Effect of a high nutrient density diet on long-term weight loss: a retrospective chart review,” (Sarter B, Campbell TC, Fuhrman, J. *Altern Ther Health Med.* 2008;14(3):48-53), I have realized that the criteria for inclusion should have eliminated 7 rather than 6 subjects from the original raw data set of 62, and 2 out of the 20 who had a 2-year follow-up visit, due to the stated inclusion criteria of either no follow-up visit or not overweight at baseline. That gives an n of 55 rather than 56 at baseline and an n of 18 rather than 19 for those who had a 2-year follow-up visit. The software (StatXact, Cytel Inc, Cambridge, Massachusetts) that generated the original calculation of weight loss and other variables for the 2-year follow-up group (using the Friedman test) used the baseline weight of the entire group for comparison and reported an inaccurate mean weight loss of 53 lbs. This was not made clear in our discussion of the results. The actual mean weight loss of the group of 18 who had a 2-year follow-up visit was 37.6 lbs. Using Analyse-it + General 1.73 software (Analyse-it Software, Ltd, Leeds, United Kingdom) to run the Friedman, t-test, and Wilcoxon tests for comparing means of the baseline vs the 24-month weight of this group, the weight loss was found to be highly significant at $P < .001$ for all three tests. Therefore, the conclusions of the article remain as originally stated, being that the high nutrient density diet has the potential for leading to significant and sustained weight loss and reduction in cardiac risk.

Barbara Sarter, PhD, RN, FNP-C, DIHom

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Acute Effects of Acu-TENS on FEV₁ and Blood β -endorphin Level in Chronic Obstructive Pulmonary Disease

Shirley P. C. Ngai, PhD; Alice Y. M. Jones, PhD, FACP; Christina W. Y. Hui-Chan, PhD; Homer P. M. Yu, MSc; C. Q. He, MD

Background • Pharmacotherapy is the mainstay of dyspnea management in patients with chronic obstructive pulmonary disease (COPD). Undesirable side effects have led to the application of alternative treatment strategies such as acupuncture. Our previous study showed that transcutaneous electrical nerve stimulation over acupuncture points (Acu-TENS), a noninvasive modality, can reduce dyspnea symptoms in patients with COPD, but the underlying mechanism is unknown.

Primary Study Objective • This study investigated the effect of acu-TENS on forced expiratory volume in one second (FEV₁), dyspnea, and β -endorphin levels in patients with COPD.

Design • A double-blinded randomized controlled trial

Setting: Hospital outpatient clinic

Participants • Forty-four subjects diagnosed with COPD

Intervention • Participants were randomly assigned to receive either acu-TENS or placebo-TENS on Dingchuan (EX-B1) for 45 minutes.

Outcome Measures • FEV₁, forced vital capacity (FVC), dyspnea visual analogue score (DVAS), respiratory rate (RR), and blood β -endorphin levels were measured before and after therapeutic intervention.

Results • Our findings showed that the increase in FEV₁ was 24.2% greater in the acu-TENS group than the placebo group ($P < .0001$). The decrease in RR and DVAS was also more in the acu-TENS group by 14.2% ($P < .0001$) and 20.7% ($P = .006$), respectively. The postintervention increase in β -endorphin was significantly higher in the acu-TENS than the placebo group (18.3%) ($P = .027$). Furthermore, the percentage reduction in RR correlated with the increase in β -endorphin ($R = -0.477$, $P = .033$).

Conclusion • An improvement in FEV₁ and dyspnea score at the end of Acu-TENS treatment was associated with a concurrent increase in β -endorphin level in patients with COPD. (*Altern Ther Health Med.* 2011;17(5):8-13.)

Shirley P. C. Ngai, PhD, is a postdoctoral fellow and **Alice Y. M. Jones, PhD, FACP**, is a professor in the Department of Rehabilitation Sciences, The Hong Kong Polytechnic University, China. **Christina W. Y. Hui-Chan, PhD**, is a professor in the Department of Physical Therapy, University of Illinois, Chicago. **Homer P. M. Yu, MSc**, is a physiotherapist and **C. Q. He, MD**, is a professor in the Department of Rehabilitation Medicine, West China Hospital, Sichuan, China.

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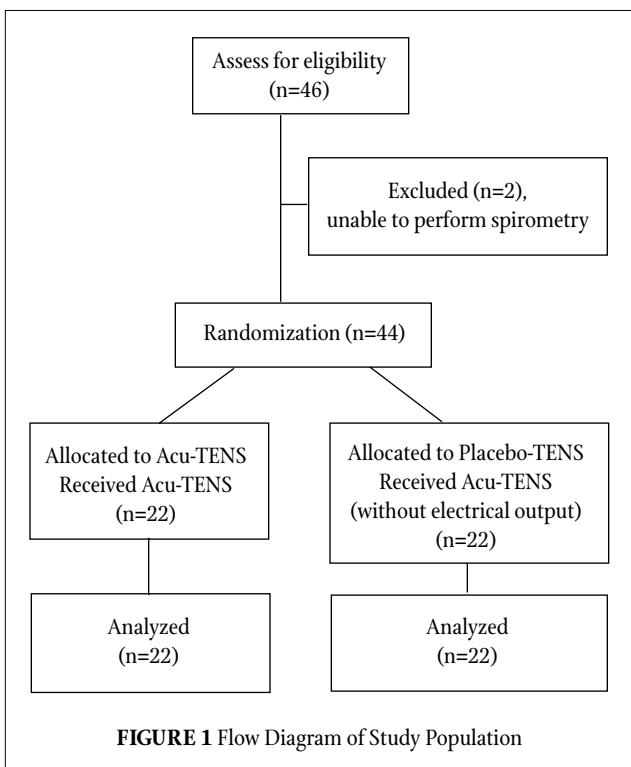
Dyspnea is a disabling symptom in patients with chronic obstructive pulmonary disease (COPD), which may account for physical inactivity leading to a poor quality of life (QOL).¹ In Western medicine, pharmacology remains the mainstay of symptomatic control in patients with COPD, and the aim of pulmonary rehabilitation is to improve patients' QOL.² In Chinese medicine, acupuncture has been used for thousands of years for health promotion and disease management. Its application is

thought to maintain a balance between yin and yang to promote the free flow of *qi* (energy).³ Acupuncture has been reported to reduce airway resistance and dyspnea score in patients with shortness of breath.^{4,5} In addition, it was found to improve the 6 minute-walk distance in patients with COPD.^{6,7} Acupuncture is invasive, however, and its application requires an experienced acupuncturist. In contrast, application of transcutaneous electrical nerve stimulation (TENS) is noninvasive. This study showed that applying TENS to acupuncture points (termed here acu-TENS) resulted in an improvement of forced expiratory volume in one second (FEV₁) and a reduction of dyspnea score in patients with COPD.⁸ We also demonstrated that acu-TENS reduced the decline of FEV₁ after exercise in participants with asthma.⁹

Acupuncture has been reported to induce the release of endorphin¹⁰ and to modulate inflammatory marker levels, including eosinophil counts and cytokines in patients with asthma.⁴ The mechanism underpinning the effect of acu-TENS has not yet been examined. This study set out to investigate whether the improvement of FEV₁ and reduction in dyspnea as a result of acu-TENS might be associated with a modulation of β -endorphin and possible inflammatory markers in patients with COPD.

MATERIALS AND METHODS

This study adopted a double-blind, randomized controlled design and was conducted in Sichuan, China. Ethics committee approvals were granted by The Hong Kong Polytechnic University and the West China Hospital, Sichuan, China, prior to the commencement of the study. Patients attending respiratory outpatient clinics at local hospitals in Sichuan were invited to participate in the study. Participants were included if they were aged 45 years or older and diagnosed clinically to have COPD as confirmed by spirometric lung function testing in accord with the diagnostic criteria established by the American Thoracic Society.¹¹ Participants who had consumed coffee, tea, or chocolate; received bronchodilators in the previous 8 hours of the measurement procedure¹²; were unable to perform spirometry testing; had difficulty communicating; or were allergic to aqueous ultrasound gel were excluded. The nature of the study was explained and written consent was obtained from all participants prior to data collection. Participants were also asked to complete a questionnaire on their medical, social, and family history. Participants meeting the inclusion criteria were randomized using a computer-generated sequence table (Random Allocation Software, version 1.0, Isfahan University of Medical Sciences, Iran) into either an acu-TENS or a placebo-TENS group. The sequence order was blinded to all involved personnel, including the patients, except for the investigator who applied the intervention. Venous blood samples were taken by a registered nurse, and all assessment and data recording were conducted by another investigator; both of them were blinded to the group allocation. Figure 1 shows the flow of the study population.



Experimental Procedures

On arrival, participants were asked to rest for 30 minutes in a sitting position to establish a steady cardiopulmonary state before recordings were made. Demographic data including age, gender, body mass index (BMI), medical history, exercise habits, and smoking history were recorded.

Following the recommendations of the American Thoracic Society,¹¹ forced vital capacity (FVC) and FEV₁ were measured using a spirometer (Pony, Cosmed, Italy) calibrated with a 3-liter syringe prior to data collection. Baseline respiratory rate (RR) was recorded. The degree of dyspnea was recorded using a 100-mm visual analogue scale (DVAS). Ten milliliters of venous blood were taken by a nurse from the cubital vein and separated into three tubes. Three milliliters of blood stored in ethylene diamine tetra acetic acid (EDTA) were sent for a differential white blood cell count. The remaining 7 milliliters of blood were divided between an EDTA tube and a lithium heparin gel tube. Samples were centrifuged and frozen until assayed. Using “sandwich” enzyme linked immunosorbent assay kits, levels of β -endorphin (Peninsula Laboratories, LLC, San Carlos, California) and interleukin-8 (IL-8), tumor necrosis factor- α (TNF- α), and C-reactive protein (CRP) (Invitrogen Corporation, Carlsbad, California) were measured by a nurse blinded to group allocation.

The acupuncture point Dingchuan (EX-B1), commonly used by acupuncturists for alleviating dyspnea,¹³ was identified bilaterally (Figure 2). This point is located at 0.5 cun lateral to the lower border of the seventh cervical vertebra. A *cun* is the traditional measurement unit for identifying an acupuncture point



FIGURE 2 Electrode Placement Over the Dingchuan (EX-B1) Acupuncture Points

and is equivalent to the distance between the medial ends of the creases of the interphalangeal joints of the subject's middle finger. The skin area over the acupuncture points was cleaned with an alcohol swab. Electrodes measuring 20 mm x 20 mm were placed over the acupuncture points and attached to a dual channel portable TENS unit (ITO 320; ITO Company Ltd; Tokyo, Japan). The stimulation frequency was adjusted to 2 Hz, with a pulse width of 200 μ s. Prior to data collection, the TENS unit settings were verified using a 100-MHz oscilloscope (MSO6014A; Agilent Technologies; Santa Clara, California).

Participants allocated to the acu-TENS group received TENS over the acupuncture points (EX-B1) for 45 minutes. Participants in the placebo-TENS group received identical electrode placements as the acu-TENS group, but electrical output from the TENS unit was disconnected inside the device despite an active display of the output indicator. Participants were informed that they might or might not feel any electrical stimulation depending on their sensitivity to the frequency applied. Blood samples and the aforementioned outcome measures were taken or recorded before and immediately after the cessation of the intervention.

Screening of patients for inclusion and exclusion criteria, identification of selected acupuncture points, and measurement of outcomes were conducted by a physiotherapist who was experienced with acupuncture. Application of acu-TENS or placebo-TENS was conducted by another physiotherapist. In other words and as mentioned above, the physiotherapist who recorded the outcome measures, the blood sampling nurse, and the participants were all blinded to group allocation.

Statistical Analysis

The sample size was determined from a pilot study of 10 participants using the change in the primary outcome measure FEV₁. To achieve a high effect size¹⁴ of 1.29, a power of 0.80 and an α value of 0.05, at least 11 participants were required per group. The demographic and baseline participant data including age, height, weight, BMI, FEV₁, FVC, percentage of predicted FEV₁ and FVC, room temperature, relative humidity, and immunological variables in the two groups were compared using independent *t*-tests. To facilitate clinical relevance and provide for intuitive comparison with previously published data, the percentage change from baseline in lung function, DVAS, β -endorphin, and immunological variables were calculated and the between-group effects were compared using univariate analysis of variance with adjustment of significant covariates, if needed. All data were analyzed using the statistical software (SPSS for Windows version 16; SPSS, Chicago, Illinois). A *P* value of less than .05 was considered statistically significant.

RESULTS

Forty-six patients were recruited for the study. Two patients were unable to follow the lung function test instructions and were excluded. The mean age of the remaining 44 participants (25 male, 19 female) was 69.1 \pm 1.6 years. Over half (52.3%) were ex-smokers, 40.9% had never smoked, and 6.8% were current

smokers. The demographic data for all participants are displayed in Table 1. Medications prescribed included aminophylline and were similar in both groups. None of the participants took medication within the 8 hours prior to data collection. No adverse effects associated with the study were reported.

TABLE 1 Demographic Data and Baseline Variables of the Two Groups*

| | Acu-TENS | Placebo-TENS | <i>P</i> value |
|--------------------------------|-----------------|-----------------|----------------|
| Age, y | 69.0 \pm 2.3 | 69.3 \pm 2.4 | .924 |
| Male (female), no. | 11 (11) | 14 (8) | .543 |
| Height, m | 1.53 \pm 0.01 | 1.56 \pm 0.02 | .240 |
| Weight, kg | 51.2 \pm 1.5 | 51.6 \pm 2.5 | .885 |
| BMI, kg/cm ² | 22.0 \pm 0.6 | 21.3 \pm 0.9 | .533 |
| Cun, cm | 1.9 \pm 0.0 | 1.9 \pm 0.0 | .742 |
| FEV ₁ , % predicted | 31.1 \pm 2.2 | 34.3 \pm 2.6 | .348 |
| FVC, % predicted | 46.4 \pm 12.8 | 49.7 \pm 10.5 | .355 |
| Duration of COPD, y | 14.9 \pm 1.7 | 15.3 \pm 2.4 | .890 |
| Smoking years, pack y | 18.0 \pm 4.7 | 14.4 \pm 3.6 | .539 |
| Smoking cessation, y | 5.7 \pm 2.0 | 5.6 \pm 2.2 | .959 |
| Room temperature, °C | 19.3 \pm 0.5 | 18.9 \pm 0.3 | .451 |
| Relative humidity, % | 58.7 \pm 1.2 | 59.7 \pm 1.0 | .533 |

*Data are mean \pm standard error of the mean.

Abbreviations: BMI = body mass index; FEV₁ = forced expiratory flow volume in one second; FVC = forced vital capacity.

Changes in Lung Function Indices

Our findings showed that FEV₁ increased by 19.6% (92 \pm 20 mL) (*P* < .001) after 45 minutes of acu-TENS but decreased by 4.7% (36 \pm 15 mL) (*P* = .026) in the placebo-TENS group, with a between-group difference of 24.2% (*P* < .0001) (Table 2). The peak expiratory flow rate (PEFR) increased by 14.5% (122 \pm 57 mL/s) (*P* = .044) in the acu-TENS group but decreased by 4.5% (74 \pm 40 mL/s) in the placebo-TENS group. The between-group difference was 19% (*P* = .007). While no significant within-group changes in FVC were noted in the acu-TENS group, a significant decrease in 4.7% (67 \pm 30 mL) in FVC was observed in the placebo-TENS group (*P* = .038), with a between-group difference of 10.2% (*P* = .047) (Table 2).

Respiratory Rate and Dyspnea Visual Analogue Score

The respiratory rate reduced significantly after acu-TENS intervention, and the reduction was 14.2% more in the acu-TENS group than the placebo-TENS group (*P* < .001) (Table 2). The DVAS reduced significantly after intervention in both groups: 62.8 \pm 4.5% in the acu-TENS group and 42.2 \pm 5.7% in the placebo-TENS group. Significantly, the reduction of dyspnea was far greater in the acu-TENS than the placebo-TENS group by 20.7% (*P* = .006) (Table 2).

Changes in β -endorphin, IL-8, CRP, TNF- α Levels and Inflammatory Cell-counts

There was a greater increase in the β -endorphin level by 18.3% (34.5 pg/mL) in the acu-TENS group than the placebo-TENS group (*P* = .027) (Figure 3). No pre- and postintervention differences were found in the inflammatory marker levels.

TABLE 2 Comparison of Physiological Variables at Pre- and Post-intervention*

| | Acu-TENS group Within-group comparison | | | Placebo-TENS group Within-group comparison | | | Acu-TENS and Placebo-TENS Between-group comparison | | |
|----------------------|---|-------------------|---------|---|-------------------|---------|---|------------------|---------|
| | Pre-intervention | Post-intervention | P value | Pre-intervention | Post-intervention | P value | % change difference | (95% CI) | P value |
| FEV ₁ , L | 0.57 ± 0.04 | 0.66 ± 0.04 | .000‡ | 0.66 ± 0.03 | 0.62 ± 0.03 | .026† | 24.2 | (13.8 to 34.7) | .000¶ |
| FVC, L | 1.09 ± 0.09 | 1.09 ± 0.06 | .968 | 1.24 ± 0.06 | 1.17 ± 0.05 | .038† | 10.2 | (0.2 to 20.3) | .047¶ |
| PEFR, L/s | 1.15 ± 0.09 | 1.27 ± 0.10 | .044† | 1.42 ± 0.10 | 1.35 ± 0.11 | .076 | 19.0 | (5.6 to 32.4) | .007¶ |
| RR, breaths/min | 25.1 ± 0.8 | 20.3 ± 0.7 | .000‡ | 22.2 ± 0.7 | 21.8 ± 0.8 | .287 | -14.2§ | (-20.0 to -8.3)§ | .000¶ |
| DVAS, mm | 55.2 ± 0.3 | 20.8 ± 0.3 | .000‡ | 53.4 ± 0.3 | 31.0 ± 0.3 | .000‡ | -20.7 | (-35.1 to -6.1) | .006¶ |

*Data are mean ± standard error of the mean.

†Within-group difference at $P < .05$.

‡ $P < .01$.

§RR was a significant covariate ($P < .05$) with adjusted means and presented.

¶Between-group difference at $P < .05$.

Abbreviations: FEV₁ = forced expiratory flow volume in 1 s; FVC = forced vital capacity; PEFR = peak expiratory flow rate; RR = respiratory rate; DVAS = dyspnea visual analogue score; CI = confidence interval; % change difference = % change in acu-TENS group - % change in placebo group.

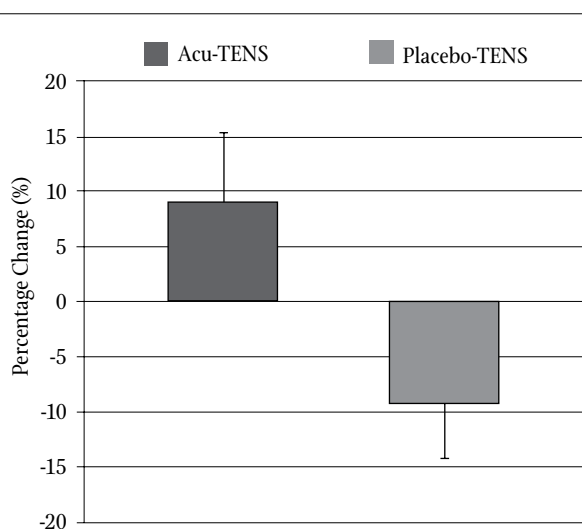


FIGURE 3 Percentage Change of β -endorphin Level After Intervention Protocols

Relationship Between β -endorphin Level and Physiological Variables

Pearson's correlation analysis demonstrated a negative relationship between respiratory rate and β -endorphin level in the acu-TENS group ($r = -0.477$, $P = .033$). No relationship between these two variables was apparent in the placebo-TENS group.

DISCUSSION

This is the first study to examine the immediate effect of acu-TENS on blood β -endorphin levels in patients with COPD. In accord with previously reported data,⁸ our findings demonstrated that 45 minutes of acu-TENS produced a significant improvement in FEV₁ and reduction in DVAS. Moreover this study also showed that these changes were accompanied by an increase in blood β -endorphin level. The magnitude of improvement in FEV₁ and DVAS in our subject cohort was 20% and 62%,

respectively, much higher than the 10% and 17% reported by Lau and Jones.⁸ Interestingly, the placebo-TENS group in this study also demonstrated a reduction in DVAS by as much as 42%, yet the change in the placebo-TENS group reported by Lau and Jones⁸ was insignificant. We postulate that these differences might be due to the fact that physiotherapy is not a profession known to the general public in China, thus it is possible that the mere fact that the participants were attended by a physiotherapist during the placebo intervention could have induced a significant comforting, relaxing, or distracting effect, which might have in turn reduced the subjective sensation of shortness of breath and thereby lowering DVAS. Dyspnea is a self-perceived experience of breathing discomfort and can occur in response to physiological, psychological, social, and environmental factors.¹⁵ An analogy could be found in self-reported analgesia. While treatment with TENS resulted in 48% of pain reduction, placebo stimulation could produce as much as 32% of pain relief.¹⁶

The difference in change in FEV₁ between this study and that of Lau and Jones⁸ could be further explained by a possible difference in disease severity between subject cohorts. Applying the GOLD classification,¹⁷ participants recruited to the current study belonged to stages III or IV while those in Lau and Jones's study⁸ belonged to stages I or II. If the effect of acupoint stimulation is to maintain body homeostasis, its effect may be less obvious in patients whose homeostasis is less disturbed. The level of β -endorphin was not measured in the Lau and Jones study, so any role of β -endorphin in the reported difference in effect between the two studies would be speculative. Responses to acu-TENS intervention in cohorts with different disease severity warrant further investigation.

The increase in absolute value of FEV₁ observed in this study was comparable to that attained in other studies. Suzuki and colleagues reported a 100-mL increase in FEV₁ after a 10-week acupuncture program.⁷ A 130-mL increase in FEV₁ was reported in patients with COPD after a single session of acu-TENS intervention.⁸ Increase in FEV₁ after an 8-week pulmonary

rehabilitation program was reported to be 120 mL,¹⁸ but the change could be as little as 20 mL.¹⁹ The increase in absolute value of FEV₁ in the acu-TENS group observed in this current study was only 92 mL, which is below the suggested clinical level of 200 mL for clinically significant bronchodilation.²⁰

However, the intention of this study was to investigate the role of acu-TENS as an adjunct modality in the management of patients with COPD and not to replace medication. A potent effect on bronchodilation was not expected from the application of a single session of acu-TENS.

Traditional Chinese Medicine often attributes a disturbance of the free flow of *qi* within the body to the cause of a disease. Stimulation of acupuncture points is thought to normalize health by maintaining the patency of *qi* pathways. It can be administered by needle acupuncture,^{5,21-23} acupressure,^{24,25} or nonpuncture electrical stimulation (acu-TENS).^{8,9} Based on Western pathophysiological principles, it is hypothesized that the improvement in respiratory function as a result of acupuncture stimulation is associated with alterations in airway resistance.^{21,26} The latter, in turn, could be a consequence of the release of opioids and modulation of the immune response.^{4,27}

TENS is a noninvasive modality originally designed for pain relief.²⁸ The working mechanism of TENS has been attributed to activation of the A α and β fibers.²⁹ Low-frequency TENS was reportedly associated with increased β -endorphin, endomorphine, and met-enkephalin levels^{10,30-32} through an action on μ - and δ -opioid receptors.^{33,34} Animal studies have shown that opioid-receptors in the medulla, where the respiratory rhythm-generating center (the pre-Böttinger complex) is located, are associated with respiratory depression when stimulated.³⁵ β -endorphin preferentially acts on μ -opioid receptors, which when stimulated can lead to a reduction in respiratory frequency.^{35,36} The current study showed that a raised β -endorphin level was correlated with a reduction of respiratory rate, suggesting that the improved dyspnea sensation could be associated with the increase in β -endorphin level found in our participants who received acu-TENS.

Participants in our acu-TENS group attained an improvement in FEV₁ and a reduction of dyspnea score, together with an increase in β -endorphin levels. In contrast, a decrease in β -endorphin level was found in the placebo-TENS group. Similar findings have been reported by Hughes and coworkers,³⁷ who compared the levels of β -endorphin after 30 minutes of high frequency–low intensity, low frequency–high intensity, and placebo TENS. They found that the β endorphin level increased in both TENS groups independent of the frequency of stimulation, but it decreased in the placebo-TENS group.

Acupuncture has been shown to reduce the level of blood inflammatory markers.^{4,27} We anticipated a possible reduction in differential white blood cell counts, TNF- α , CRP, and IL-8 in our participants after acu-TENS. However, this was not observed in the present study. The negative finding could be attributed to the fact that a single session of 45 minutes stimulation did not reach the treatment period required to induce the anticipated effects. Indeed,

previous reports demonstrating positive effects involved treatment protocols which lasted for several weeks.^{4,27} The effect of long-term acu-TENS on the immune system warrants further investigation.

CONCLUSION

This study showed that 45 minutes of acu-TENS produced a significant improvement in FEV₁, PEF_R, and a decrease in RR and DVAS. These changes were accompanied by an increase in the β -endorphin level. No significant changes in inflammatory marker levels were demonstrated with a single session of acu-TENS. The long-term effect of acu-TENS warrants further investigation.

Acknowledgments

This study was conducted just prior to the May 12, 2008, Sichuan earthquake. Many of these participants were in the most severely affected area. The authors are sincerely grateful to the patients for their participation in this study and hope that they were spared by the catastrophe.

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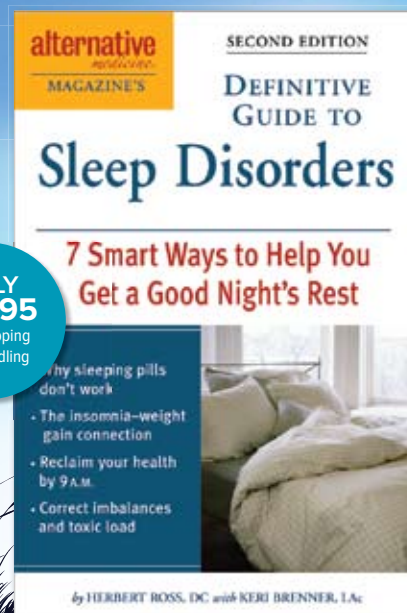
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Determinants of Meditation Practice Inventory: Development, Content Validation, and Initial Psychometric Testing

Anna-leila Williams, PhD, PA, MPH; Jane Dixon, PhD; Ruth McCorkle, PhD, FAAN; Peter H. Van Ness, PhD, MPH

Background • Meditation health benefits have been difficult to document, as many efficacy studies are marred by lack of statistical power secondary to small sample size and/or threats to validity from high attrition. To date, no published studies have examined barriers to meditation that are likely responsible for low enrollment and high attrition.

Objective • To develop an instrument to capture barriers to meditation use, namely, the Determinants of Meditation Practice Inventory (DMPI).

Design • A five-step, mixed-methods approach was used, including literature review, qualitative interviews, content validation, reliability testing, and construct validation.

Participants/Setting • Four distinct participant groups contributed. Four meditation teachers participated in qualitative interviews. Five expert panelists conducted the content validation. Ten nonmeditators participated in the pilot test. For reliability testing and construct validation, 150 cancer family caregivers participated.

Outcome Measures • Big Five Inventory (BFI) and Caregiver Reactions Assessment (CRA) were used to test convergent construct validity.

Results • The three content domains are perceptions and misconceptions, pragmatic concerns, and sociocultural beliefs. Initially, 53 items were generated. Three reviews by the expert panel concluded with a 22-item survey. After pilot testing, a 17-item survey was created. Data from 150 caregivers showed Cronbach's coefficient alpha of 0.87. The intraclass correlation for baseline and retest was 0.86 (confidence interval 0.82-0.90). BFI and CRA were significantly and positively correlated with DMPI.

Conclusion • Preliminary results indicate the DMPI is psychometrically sound. By identifying barriers to meditation, the DMPI will enable researchers to address the needs and concerns of the target population when designing recruitment and intervention procedures, potentially maximizing recruitment, minimizing attrition, and optimizing interpretation of results. (*Altern Ther Health Med.* 2011;17(5):16-23.)

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During the past several decades, meditation practices have been studied as potential clinical interventions for a host of ailments.¹ Recently, the Agency for Healthcare Research and Quality contracted a systematic review and synthesis of the evidence on the use of meditation as a therapeutic intervention.

In their publication, *Meditation Practices for Health: State of the Research*,² they report on 813 unique meditation studies and state that many of these studies had “significant threats to validity in every major category of quality measured, regardless of study design.” Among the factors undermining validity was high attrition. In addition, many small studies did not demonstrate efficacy of meditation; however, when a study is underpowered secondary to inadequate sample size, lack of efficacy is impossible to determine.

National surveys estimate that less than 10% of the US adult population practices meditation.^{3,4} With only a small segment of the population engaged with meditation, there may be unappreciated barriers to practice that are responsible for the low enrollment and high attrition rates that plague meditation studies. To date, there are no published studies examining barriers to meditation, and no valid and reliable instrument exists that ventures to capture the determinants of meditation use.

The purpose of our study was to develop an instrument to measure barriers to meditation: the Determinants of Meditation Practice Inventory (DMPI). We developed the DMPI using a

standardized and replicable procedure of content validation with an expert panel (EP) and community-based sample. Psychometric testing included evaluation of internal consistency, estimation of construct validity, and test-retest reliability testing with a general population sample (N = 150).

METHODS

DMPI Development and Content Validation

Development and content validation followed a five-step standardized process:^{5,6} (1) delineation of content domains, (2) development of operational definitions of the domains, (3) item generation, (4) content validation by an expert panel, and (5) content validation and pilot testing with a community-based sample.

Step One: Delineating Content Domains. A triangulated approach was used to delineate the content domains; it entailed a focused literature review followed by qualitative individual interviews with meditation teachers.

It is customary when establishing content domains to rely on qualitative studies of the topic;⁷ however, our literature search revealed no identifiable published qualitative studies of barriers to meditation practice. Subsequently, English translations of the ancient texts the Baghavad Gita⁸ and the Yoga Sutras⁹ were reviewed, as were modern-day anecdotal, unreferenced texts about meditation practice.^{10,11} The barriers identified during the literature review included affinity for diversion; discomfort with being with oneself and with silence; work and family responsibilities; lack of support from family, friends, community, and social leaders; lack of knowledge about meditation; and lack of perceived personal need for meditation.

Qualitative individual interviews were conducted with four meditation teachers representing Vipassana, Zen, and Shambhala lineages. Open-ended questions were asked to elicit the attitudes, beliefs, and cultural contexts the teachers observed as influencing the decision to practice meditation. Data saturation was achieved. The qualitative interviews independently confirmed barriers identified by the literature. Interview notes, analyzed using content and thematic analysis, yielded three content domains: (1) perceptions and misconceptions, (2) pragmatic concerns, and (3) sociocultural beliefs.

Step Two: Developing Operational Definitions of the Domains. Using data from the literature review and qualitative interviews, two of the authors (AW and JD) developed operational definitions for the domains. The domains and definitions were then sent to the EP (described in detail in Step Four: Content Validation) with the instructions to comment on their appropriateness and to identify any overlooked concepts. The EP confirmed the domains and definitions, which are the following:

Perceptions and Misconceptions. Items address the respondent's understanding of the practice of meditation. Included are items pertaining to perceived physical, mental, and emotional constraints necessary to practice, as well as presumed outcomes of the practice.

Pragmatic Concerns. Items address the respondent's practical and technical barriers to practicing meditation. Included are

items pertaining to the environment, time, priorities, and intrinsic and extrinsic motivation.

Sociocultural Beliefs. Items address the respondent's social and cultural barriers to practicing meditation. Included are items pertaining to religious beliefs, family and friend support, and beliefs about appropriate interpersonal behaviors and the supernatural.

Step Three: Initial Item Generation. Based on the three content domains, 53 items were generated for the DMPI.

Step Four: Content Validation by an Expert Panel. A five-member EP was assembled representing meditation researchers, practitioners, teachers, and clinicians. The EP received a detailed description of the intent of the DMPI and was instructed to follow a three-step process. Step one was to read each item and provide two ratings for relevance and clarity, respectively. Our slight adaptation of the widely used method described by Lynn (1986)⁶ separates relevance and clarity because they are distinct issues, and weaknesses in relevance vs clarity may call for different remedies. This approach has been successfully used in development of other instruments by one of the authors (JD).¹²⁻¹⁴ Possible ratings ranged from 1 (not relevant) to 4 (highly relevant) for relevance and 1 (very confusing) to 4 (very clear) for clarity. For step two, the EP suggested how to reword the item to improve relevance and clarity, if needed.⁵ For step three, the EP generated items representing overlooked concepts.⁶ The EP members completed their reviews independently. Three content validation reviews were conducted with 100% EP participation.

A content validity index (CVI) for each item was generated from the relevance scores by calculating the proportion of 3 or 4 ratings for the item.⁷ Similar calculations were done with the clarity scores. These will hereafter be referred to as the item-CVI-relevance and item-CVI-clarity, respectively. These are distinct from the survey-CVIs for clarity and relevance, which were calculated by taking an average of the item-CVIs.¹⁵

The disposition of items (whether they were retained unchanged, revised, or deleted), the number of items newly generated, and the survey-CVIs for relevance and clarity at the end of each review are summarized in Table 1. An item was retained unchanged if it had item-CVIs for both clarity and relevance greater than or equal to 0.80. An item was revised if the item-CVI-relevance was high and one or more EP members suggested rewording to improve clarity. For example, in review one, "It seems boring" was revised to "I'm concerned meditation might be boring." An item was deleted if the item-CVI-relevance was low, regardless of item-CVI-clarity. A newly generated item was one that was developed by an EP member for evaluation by the whole EP. "I'm concerned meditation will conflict with my religion" was newly generated during review one and received an item-CVI-relevance and item-CVI-clarity of 1.0 during review two, indicating the highest ratings possible from all EP members. In contrast, "I would just fall asleep" was newly generated during review one, but received an item-CVI-relevance of 0.60 in review two, so it was deleted.

For review two, the EP received an additional instruction for evaluation of items that addressed the same concept in a slightly

TABLE 1 Expert Panel Review Noting Item Disposition and Survey-Content Validity Index for Relevance and Clarity

| Review | No. Items Reviewed | No. Items Unchanged | No. Items Revised | No. Items Deleted | No. Items Newly Generated | Survey-CVI-Relevance* | Survey-CVI-Clarity* |
|--------|--------------------|---------------------|-------------------|-------------------|---------------------------|-----------------------|---------------------|
| 1 | 53 | 27 | 9 | 17 | 12 | 0.77 | 0.91 |
| 2 | 48 | 20 | 3 | 25 | 0 | 0.76† | 0.86† |
| 3 | 23 | 22 | 1 | 0 | 0 | 0.88 | 0.97 |

*Survey-CVIs were calculated by taking an average of the item-CVIs.

†Only the 27 items that were not part of a cluster decision were included in the calculation of the survey-CVIs.

Abbreviation: CVI, content validity index

different way. Two of the authors (AW and JD) clustered the conceptually similar items together. EP members were asked to select their favorite from among the cluster and rate that item. For example, the following two items formed a cluster: “I prefer to be doing something productive” and “I prefer to be accomplishing something.” Another cluster consisted of “I cannot stop my thoughts,” “It’s hard for me to calm my thoughts down,” and “It’s hard for me to concentrate.” If the EP felt that more than one item from the cluster should be included, he or she was asked to comment to that effect and rate all the items they wished to include. Only items that were not part of a cluster decision (27 of 48 items) were included in the calculation of the survey-CVIs. These 27 items were rated by all experts, but the clustered items were not.

In review three, the EP members evaluated the items selected from the cluster process in review two that now needed clarity and relevance ratings from the whole EP as stand-alone items and as a result of revisions (nine items). Fourteen items received item-CVIs for relevance and clarity of greater than or equal to 0.80 on the two previous reviews, so for the third review, the EP members were asked to simply comment if they had concerns about including these items in the final instrument. The survey-CVIs at the conclusion of all EP reviews were 0.88 for relevance and 0.97 for clarity.

Step Five: Estimating Content Validity Using a Community-based Sample. Once the list of items had been reduced and revised by the EP, it was converted into a Likert scale with 22 items. An introductory paragraph and instructions for the respondent were added. With ethical approval from the Yale School of Nursing Human Subjects Research Review Committee, a sample of 10 non-meditators from the community was recruited to provide content validation. The sample was purposefully recruited to consist of five men and five women representing a range of ages (30 to 79 years) and diverse race/ethnicity, education level, and marital status. Participants were asked to comment on the readability and interpretability of the 22-item version of the DMPI and also asked if the items reflected their barriers to meditation.¹⁶ First, participants answered the questionnaire in its entirety, responding to the questions thinking only of themselves. Second, the investigator (AW) queried participants about each individual item, asking (1) the participant to state in his/her own words what s/he thought the item was asking, (2) if the content was relevant to the participant or people s/he knows, and (3) the participant to provide sugges-

tions for rewording to improve clarity if necessary. Finally, the participant was asked to identify any other questions or topic areas that might be important to include on the DMPI. A constant comparison of participants’ responses was done so when a participant identified a concern about an item, verbal probing techniques were used with subsequent participants relative to that concern. Participants’ responses were summarized for common themes and discrepancies. In addition, participant and item sample means and standard deviations (SDs) were calculated to summarize the variability of responses (and not for inferential purposes) (Table 1a).

All pilot test participants demonstrated reasonable variability in their responses except for participant #4 (mean: 1.14; SD: 0.35), so item sample means and standard deviations were recalculated without participant #4 (Table 1a).

Generally speaking, when an item showed low response variability and participants commented negatively, it was considered for deletion. Three items met these criteria and were deleted. Items with low variability coupled with favorable comments or no negative comments were retained. Two items demonstrated reasonable variability; however, the participants’ comments indicated they were confused by the content. These two items were deleted. Two items related to prayer and religion evoked considerable discussion, with approximately half the participants stating the questions were important and should be retained, and about half the participants stating “religion-related” questions should not be included. The decision was made to retain these items to see how they function with a larger sample. Two items were reworded based on participants’ feedback to improve clarity.

A 17-item version of the DMPI was developed for administration to 150 family caregivers.

Sample and Setting

Family caregivers to adults with cancer have been identified as a highly stressed population who could potentially benefit from meditation. Consequently, they were chosen as the target population for construct validity and reliability testing. With ethical approval from the Yale School of Nursing Human Subjects Research Review Committee and the Yale-New Haven Hospital Institutional Review Board, a sample of 150 family caregivers identified by adult patients at the Yale Comprehensive Cancer Center, New Haven, Connecticut, was enrolled from May 2008 to March 2009. The family caregiver did not need to be a blood or adopted relative or household member. Consistent with other descriptive

TABLE 1A Pilot Sample Responses, Means, and Standard Deviations for Items and Participants

| Reviewer/Item | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | M | SD | M w/o 4 | SD w/o 4 |
|---------------|------|------|------|------|------|------|------|------|------|------|------|------|---------|----------|
| A.1. | 4 | 2 | 2 | 1 | 4 | 2 | 4 | 4 | 4 | 4 | 3.10 | 1.20 | 3.03 | 1.29 |
| A.3.a. | 1 | 1 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 1.70 | 0.48 | 1.69 | 0.56 |
| A.5.a. | 5 | 1 | 2 | 1 | 3 | 2 | 2 | 2 | 3 | 2 | 2.30 | 1.16 | 2.05 | 0.69 |
| A.9.a. | 2 | 1 | 2 | 1 | 3 | 2 | 2 | 2 | 2 | 2 | 1.90 | 0.57 | 1.83 | 0.69 |
| A.11. | 1 | 1 | 3 | 1 | 4 | 4 | 3 | 4 | 3 | 2 | 2.60 | 1.26 | 2.76 | 1.15 |
| A.14.a. | 2 | 1 | 3 | 1 | 2 | 2 | 4 | 3 | 3 | 4 | 2.50 | 1.08 | 2.51 | 1.10 |
| A.15. | 2 | 1 | 2 | 1 | 3 | 2 | 2 | 2 | 2 | 3 | 2.00 | 0.67 | 1.96 | 0.77 |
| A.16.a. | 4 | 3 | 4 | 2 | 3 | 4 | 4 | 4 | 3 | 4 | 3.50 | 0.71 | 3.13 | 1.14 |
| A.18.a. | 4 | 4 | 2 | 2 | 4 | 4 | 4 | 5 | 2 | 4 | 3.50 | 1.08 | 3.29 | 1.28 |
| A.19.b. | 2 | 1 | 5 | 2 | 2 | 4 | 3 | 4 | 4 | 1 | 2.80 | 1.40 | 2.69 | 1.16 |
| B.1.a. | 2 | 1 | 1 | 1 | 4 | 4 | 1 | 1 | 2 | 1 | 1.80 | 1.23 | 1.89 | 1.25 |
| B.2. | 1 | 1 | 2 | 1 | 3 | 2 | 2 | 2 | 2 | 4 | 2.00 | 0.94 | 2.10 | 0.94 |
| B.9. | 1 | 1 | 2 | 1 | 4 | 4 | 1 | 1 | 2 | 1 | 1.80 | 1.23 | 1.89 | 1.25 |
| B.11.a. | 4 | 3 | 1 | 1 | 4 | 2 | 4 | 4 | 4 | 2 | 2.90 | 1.29 | 2.80 | 1.25 |
| B.13. | 1 | 2 | 2 | 1 | 3 | 4 | 4 | 5 | | 4 | 2.89 | 1.45 | 3.17 | 1.37 |
| B.16.a. | 2 | 1 | 1 | 1 | 3 | 2 | 2 | 1 | 2 | 3 | 1.80 | 0.79 | 1.84 | 0.81 |
| C.1.a. | 1 | 1 | 1 | 1 | 2 | 3 | 2 | 2 | 2 | 1 | 1.60 | 0.70 | 1.70 | 0.71 |
| C.4. | 1 | 3 | 1 | 1 | 2 | 3 | 2 | 2 | 2 | 1 | 1.90 | 0.99 | 1.77 | 0.66 |
| C.9. | 1 | 2 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 4 | 1.90 | 0.88 | 1.98 | 0.89 |
| C.10. | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 1 | 2 | 1 | 1.40 | 0.52 | 1.44 | 0.58 |
| C.16. | 1 | 2 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 4 | 1.90 | 0.88 | 1.98 | 0.89 |
| C.17. | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 1 | 2 | 2 | 1.50 | 0.53 | 1.56 | 0.58 |
| Mean | 2.00 | 1.64 | 1.91 | 1.14 | 2.86 | 2.73 | 2.55 | 2.55 | 2.48 | 2.55 | | | | |
| SD | 1.31 | 1.00 | 1.06 | 0.35 | 0.83 | 0.94 | 1.01 | 1.34 | 0.75 | 1.26 | | | | |

caregiver studies,^{17,18} *family caregiver* was defined as the primary person upon whom the patient relies for assistance with physical care, symptom management, and psychosocial needs and who does not receive financial remuneration for caregiving. Men and women over the age of 18 years were eligible to participate. Participants had to have no prior experience with meditation (other than prayer).

Estimating Construct Validity

Based on the Theory of Planned Behavior (TPB),¹⁹ two established instruments—the Caregiver Reactions Assessment (CRA)²⁰ and the Big Five Inventory-Neuroticism Subscale (BFI)²¹—were chosen to test for convergence with the DMPI by means of positive correlation. TPB explains individual behavior through serial stages—determinant, motivational, and volitional—that leads to intention and behavior. BFI is a personality inventory; TPB identifies personality as a determinant variable. CRA measures perceived burden; TPB identifies perceived facilitating and inhibiting power, perceived control and self-efficacy,

and attitude toward behavior as motivational variables. We hypothesized that participants with high-perceived burden (as measured by the CRA) and high neuroticism personality trait (as measured by the BFI) would identify a high number of barriers to meditation (as measured by the DMPI).

Reliability Testing

Immediately after completing baseline data, all participants were invited to participate in the DMPI readministered in order to attain test-retest reliability data. A retest date was scheduled approximately 1 week hence (plus or minus 1 day). Power analysis for reliability testing for a continuous measurement scale indicates with two observations per participant using a one-sided α equal to 0.05 and with an observed intraclass correlation coefficient of 0.85, one can achieve a power of 88% for a sample of 100.²²

Analysis

Relationships between items were assessed by inter-item correlations. Item-instrument correlation was calculated for each

item. Internal consistency was assessed by calculating Cronbach's coefficient α for the total DMPI. Individual items were deleted one at a time, and the total DMPI α was recalculated to see the effect of the individual items on the total scale.

Each item was evaluated for distribution of responses and potential ceiling and floor effects. A comparison of participants who completed a retest and those who did not was conducted by age, gender, and DMPI baseline score. Test-retest reliability testing was completed by calculating an intraclass correlation coefficient (ICC) per total DMPI score for each participant. Using linear mixed effect modeling, a confidence interval (CI) was calculated for the ICC.²² We calculated the percentage of items that resulted in identical scores on the test and retest, as well as the percentage that varied by one (eg, baseline response: Strongly Agree; retest response: Agree); varied by two (eg, baseline response: Neither Agree nor Disagree; retest response: Strongly Disagree); or varied by greater than two (eg, baseline response: Disagree; retest response: Strongly Agree).

For estimation of construct validity, associations among total scores on the DMPI and CRA, and the DMPI and BFI-neuroticism subscale were evaluated for convergence by calculating a Pearson correlation coefficient.

RESULTS

The sample of family caregivers (N = 150) was comprised predominantly of women at approximately a 2:1 ratio to men (65.3% women, 34.7% men). The National Institutes of Health method of obtaining demographic data was used whereby Latino/Hispanic ethnicity was queried independent of race. Eight percent of participants self-identified as Latino/Hispanic. Most of the participants self-identified as white (83.3%). The participants were well educated, with almost two-thirds having at least some college education. Approximately 57% of participants were employed outside the home either full-time or part-time. Further demographic characteristics are shown in Table 2.

Examination of frequency distribution of responses indicated response variability for each item, with the full range of possible responses (1-5) used by the participants. Two of the 17 items showed evidence of a floor effect (>40% of respondents chose 1, "Strongly Disagree"); there was no evidence of a ceiling effect. Table 3 shows each item's mean and standard deviation. Internal consistency reliability, an indicator of the degree to which the individual items correlate with each other and the instrument as a whole, was tested using Cronbach's coefficient alpha. The 17-item DMPI had an α of 0.87. Item-instrument correlations, as well as the instrument coefficient α with each individual item deleted are displayed in Table 3. Item-instrument correlations ranged from 0.42 to 0.66 with the exception of item #8, "Prayer is my form of meditation," which had an item-instrument correlation of -0.08. When item #8 was deleted, the instrument α changed from 0.87 to 0.88. Deletion of any item other than item #8 leads to slightly lower alpha coefficients. Because the instrument alpha change was modest, the decision was made to retain item #8. All other items also were retained.

TABLE 2 Study Sample Demographic Characteristics (N = 150)

| Characteristic | Mean | SD |
|-------------------------------|--------------------|------------|
| Age in years (range) | 52.3 (18.0 - 84.0) | 16.2 |
| Characteristic | N | Percentage |
| Gender | | |
| Men | 52 | 34.7 |
| Women | 98 | 65.3 |
| Latino/Hispanic | 12 | 8.0 |
| Race | | |
| White | 125 | 83.3 |
| African American | 12 | 8.0 |
| Asian | 6 | 4.0 |
| Other | 2 | 1.3 |
| Not reported | 5 | 3.3 |
| Marital status | | |
| Single | 30 | 20.0 |
| Married | 107 | 71.3 |
| Living with partner | 5 | 3.3 |
| Divorced/separated | 3 | 2.0 |
| Widowed | 5 | 3.3 |
| Highest grade level completed | | |
| Less than high school | 7 | 4.7 |
| High school graduate/ GED | 33 | 22.0 |
| Trade or technical school | 10 | 6.7 |
| Some college | 33 | 22.0 |
| College graduate | 37 | 24.7 |
| Graduate school | 28 | 18.7 |
| Not reported | 2 | 1.3 |
| Religious affiliation | | |
| None | 16 | 10.7 |
| Protestant | 37 | 24.7 |
| Catholic | 80 | 53.3 |
| Jewish | 4 | 2.7 |
| Other | 12 | 8.0 |
| Not reported | 1 | 0.7 |
| Employment status | | |
| Full-time | 55 | 36.7 |
| Part-time | 31 | 20.7 |
| Unemployed | 4 | 2.7 |
| Disabled | 4 | 2.7 |
| Retired | 35 | 23.3 |
| Homemaker | 15 | 10.0 |
| Student | 6 | 4.0 |

Correlations of the DMPI and BFI and CRA were .42 and .32, respectively. Both correlations are in the expected direction, highly significant ($P < .0001$), and of medium magnitude.²³

Test-retest reliability testing was completed on 108 of 150 participants (72% of the sample). Of those who did not participate in the retest (n=42), two declined and 40 could not be contacted. Retest completers and noncompleters were compared by age, gender, and baseline DMPI score. Significance testing did not yield evidence that completers and noncompleters differ significantly by gender ($\chi^2 P$ value = .55) or baseline DMPI score (t -test P value = .63); the mean age of noncompleters (44.7 y) was significantly younger than completers (55.2 y) (t -test P value = .0002).

TABLE 3 Determinants of Meditation Practice Inventory Item Means, Standard Deviations, Item-instrument Correlation, and Instrument Cronbach's Coefficient alpha With Each Item Deleted

| Item Number and Phrase* | Mean (SD) | Item-instrument Correlation | α When Item is Deleted |
|--|------------|-----------------------------|-------------------------------|
| 1. I can't stop my thoughts. | 2.9 (1.18) | 0.47 | 0.86 |
| 2. I am uncomfortable with silence. | 2.1 (1.19) | 0.44 | 0.86 |
| 3. I can't sit still long enough to meditate. | 2.6 (1.32) | 0.63 | 0.85 |
| 4. I prefer to be accomplishing something. | 3.2 (1.23) | 0.48 | 0.86 |
| 5. Meditation might be boring. | 2.3 (1.07) | 0.57 | 0.85 |
| 6. It is a waste of time to sit and do nothing. | 2.3 (1.27) | 0.47 | 0.86 |
| 7. I don't know much about meditation. | 3.0 (1.29) | 0.66 | 0.85 |
| 8. Prayer is my form of meditation. | 3.4 (1.28) | -0.08 | 0.88 |
| 9. There is no quiet place where I can meditate. | 2.0 (1.01) | 0.58 | 0.85 |
| 10. I don't have time. | 2.4 (1.20) | 0.52 | 0.86 |
| 11. There is never a time when I can be alone. | 2.2 (1.22) | 0.56 | 0.85 |
| 12. I wouldn't know if I were doing it right. | 2.7 (1.22) | 0.53 | 0.86 |
| 13. I'm concerned meditation will conflict with my religion. | 1.6 (0.67) | 0.42 | 0.86 |
| 14. My family would think it was unusual. | 2.0 (1.00) | 0.51 | 0.86 |
| 15. I would feel odd meditating. | 2.0 (0.99) | 0.65 | 0.85 |
| 16. I don't believe meditation can help me. | 2.1 (1.04) | 0.57 | 0.85 |
| 17. I wonder if meditation might harm me. | 1.5 (0.72) | 0.46 | 0.86 |

*All item phrases were preceded by, "It will be difficult for me to meditate because . . ."

The ICC for baseline and retest total DMPI scores was 0.86 ($df = 107$, $\alpha = 0.10$, CI 0.82-0.90). An identical response on the baseline and retest scores occurred most frequently; responses varying by greater than two were rare (Table 4).

DISCUSSION

The main purpose of this article is to present the standardized and replicable process we used to develop the DMPI. Our study used a triangulated approach to instrument development that combined literature review, qualitative, and quantitative methods. Preliminary steps in the process, namely content validation, formed the foundation for subsequent steps. By using multiple resources, a comprehensive approach to content validation that integrated scholarly and grassroots perspectives was achieved and allowed for reciprocal confirmation of results. As such, we were able to delineate content domains, operationalize domain definitions, and develop items, confident that we had included widely representative viewpoints about barriers to meditation.

The EP, comprised of meditation researchers, practitioners, teachers, and clinicians, was assembled with the deliberate intention of garnering diverse perspectives. The EP was diligent in the execution of their duties, with 100% participation through all three reviews. In total, the EP reviewed 124 items, among which were 12 items they generated and 13 items they revised. Survey-CVI-relevance of 0.88 and survey-CVI-clarity of 0.97 at the conclusion of EP reviews indicate a high level of cognitive cohesion about the barriers to meditation among experts with distinct

TABLE 4 Frequency of Differences Between Determinants of Meditation Practice Inventory Baseline and Retest Item Score (N = 108)

| Retest Difference/ Item No. | Differed by > 2 | Differed by 2 | Differed by 1 | No Difference |
|-----------------------------|-----------------|----------------|----------------|---------------|
| 1 | 3 | 8 | 34 | 63 |
| 2 | 5 | 11 | 22 | 70 |
| 3 | 2 | 9 | 36 | 61 |
| 4 | 5 | 12 | 25 | 66 |
| 5 | 0 | 9 | 32 | 67 |
| 6 | 1 | 9 | 34 | 64 |
| 7 | 2 | 9 | 38 | 59 |
| 8 | 3 | 11 | 28 | 66 |
| 9 | 0 | 5 | 27 | 76 |
| 10 | 0 | 10 | 24 | 74 |
| 11 | 1 | 4 | 32 | 71 |
| 12 | 1 | 7 | 33 | 67 |
| 13 | 0 | 3 | 22 | 83 |
| 14 | 1 | 6 | 25 | 76 |
| 15 | 0 | 4 | 16 | 88 |
| 16 | 0 | 5 | 21 | 82 |
| 17 | 0 | 0 | 19 | 89 |

areas of knowledge and experience.

Pilot testing and content validation with a community-based sample further refined the DMPI. The sample was purposefully recruited to vary on several demographic features so as to gain broad feedback on whether the DMPI was readily understandable and appropriately captured barriers to meditation. Similar to the EP, the pilot test participants assiduously carried out their responsibilities, providing thoughtful commentary and adding to the clarity of the DMPI. Their feedback led to elimination of five items, representing a 23% reduction in the length of the DMPI (from 22 items to 17 items). While this sizable reduction seemed draconian at the time, the respectable indicators of internal consistency attained with the larger sample of 150 supports the process, at least at this initial phase of psychometric testing.

Cronbach's coefficient α for the 17-item DMPI is 0.87, indicating the items hold together in a coherent way. The exception is item #8, "Prayer is my form of meditation," which had an item-instrument correlation of -0.08 , demonstrating negligible contribution to the instrument as a whole. The decision was made to retain item #8 to see how it performs with larger, more diverse samples.

The 108 retest participants showed no statistically significant difference by gender or baseline DMPI total scores from those who did not complete a retest; however, noncompleters were on average younger than completers. This may reflect the increased likelihood that younger participants were employed outside the home and/or had other dependents and consequently would have greater difficulty scheduling a retest date. The ICC was used to compare total DMPI scores at two time points, baseline and retest 1 week hence. The ICC complements Cronbach's coefficient α in testing reliability, and ideally, the two tests should provide similar results. Our test results were complementary and confirmatory ($\alpha=0.87$, $ICC=0.86$ [CI 0.82-0.90]).

Based on the TPB, we hypothesized the DMPI would correlate with BFI and CRA, each of which was purported to measure different components of the TPB. BFI and CRA do not measure the same construct as the DMPI nor do they measure a planned behavior but rather variables leading to a planned behavior; therefore, we expected the correlations would be positive yet modest. Though estimation of construct validity, as assessed by this method, confirmed the hypothesized relationships with statistically significant, positive correlations, the results must be interpreted with caution. Future study with confirmatory factor analysis will allow us to estimate construct validity by testing a hypothesis about the relationship between the items and their underlying latent constructs (namely, the content domains).

It should be noted that the DMPI was designed to identify barriers to meditation at the exclusion of identifying facilitators. When one looks at determinants to a planned health behavior, barriers and facilitators are often equally important.²⁴ By excluding facilitators to meditation, we are neither ignoring nor diminishing their importance. Rather, with our sample size constrained by resources, it became apparent that we would have data sufficient only to interpret psychometric testing of an instrument addressing a single construct.

Reliability testing of the DMPI involved retesting participants after 1 week. The relatively modest window between testing was chosen in an attempt to minimize variability in responses secondary to the rapidly changing circumstances of being a family caregiver. With only 1 week between test and retest, however, the risk for "practice effect" is increased.²⁵

The sample for this study is predominantly white educated women from the northeastern United States who are in the highly stressful role of caring for an adult with cancer. Therefore, generalizability of the results is limited. Future study should expose the DMPI to other populations in other settings.

CONCLUSIONS

High-quality scientific evidence for meditation's efficacy is limited in part because many research studies have been undermined by small sample sizes that limit statistical power so that an effect is not identified when it might, in fact, be present. High attrition has also characterized many meditation studies, and this shortcoming has the potential to introduce bias when missing data is not handled properly. Descriptive work identifying potential barriers to meditation practice will provide the structure to frame meditation interventions in an accessible form. For example, if many members of a target population identify "I can't sit still long enough to meditate" as a barrier, researchers can design recruitment materials that assure potential participants that they can walk or lie down to meditate. From a statistical standpoint, the DMPI may help researchers differentiate between meditation intervention responders and nonresponders, as well as completers and noncompleters. Ideally, by identifying and addressing barriers, recruitment will be optimized, attrition minimized, and interpretation of study results maximized. The development of the DMPI, as presented here, is one step in the process to promote methodologic rigor in meditation research. Preliminary data indicate the current version of the DMPI is a psychometrically sound instrument that is ready to be tested with larger and more diverse samples.

The DMPI is not intended as a screening tool to exclude from meditation research those individuals who have a high number of barriers to meditation. Rather, by identifying and addressing barriers early, meditation interventions can become more inclusive of a larger segment of the population. Ultimately, the DMPI may help advance the science of mind-body medicine and allow for evidence-driven clinical decisions about the possible salutatory effects of meditation.

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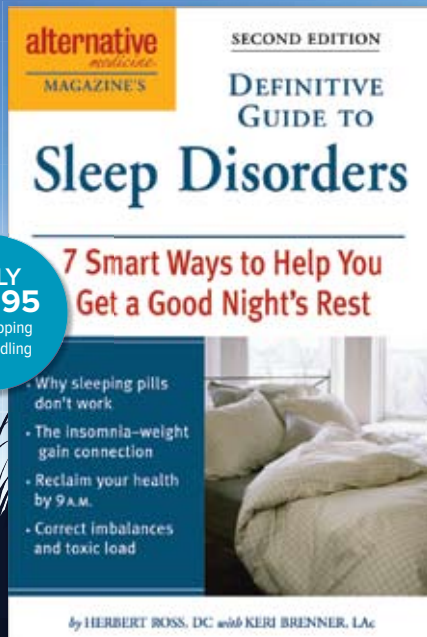
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Three Cases of Chemotherapy-induced Peripheral Neuropathy Successfully Treated With Therapy Based on Kampo Diagnosis

Hirasaki Yoshiro, MD, PhD; Nobuyasu Sekiya, MD, PhD; Atsushi Chino, MD, PhD; Keigo Ueda, MD, PhD;
Hideki Okamoto, MD, PhD; Takao Namiki, MD, PhD

Patients undergoing chemotherapy often develop symptoms of neurological side effects such as numbness, pain, and weakness in a stocking-and-glove pattern. Yet few therapies are available to treat this condition. We examined the efficacy of therapy based on Kampo diagnosis in three cases of chemotherapy-induced peripheral neuropathy (CIPN). These patients all had severe cases, and the symptoms of CIPN interfered with their daily lives even after the cessation of the offending drugs. Early cessation of the drug therapy would be ideal, but in some cases

where chemotherapies were effective against cancer, CIPN was worsened by prolonged administration. With the initiation of therapy based on Kampo diagnosis, the subjects of these case reports showed marked improvement in their daily activities. The Kampo diagnosis of CIPN is not only *Jinkyō*, as *Tankaku*, *Kiutsu*, and other Kampo clinical conditions can be candidates. We consider that the traditional way of Kampo diagnosis can provide options for the treatment of CIPN. (*Altern Ther Health Med.* 2011;17(5):26-30.)

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Patients undergoing chemotherapy often develop neurological side effects such as numbness, pain, and weakness in a stocking-and-glove pattern, which have negative effects on their quality of life. Yet few therapies are available to treat this condition.¹ We examined the efficacy of therapy based on Kampo diagnosis in three cases of chemotherapy-induced peripheral neuropathy (CIPN).

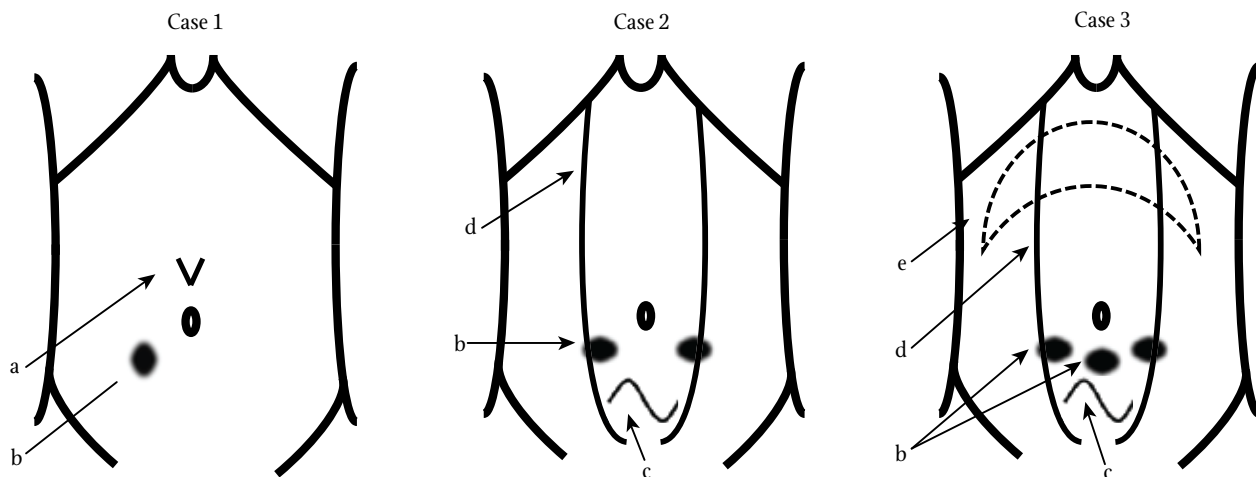
CASES

Case 1

A 45-year-old woman with chief complaints of abnormal sensations and edema of the extremities had been diagnosed with breast cancer and cancerous pleurisy (stage 4), with no indication for surgical treatment. She was given eight courses of docetaxel

therapy, a total amount of 960 mg over 5 months (from December 2006 to May 2007) after eight courses of fluorouracil, epirubicin, and cyclophosphamide therapy, which proved to be effective for tumor size reduction. But she began to feel abnormal sensation and pain in her extremities and had difficulty in walking, going down steps, and standing up from bed because of edematous extremities. Docetaxel was changed to anastrozole, and therapies with a diuretic and oral steroid were initiated. But the edema worsened and the pain continued. She visited our outpatient clinic for the treatment of CIPN in June 2007. She stood 152.5 cm tall and weighed 60 kg. There were no abnormal findings in the head/neck region, chest, or abdomen. She had abnormal sensations and edema in her legs (right leg measured 41 cm around the calf and the left 43 cm) as well as numbness in her fingers.

The Kampo medical findings were as follows. Her pulse was sunken, slow, thin, and stagnant. The tongue revealed a slightly red tongue body coated with moist white moss. As shown in Figure 1, abdominal tension was moderate. Palpitations were evident on touch of the superior part of the umbilicus, as well as tenderness in the lower right part of the paraumbilical area. We diagnosed her as having *Tankaku* (phlegm node) on the basis of the leg edema and numbness of the extremities and as having *Oketsu* (blood stasis) according to the tenderness in the lower abdomen and pain in the legs. We subsequently prescribed *nichintogokeishibukuryoganryo* (combination of Kampo decoctions, *nichinto* for *Tankaku* and *keishibukuryogan* for *Oketsu*). The clinical course is shown in Figure 2. A diuretic response was observed



| Findings | Japanese name | Indication |
|--|---------------|--|
| a Evident palpitation of aorta on touch | Fukudo | Nervous psychological state |
| b Tenderness in the lower parts of the para-umbilical area | Seiboattsu | Oketsu state (blood stasis) |
| c Flaccid lower abdomen | Shohukufujin | Jinkyō state |
| d Tense abdominal rectus muscles | Fukuhikokyū | Yin liquid (blood and water) insufficiency |
| e Gaseous distension | Ko-on | Kiutsu state (stasis of ki power) |

FIGURE 1 Findings by abdominal examination

immediately after administration of Kampo medications, with a reduction in body weight by 5 kg in 2 weeks. Pain and numbness began to improve. After 6 weeks, her pain had decreased to a 4 out of 10 by numerical rating scale, and she was able to return to her work. After 3 months the pain had almost disappeared. Her difficulty in walking also gradually disappeared.

CASE 2

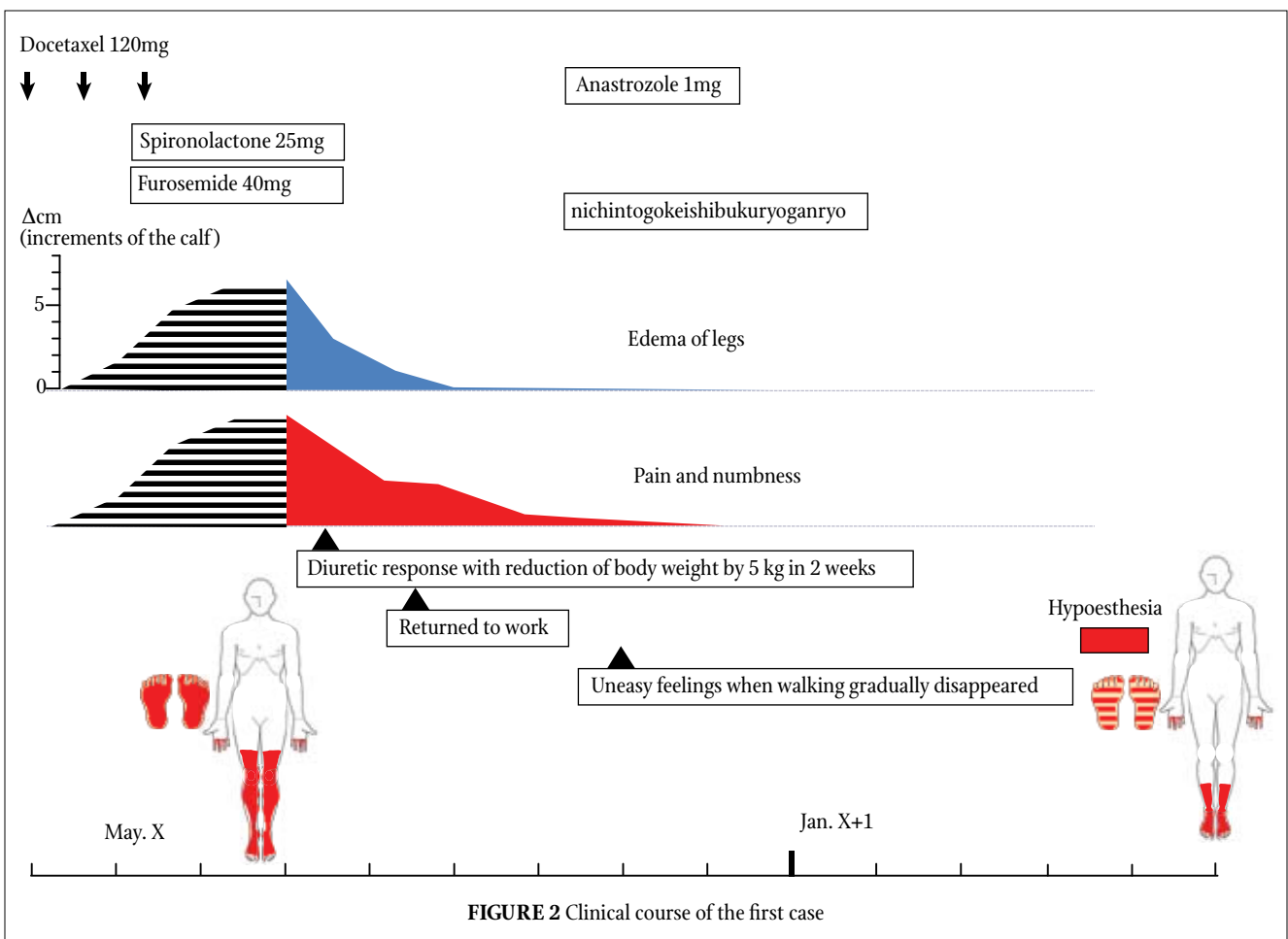
A 45-year-old man with chief complaint of numbness of the extremities had been diagnosed as left testicular cancer and had undergone an orchiectomy. Subsequently, three courses of bleomycin, etoposide, and cisplatin (BEP) therapy and two courses of paclitaxel, ifosfamide, and carboplatin therapy, which included 665 mg of cisplatin and 550 mg of paclitaxel in total, were performed for 6 months (from December 2006 to May 2007) to treat metastasis of the liver and retroperitoneal lymph nodes. He began to feel numbness in his hands and feet in January 2007. Although his chemotherapy treatments were effective, resulting in mass reduction of the liver metastasis and normalization of tumor markers even after their completion, the side effects gradually worsened, and the affected areas reached the upper arms and upper legs. He could not drive a car or walk by himself. He began to live in a wheelchair. He was so physically challenged that he qualified for the first degree of assistance by the Japanese government. He was given mecobalamin (1500 mg/day) for the treatment of CIPN, but it was ineffective. He then visited our outpatient clinic for relief of his symptoms (September 2007). He was 171.8 cm tall and weighed 45 kg. Ataxic gait, Romberg sign,

hyperesthesia in distal areas of all limbs, diminished vibratory sense, and areflexia in all limbs were observed. Subjective symptoms were numbness of extremities (from upper arms to fingers and from upper legs to toes); intolerance to cold; difficulty in writing, using chopsticks, and hearing; and edema of the legs in the evening. His pulse condition was sunken, fast, weak, and thin. The tongue showed dark red tongue body coated with yellow moss. Abdominal tension was moderate, and abdominal rectus muscles on both sides were tense. Tension of the lower abdomen was flaccid. There were tender points in the lower part of the paraumbilical area (Figure 1). We diagnosed him as *Jinkyō* (kidney *Ki* deficiency) on the grounds of numbness, edema, flaccid lower abdomen, hearing difficulty, and intolerance to cold and then prescribed 7.5 g of *goshajinkigan* extract granules.

After 3 weeks, the patient's difficulty in standing up was slightly ameliorated. He began to feel that his feet were warmer. He gradually started to walk again, and the feeling of numbness when sleeping decreased. As the numbness improved further, he could grip a pencil again. He could walk down stairs using a handrail. He no longer needed a wheel chair. Seven months after the start of Kampo medication, he was able to walk nonstop for 30 to 40 minutes.

CASE 3

A 69-year-old man with the main complaint of numbness of the feet and fingers had been diagnosed with right testicular cancer and had undergone a right orchiectomy. He subsequently underwent two courses of BEP therapy and two courses of etopo-



side and cisplatin therapy from January to May 2006, which included 700 mg cisplatin in total for metastasis of retroperitoneal lymph nodes. He began to feel decreased sensation, pain, and numbness in the soles of both feet in April 2006. He was given mecobalamin (1500 mg/day) and clonazepam (0.5 mg/day) to relieve the symptoms, but they had no effect. When he visited our department for Kampo therapy in February 2007, he was using a walking stick. As concomitant diseases, he developed a bleomycin-induced interstitial pneumonia and insomnia. He was 158 cm tall and weighed 73 kg. Hypoalgesia (in distal sites of all fingers, especially in the bilateral first and second fingers), diminished vibratory sense, hyporeflexia in upper limbs, diminished patellar tendon reflex, and absence of Achilles tendon reflex were observed. Subjective symptoms were numbness of feet and fingers, abnormal sensation of the soles, intolerance to cold, loss of concentration, fatigability, sleepiness in the daytime, tendency for feet to become swollen, constant urge to urinate, polyuria, leg cramps, and abdominal fullness with flatus and constipation. His pulse was thick and stagnant. The tongue showed a tongue body that was dark red, swollen, tooth-marked, and moist with a coating of white moss. Abdominal conditions showed bilateral tense abdominal rectus muscles on both sides, flaccid lower abdomen, tender points in the lower part of the

paraumbilical area, and gaseous distension (Figure 1).

At first, we diagnosed him as *Jinkyō*, based on the numbness of feet, flaccid lower abdomen, and dark red tongue and prescribed *hachimigan* at 40 pills per day. But as the numbness did not improve in the first 6 weeks, we rediagnosed him as *Kiutsu* (stasis of *Ki* power) on the grounds that he had fatigability and gaseous distension and prescribed 4 g of *kumibinroto* extract granules. Then his constipation improved, and numbness of feet began to lessen. At 4 months after starting *kumibinroto*, his pain disappeared. He could walk without a stick, and he regained the feeling of setting his feet on the ground. The feeling of numbness still continued but was reduced to 80% by taking *kumibinroto* for 5 months. After 1 year and 3 months, he could take his dog out for walks in the morning and evening.

DISCUSSION

In case 1, the diagnosis was *Tankaku (Tanhe)*, which is defined as “in patients with a state of *Hikyo* (spleen *Ki* deficiency), wet phlegm drains outward to the skin and consolidates to make phlegm nodes of all sizes. They are often found in the neck, extremities and back.”² The components of *nichintogokeishibukuryoganryo* are shown in Table 1.

In Kampo medicine theory, the kidney functions to control

TABLE 1 Composition and doses of nichintogokeishibukuryoganryo

| Japanese | Chinese | Pharmaceutical name | Dose (g/day) |
|-----------|------------|---------------------------------------|--------------|
| Hange | Banxia | <i>Rhizoma Pinelliae Ternatae</i> | 5 |
| Chinpi | Chenpi | <i>Pericarpium Citri Reticulatae</i> | 4 |
| Shokyo | Shengjiang | <i>Rhizoma Zingiberis Officinalis</i> | 2 |
| Kanzo | Gancao | <i>Radix Glycyrrhizae Uralensis</i> | 2 |
| Bukuryo | Fuling | <i>Sclerotium Poriae Cocos</i> | 5 |
| Keihi | Guipi | <i>Ramulus Cinnamomi Cassiae</i> | 5 |
| Shakuyaku | Shaoyao | <i>Radix Paeoniae Lactiflorae</i> | 5 |
| Botanpi | Mudanpi | <i>Cortex Moutan Radicis</i> | 5 |
| Tonin | Taoren | <i>Semen Persicae</i> | 5 |

The upper 5 herbs comprise nichinto, which is the decoction for Tankaku. The lower 5 herbs comprise keishibukuryoganryo for Oketsu. For a daily dose, these nine herbs were mixed in 600ml of water and boiled for 30 minutes, then the mixture was passed through a sieve. The extract was divided and orally administered in three equal daily doses.

growth and aging as well as to regulate water metabolism. Its dysfunction sometimes results in edema, back pain, numbness, or leg disease.³ In case 2, we prescribed the extract of *goshajinkigan*. This decoction is used to cure patients with the *Jinkyō* condition who feel dullness in the lower back and sometimes have swollen legs with oliguria. The components of *goshajinkigan* are shown in Table 2.

Kumibinroto is made and has been traditionally used in Japan. This decoction is used for the treatment of *Kakke* (a comprehensive term of leg diseases including beriberi) patients who have shortness of breath and edematous legs in the *Kiutsu* (stagnant *Ki*) condition. In case 3, such symptoms as abdominal fullness with flatus, fatigability, and sleepiness in the daytime were considered as those of *Kiutsu*. The components of *kumibinroto* are also shown in Table 2. The effectiveness of a decoction is usually assessed by in 1 to 2 months. If symptoms besides the chief complaint are not showing improvement, we reassess and redirect

TABLE 2 Compositions of the extract granules orally administered daily

| Goshajinkigan | | | |
|---------------|--------------|---------------------------------------|--------------|
| Japanese | Chinese | Pharmaceutical name | Dose (g/day) |
| Jio | Dihuang | <i>Radix Rehmanniae Glutinosae</i> | 5 |
| Sanshuyu | Shanzhuyu | <i>Fructus Corni Officinalis</i> | 3 |
| Sanyaku | Shanyao | <i>Radix Dioscoreae Oppositae</i> | 3 |
| Botanpi | Mudanpi | <i>Cortex Moutan Radicis</i> | 3 |
| Bukuryo | Fuling | <i>Sclerotium Poriae Cocos</i> | 3 |
| Takusha | Zexie | <i>Rhizoma Alismatis Orientalitis</i> | 3 |
| Keihi | Guipi | <i>Ramulus Cinnamomi Cassiae</i> | 1 |
| Bushi | Fuzi | <i>Radix Lateralis Aconiti</i> | 1 |
| Goshitsu | Niuxi | <i>Radix Achyranthis Bidentatae</i> | 3 |
| Shazenshi | Cheqianzi | <i>Semen Plantaginis</i> | 3 |
| Kumibinroto | | | |
| Japanese | Chinese | Pharmaceutical name | Dose (g/day) |
| Binroji! | Binglangzil! | <i>Semen Arecae Catechu</i> | 2.7 |
| Koboku | Houpo | <i>Cortex Magnoliae Officinalis</i> | 2 |
| Keihi | Guipi | <i>Ramulus Cinnamomi Cassiae</i> | 2 |
| Kippi | Jupi | <i>Exocarpium Citri Reticulatae</i> | 2 |
| Soyo | Suye | <i>Folium Perillae Frutescentis</i> | 1 |
| Kanzo | Gancao | <i>Radix Glycyrrhizae Uralensis</i> | 0.7 |
| Daio | Daihuang | <i>Radix et Rhizoma Rhei</i> | 0.7 |
| Shokyo | Shengjiang | <i>Rhizoma Zingiberis Officinalis</i> | 0.7 |
| Mokko | Muxiang | <i>Radix Aucklandiae Lappae</i> | 0.7 |
| Goshuyu | Wuzhuyu | <i>Fructus Evodiae Rutaecarpae</i> | 0.7 |
| Bukuryo | Fuling | <i>Sclerotium Poriae Cocos</i> | 2 |

the Kampo therapy.

We summarized the clinical features of these three cases in Table 3. All three patients had severe cases and the symptoms of CIPN interfered with their daily lives even after the cessation of the offending drugs. The mechanisms underlying CIPN include damage to neural cell bodies in dorsal root ganglia and axonal

TABLE 3 Clinical features of three cases

| Case | Age/ Sex | Type of cancer | Offending drug | Time from cessation of drug to administration of KAMPO | Interval until effect | Effective decoction | NCI-CTC grade |
|------|-------------|----------------------|-------------------------|---|--------------------------|-------------------------------------|------------------|
| 1 | 45F | Breast cancer | Docetaxel | 2 months | 2 weeks | Nichintogo-keishibukuryo- ganryo | 3→2 |
| 2 | 45M | Testicular cancer | Paclitaxel Cisplatin | 4 months | 3 weeks | Goshajinkigan | 3→2 |
| 3 | 69M | Testicular cancer | Cisplatin | 9 months | 10 weeks | Kumibinroto | 3→2 |

| Grade 1 | Grade 2 | Grade 3 | Grade 4 |
|--|--|---|--|
| loss of deep tendon reflexes or paresthesia (including tingling) but not interfering with function | objective sensory loss or paresthesia (including tingling), interfering with function, but not interfering with activities of daily living | sensory loss or paresthesia interfering with activities of daily living | permanent sensory loss that interferes with function |

toxicity. Its incidence is related to cumulative dose.⁴ Early cessation of the offending drug would be favorable, but in some patients whose cancers were reacting favorably to chemotherapy, their CIPN was worsened by the necessarily prolonged administration of the drugs (especially in case 2). With the administration of therapy based on Kampo diagnosis, the patients showed marked improvement in their daily activities.

We have previously reported the efficacy of Kampo medicine in a case of atopic dermatitis.⁵ It is also effective in the treatment of CIPN. The Kampo diagnosis of CIPN is not always *Jinkyo*. *Tankaku*, *Kiutsu*, or other Kampo clinical conditions can be candidates. In Japan, we traditionally use the Kampo term “*Dobyoichi (tongbingyizhi)*,” which means different treatments for the same disease.⁶ The paradigm of Kampo medicine is different from that of Western medicine, and we sometimes confront the discrepancy between these diagnoses. We are Western medicine-trained doctors and also Kampo medicine specialists. We put emphasis on the effectiveness of therapies by traditional Kampo diagnosis. We also believe that the traditional way of Kampo diagnosis can provide options for the treatment of CIPN.

In Japan, Kampo medicine is becoming more and more popular among Western medicine-trained doctors. The Japan Society for Oriental Medicine has 8655 members and 2151 certified specialists (as of July 2011). More than 70% of doctors have experience in prescribing Kampo drugs, which are covered by government health insurance. On rare occasions, Kampo medications can cause side effects, such as pseudoaldosteronism from licorice and interstitial pneumonia from *Scutellaria baicalensis*, so scheduled inspections for such possible side effects by Western doctors are called for. On the other hand, mastery of traditional Kampo diagnosis is needed for a doctor to perform the most effective Kampo therapy. For these reasons, Kampo medicine was added to the medical education core curricula by the Japanese educational ministry in 2001, and it is the topic of lectures at medical universities.

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GLOSSARY

Dobyoichi (tongbingyizhi) When literally translated into English, this can be expressed as “different treatments for the same disease.” In the condition where diagnoses by Kampo medicine of a disease are different, therapies based on Kampo medicine for them can also be different.

Hachimigan (baweiwan) Also known as *hachimijogan*. This is one of the decoctions for curing the *Jinkyo* state.

Hikyo (pixu) Spleen *Ki* deficiency. By organ pattern identification in Oriental medicine, the spleen is related to the digestive system. This deficiency causes dysfunction of the digestive system, resulting in production of pathological water and in *Ki* power deficiency.

Jin (shen) Kidney by organ pattern identification in Oriental medicine. This organ functions to control growth and aging as well as to regulate water metabolism.

Jinkyo (shenxu) Kidney *Ki* power deficiency. This causes gait impairment, lumbago, hair loss, and premature aging, among other conditions.

Kakke (jiaoqi) A comprehensive term of leg diseases including beriberi.

Ki (qi) One of the three important factors in Kampo medicine, coupled with *Ketsu* (*xue*, blood) and *Sui* (*shui*, water). Fundamental energy for human beings possessing mind and spirit. *Ki* totally controls human life function. Its deficiency (*Kikyo*) and stasis (*Kiutsu*) are considered a pathologic state.

Kiutsu (qiyu) Stasis of *Ki* power. This causes melancholia, lump sensation in the throat, feeling of distress in the chest, distention of the abdomen, hypesthesia of the extremities, and other conditions. The symptoms accompanied by this state are sometimes intermittent and often change localization.

Oketsu (xueyu) Blood stasis, which refers to a state of insufficient blood-circulation. This can be a cause of vascular infarctions, menstrual disturbances, cancers, dermatitis, pigmentation, pain, and cold intolerance.

Shofukufujin (xiaofuburen) Flaccid lower abdomen, which means the patient is in *Jinkyo* state.

Tankaku (tanhe) Phlegm nodes, often found in the neck, extremities and back. In patients with a state of *Hikyo* (spleen *Ki* deficiency), when wet phlegm drains outward to the skin, it consolidates to make phlegm nodes of all sizes.



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A Proposed Conceptual Model for Studying the Use of Complementary and Alternative Medicine

Matthew A. Davis, DC, MPH; William B. Weeks, MD, MBA; Ian D. Coulter, PhD

A conceptual model has the ability to combine theories, illustrate relationships, and describe behaviors. We propose a conceptual model to describe the interrelated factors that dictate and influence complementary and alternative medicine (CAM) use in the United States based on sociologic theories including Parson's Sick Role and Suchman's Stages of Illness as well as the Andersen Sociobehavioral Model of health services utilization. In our conceptual model, we distinguish CAM use by symptomatic vs asymp-

tomatic individuals, practitioner-based CAM services from products and self-administered CAM therapies, and the two ultimate endpoints: either the conclusion of CAM treatment or continuous CAM treatment. The development of our model underscores the importance of classifying CAM therapies based on the decision process of the CAM consumer rather than mechanism of action or CAM belief system in studying CAM health services utilization. (*Altern Ther Health Med.* 2011;17(5):32-36)

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Cross-sectional studies conducted in the 1990s were the first to demonstrate the high rates of utilization of unconventional health care, now commonly referred to as complementary and alternative medicine (CAM), in the United States.^{1,2} These early reports found that approximately one in three respondents used some form of CAM defined as "interventions not taught widely at US medical schools or generally available at US hospitals."

Adults were asked if they used CAM therapies in the past 12 months and, if so, which therapies they used. If group CAM therapies are excluded, the most common practitioner-based CAM therapies used were chiropractic care, massage, energy healing, and acupuncture. The most common nonpractitioner-based CAM therapies included relaxation techniques, herbal medicine, and megavitamins. National estimates were that 427 million visits were made to CAM providers in 1990, and this increased to 629 million in 1997, exceeding annual estimates of total provider visits to all US medical physicians.^{1,2}

Larger studies that investigated US CAM use have documented lower rates of practitioner-based CAM use and higher rates for nonpractitioner-based CAM services.³⁻⁶ The most consistent and largest-scale data collection was from a repeat supplement questionnaire of the National Health Interview Survey (NHIS) conducted by National Center for Health Statistics in 2002 and 2007.^{5,6} According to the NHIS data, the best and most current estimate is that four out of 10 individuals in the United States use one form of CAM.⁵ In this data, the definition of CAM is broad and encompasses practitioner-based CAM therapies (eg, chiropractic, acupuncture, and massage), natural products, deep breathing exercises, personal meditation, and diet-based therapies. Recent reviews of the many cross-sectional CAM utilization studies have found considerable variation in the definitions of CAM with little consistency throughout the literature.^{7,8} This is not surprising considering the extensive diversity of CAM practices and products. Inconsistencies in the definition^{9,10} and the classification of CAM subtypes continue to impair our ability to draw meaningful inferences regarding utilization.

The high prevalence of CAM use in the United States has sparked interest in the development and use of conceptual models

and theories to explain and predict CAM use.¹¹ While theories and models are sometimes used interchangeably, these terms are distinct in meaning and practice.¹² Theories are typically specific to another discipline (originate from sociology, psychology, etc) and function to describe, explain, or predict limited properties of reality. Therefore, a theory addresses an aspect of reality by stating what something is, how something happens, or why it happens. Conceptual models, on the other hand, tend to identify and describe specific types of behavior in specific situations or contexts.¹² Conceptual models have the ability to draw on numerous theories simultaneously while illustrating the causal linkages between elements.

Broadly, the previous applications of theories and models originating from medical sociology, psychology, and marketing research to CAM can be separated into either health care utilization models or health behavior theories.¹¹ The most common theories and models used to date in the CAM literature include the Andersen Sociobehavioral Model,¹³⁻²¹ Health Locus of Control,^{14,22-24} and Self-regulatory Model.^{25,26} Given the diversity of CAM practices, the unique underlying drivers of utilization, and ultimate endpoints of CAM use, a conceptual model that addresses these various aspects would be valuable to CAM education and future inquiry. In this article, we propose a conceptual model that describes the factors involved in CAM use.

DEVELOPMENT OF THE CONCEPTUAL MODEL

To construct our conceptual CAM utilization model, we built upon prominent theories and health utilization models from the sociology and psychology literature base. Here we briefly describe the theories and models that most influenced the development of our conceptual model, which include Parson's Sick Role Theory, Suchman's Stages of Illness Theory, and the Andersen Sociobehavioral Model of health care utilization.

Parson's Sick Role Theory

In our conceptual model, we delineate the transition from wellness (asymptomatic) to sickness as a driver of CAM use. A central construct of health service utilization theory is the "sick role concept" first introduced by Talcott Parsons in 1951. The sick role concept suggests that the experience of being sick extends beyond physical and physiological symptoms to include the impact of socio-cultural factors. The sick role concept outlines the transition from the presence of symptoms to sickness and the interplay between the culture and ill person. Parson's sick role has four major tenets: (1) when an individual becomes sick, society excuses him or her temporarily from social duties; (2) a sick person is not expected to heal him/herself and thus requires assistance; (3) there exists general agreement that becoming sick is an undesirable state; and (4) to get well, the sick individual must seek medical treatment. The sick role concept channels the sick into seeking medical treatment, so the sick individual relinquishes self-responsibility to enter into a relationship of dependency with the health care provider. Though the sick role concept was instrumental to later medical sociological work, it fell under considerable scrutiny, including its application to CAM.²⁷

Suchman's Stages of Illness Theory

Another seminal health services utilization theory is Suchman's Stages of Illness.²⁸ This theory details a linear relationship between five different points in the individual's decision process to utilize health care. According to Suchman, the five stages of the decision process are (1) the symptom experience stage, (2) the assumption of the sick role stage, (3) the medical care contact stage, (4) the dependent-patient role stage, and (5) the recovery or rehabilitation stage. During the initial stage, the individual weighs the severity of symptoms including pain, discomfort, and emotion. This includes the acknowledgment that something is wrong. Similar to Parson's Sick Role, the individual then assumes the role of being sick and proceeds to seek health care and explores their personal lay referral system. During the fourth stage, the individual may take on a dependent role; however, there are significant factors that impact this transition that relate to physical, social, and psychological facets. This is a critical point in the model where the patient-practitioner relationship may impact health care consumption and is a particularly important aspect in CAM utilization. The fourth stage can also be disrupted if the sick individual's beliefs clash with the practitioner's. This tipping point is also relevant to explaining the crossover between conventional health care and CAM use, as alignment with personal beliefs is an important factor in CAM use.^{8,29} The final stage involves the relinquishment of the sick role by the individual except when a condition is incurable and entails ongoing treatment. Interestingly in CAM, continuous treatment may ensue among asymptomatic individuals.

The Andersen Sociobehavioral Healthcare Utilization Model

The sociobehavioral model most often used to predict health care utilization is the Andersen Model initially developed in 1968.³⁰ Since its original iteration, the Andersen Model has been revised multiple times. The first version included three primary determinants of health service utilization: (1) predisposing characteristics (demographics, position within the social structure, and health beliefs, attitudes, knowledge, and values); (2) enabling resources (financial and physical access to health care services); and (3) need (both self-perceived and evaluated health status). The perception of need is a large constituent overriding the utilization of health services in this model and is based within social context. In the 1970s, the model was expanded to include aspects of the health care delivery system (policy, availability of resources, and its organization) as well as a component of the individual's satisfaction with the health care services such as convenience, availability, provider characteristics, and quality. Again in the 1980s and 1990s, the model was modified and now includes the impacts of health in a linear fashion with determinant subsets including (1) primary determinants (population characteristics, the health care system, and external environment); (2) health behaviors (personal health characteristics and the use of health services); and (3) health outcomes (perceived health status, evaluated health status, and consumer satisfaction). The Andersen Sociobehavioral Model has been used with two slight modifica-

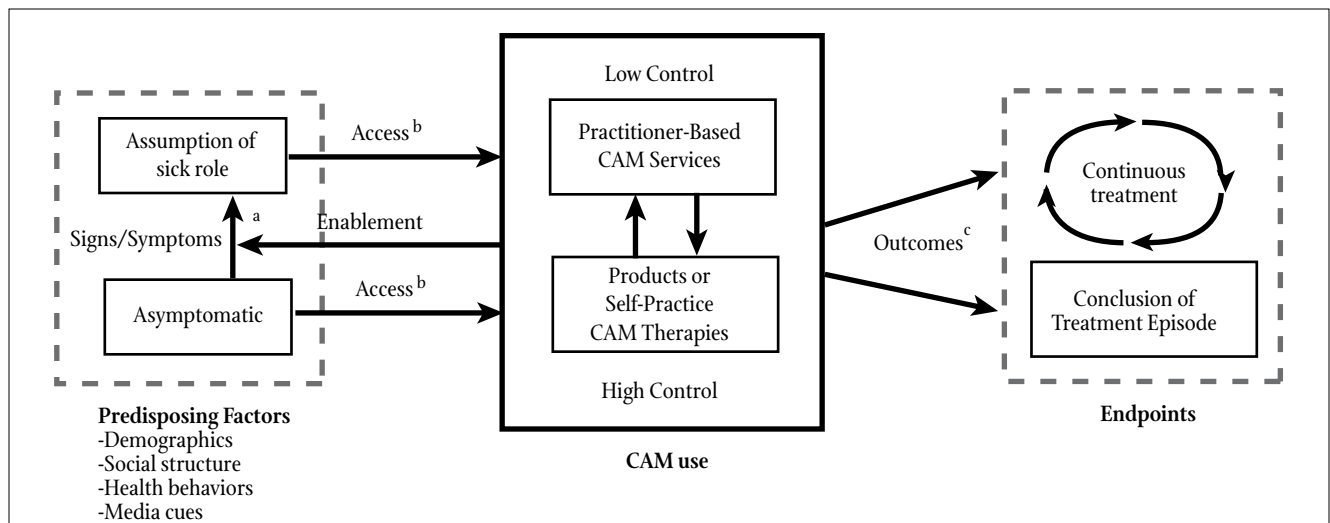


FIGURE Proposed Conceptual CAM Utilization Model

- a: Self-perceived health status; may be influenced by evaluated health status (enablement by CAM services)
- b: Access to CAM services; financial (income and health insurance), geographic, temporal, sociocultural, and physical
- c: Outcomes of CAM experience; effectiveness, costs, satisfaction/dissatisfaction with practitioner and experience

tions for the study of CAM: (1) factors added to predisposing, enabling, and need factors specific to CAM and (2) health services was expanded to include nonpractitioner-based therapies and products.^{20,21} Of particular relevance to our conceptual model was the impact of evaluated health status (diagnostics employed by health practitioners) on health service utilization.

THE CONCEPTUAL MODEL

Factors Pertaining to the Use of Complementary and Alternative Medicine

The proposed conceptual model describes the use of CAM and how the various factors influencing utilization may interact (Figure). A unique feature of our proposed model is that we delineate CAM services used as treatment for a specific medical condition vs for other reasons (asymptomatic use).³¹ The decision to make this distinction was influenced by the early sociological work of Parson and Suchman. Use of CAM while asymptomatic may include uses for prevention, general health maintenance, or mere curiosity. Therefore, the assumption of a “sick role” as described by Parson and Suchman does not necessarily have to occur in order to utilize CAM. Although seeking health care services asymptotically is not entirely unique to CAM (for instance, an individual may seek a general checkup under medical care), we theorize that the prevalence of asymptomatic use is higher among CAM therapies as CAM users are more likely to be philosophically committed to holistic values²⁹ and disease prevention.

However, individuals may transition into the “sick role” before using CAM services. An interesting point is that the transition to a “sick role” state is influenced by other factors that may accelerate or decelerate the transition process. This transition may be influenced by cues from the media and culture as described in Rosenstock’s Health Belief Model.³² For example, if an individual experiences aches from osteoarthritis and encour-

ters an advertisement suggesting that these symptoms are somehow abnormal and could be alleviated with a nutritional supplement, this may encourage the transition to the role of being sick, thus leading one to take action (ie, use the nutritional supplement). Additionally, this transition may be facilitated by interaction with a CAM practitioner. In this regard, the diagnosis, whether it is based on conventional diagnosis or on CAM philosophy and practice, may perpetuate the individual’s view of him/herself as sick and in need of health services. The CAM practitioner may legitimize the individual who has been rejected by the medical profession as a “malingerer.” This may be especially common for conditions such as low back pain, a common condition treated by CAM practitioners.³³ Such enablement by a CAM practitioner may promote and facilitate further care either intra- or interprofessionally.

Other factors, as in the Andersen Sociobehavioral Model, included in our conceptual model that predispose one to use CAM include (1) demographics (age, gender); (2) social structure (educational background, occupation, ethnicity, support of friends and family); and (3) health beliefs and behaviors. A recent systematic review of the characteristics of CAM users found that being female of middle age with a higher educational background are proclivities of CAM use⁷; however, many of the studies focused on different types of CAM services and products. We theorize that these factors may differ dramatically based on whether the individual uses CAM for treatment of a specific medical condition vs use for some other reason.

Access to CAM Services

A theoretical model to explain the use of CAM would be incomplete without addressing access to CAM services. Barton describes five dimensions to the access of health care services: (1) financial, (2) geographic, (3) sociocultural, (4) temporal, and (5)

physical.³⁴ Many studies investigating CAM use have uncovered that use is higher among more affluent populations, specifically with higher incomes.⁷ We define financial access to CAM services as the ability to pay for the CAM services or have access through a health insurance plan. The original version of the Andersen Sociobehavioral Model considers financial access as an enabling factor.³⁰ The ability to either pay directly for a CAM service (out-of-pocket) or indirectly through a health insurance premium will dictate an individual's use of CAM. A considerable portion of expenditures on CAM continue to be from out-of-pocket payments³⁵ despite a trend of increased coverage by government and private insurers.³⁶ The state of Washington serves as an interesting example; in 1996, private insurers covered CAM practitioner-based services, and consequently, a substantial portion of health insurance beneficiaries have used the service (in 2002, of 600 000 enrollees, 13.7% had made a claim for a CAM service).³⁷ The increase in access to CAM services has encouraged utilization by reducing the financial barrier. Among the uninsured, it is possible that a higher barrier of financial access to traditional medical care may lead an individual to seek a less expensive CAM service. Geographic access is having CAM services available in a given area. For instance, the number of chiropractors per county differs dramatically throughout the United States.³⁸ Undoubtedly, there will be areas where there is limited access to CAM services because services are not available in a given area. Conversely, access or lack of access to medical physicians may influence CAM use.^{39,40}

Access to CAM services may also be affected by personal sociocultural, temporal, and physical factors as well. Sociocultural factors include potential barriers in communication or rituals across groups. Temporal and physical factors relate to a patient's ability to see a CAM practitioner (for instance an appointment time conducive to one's work schedule) and physically have access to a practitioner's office.

Differentiation of Complementary and Alternative Medicine Services

The National Institute of Health's National Center for Complementary and Alternative Medicine (NCCAM) classifies CAM practices into five domains: (1) whole medical systems, (2) mind-body medicine, (3) biologically-based systems, (4) manipulative and body-based practices, and (5) energy medicine.⁴¹ The five domains as described by NCCAM differentiate CAM services by mechanism of action which is applicable for directing study; however, the NCCAM system may not be feasible parameters for studying CAM utilization.

We separate CAM practices into two categories, either practitioner-based products or services (eg, chiropractic, acupuncture, massage therapy, osteopathy, Reiki practitioners) and self-practice CAM therapies. Self-practice therapies include products such as natural supplements (megavitamins, herbals, and minerals) as well as self-practice CAM activities such as yoga, meditation, and deep breathing. Our decision to separate CAM practices in this fashion is based on the process of selecting a CAM therapy. In other words, a patient's decision to either self-

treat with a CAM product or therapy is very different than a decision to consult a CAM practitioner. Previous authors have suggested the creation three categories of CAM: (1) CAM providers, (2) CAM products, and (3) self-practices.²¹ Although it could be argued that a CAM product is dissimilar to self-practice therapy such as yoga, our rationale in combining these into one category stems from control to self-treat using the modality. The difference in either self-treatment or consulting a CAM practitioner may be based in part on perception of control.

The "locus of control" concept is a psychological theory that differentiates individuals who perceive having greater control over their actions and fate (high internal locus of control) vs those individuals who perceive lower personal control (high external locus of control).⁴² Thirteen different cross-sectional studies have examined CAM vs non-CAM users' locus of control metrics with little consistency of findings.⁸ In these studies, definitions of CAM varied, and perhaps an interesting study would be to compare users of different service types within the CAM realm. We illustrate the gradient between our two categories of CAM therapy based on perceived control in our model; we theorize that CAM users with a high internal locus of control are more likely to utilize CAM products or self-practice therapies as opposed to practitioner-based CAM services.

We describe the two categories of CAM as potentially impacting each other's use. For example, a CAM practitioner may recommend either a CAM product or self-therapy intervention.

The Endpoints of Complementary and Alternative Medicine Use

The two ultimate endpoints of CAM use are either the conclusion of treatment or the continuation of treatment. The concept of continuous treatment is in part a unique aspect of CAM services. Continuous treatment may occur in the case of CAM use as a preventive modality or as ongoing symptom relief for a chronic condition.

The divergence between the two ultimate endpoints of care is dictated by the individual's personal characteristics and health status, as well as the outcomes of the CAM experience (the perceived effectiveness of addressing their personal goals, the associated costs, and satisfaction with CAM). In cases where treatment is concluded for a specific treatment episode, the experience with CAM will then in turn influence future use of CAM services.

FUTURE USES OF THE CONCEPTUAL MODEL

Our proposed conceptual model may serve as a reference for future CAM education as well as help direct future research inquiry. The paradigms used to describe medical service utilization in public health texts and the health sociology literature are not necessarily applicable to CAM use. The proposed conceptual CAM utilization model is aimed at describing the unique ways in which individuals come to use CAM, the interaction of different CAM practices, and the ultimate endpoints. Although the model is subject to future changes, it provides an initial framework to conceptualize CAM utilization and potentially form more quantitative models.

Informal review of our conceptual model suggests a number of new areas of new CAM inquiry. These may include (1) investigation of the sociodemographic characteristics of individuals who use CAM either for medical condition management vs those who use CAM for other reasons, (2) examination of the impact of the media as a driver of CAM use, (3) investigation of CAM practitioner treatment enablement, (4) investigation of the relationship between use of CAM practitioners and CAM products or self-treatment therapies, (5) examination of personal locus of control based on the type of CAM use, and (6) evaluation of the factors that result in continuous CAM treatment.

However, there exist a number of inherent limitations of our conceptual model. First, our model demonstrates potential linear relationships of factors related to CAM use based largely in theory. Some authors argue that linear paradigms to explain health service utilization altogether are flawed, as human behavior might best be explained using chaos theory.⁴³ Second, our model does not predict or quantitatively measure CAM use. Lastly, our model is focused on CAM utilization and neglects to incorporate the impact of concurrent medical care or referral to CAM practices by practitioners of conventional medicine.

As CAM health services research further develops, a conceptual model that describes CAM use may be valuable. We propose a conceptual model that combines prominent sociologic and psychological theories that specifically addresses the unique aspects of CAM use, which may help direct future research and educational activities.

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An Examination of CAM Journals in the Journal Citation Reports

Matthew A. Davis, DC, MPH

Background • During the last decade, research on complementary and alternative medicine (CAM) has grown substantially. Few studies have investigated the quantity and impact of peer-reviewed complementary and alternative medicine publications longitudinally.

Objective • To quantitatively examine peer-reviewed CAM publications in the Journal Citation Reports from 2000 to 2008.

Design and Setting • We performed descriptive analyses of journals in the “integrative & complementary medicine” subject category published in the annual Journal Citation Reports by Thomson Reuters from 2000 to 2008. For comparison, we also extracted data from journals in the “general internal medicine” (GIM) subject category for each year.

Primary Outcome Measures • Annual total number of articles

published, total citations, and journal impact factor.

Results • The number of CAM journals increased from seven to 13, and consequently, the total number of articles published in CAM journals doubled from 2000 to 2008. During the 9-year time span, the total citations of CAM journals increased by 488%, and the mean journal impact factor of CAM journals increased from 0.71 to 1.60. Although the mean journal impact factor of GIM journals was twice that of CAM journals, the median journal impact factors were similar between CAM and GIM journals.

Conclusion • The number of peer-reviewed CAM journals and cites in the Journal Citation Reports has increased significantly during the past decade. However, there remain a small number of journals specifically devoted to CAM research. (*Altern Ther Health Med.* 2011;17(5):38-42.)

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During the last decade, the use of complementary and alternative medicine (CAM) has grown,¹ and as a result, so have CAM research activities. In 1998, the Office of Alternative Medicine was reestablished as the National Center for Complementary and Alternative Medicine (NCCAM). NCCAM, a member of the 27 institutes/centers that comprise the National Institutes of Health, provides funding opportunities for research on CAM and trains CAM researchers.

NCCAM’s budget for 2010 was \$128 844 000.² Research opportunities via NCCAM and other funding agencies have likely resulted in an influx of research publications in the biomedical literature, but few studies have investigated this quantitatively.

Measuring the influence of peer-reviewed publications is a challenge. Despite its shortcomings,^{3,4} the journal impact factor (IF) is often used as a surrogate measure of journal quality and influence by librarians and researchers alike. There are over 16 000 peer-reviewed journals and over 1.5 million peer-reviewed articles published annually, and therefore librarians must choose which journals to purchase^{5,6}; journal IF has historically been used as part of this process. Additionally, researchers consider a journal’s IF when deciding where to publish their work. The journal IF is defined as the average number of times an article from the past 2 years is cited in the current year.³

We sought to examine CAM publications in the Journal Citation Reports (JCR) quantitatively from 2000 to 2008, the same time period that CAM research funding increased significantly.

METHODS

Data Source and Study Design

Thomson and Reuters’ Institute for Scientific Information

(ISI) publishes the JCR annually. Journals are selected by ISI for inclusion in the JCR via a formal evaluation. The journal selection process for the JCR is based on journal citation data, adherence to publication standards, and expert opinion.⁷ Given the large number of journals published, it is not economically feasible to collect data on all journals. Through the selection process, the ISI attempts to capture the most influential journals in the JCR analyses. The JCR allows researchers to use these data for study such as this report (personal communication, Maria Logo, March 2010).

In 2000, the JCR included a subject category called “integrative & complementary medicine.” We used this subject category to identify CAM journals (Table 1) in the JCR. However, from 2000 to 2008, the journal *Altex: Alternatives to Animal Experimentation* was included in this subject category. Considering this journal is unrelated to CAM, we excluded this

journal from our analyses.

For comparison purposes, we also extracted data on medical journals using the JCR subject category “medicine general & internal” (GIM). Upon review, we discovered that *The American Journal of Chinese Medicine* was in both the GIM and CAM subject categories. We decided to only include this journal in the CAM subject category.

We extracted data on journal IF, total articles, total citations, and the immediacy index for CAM and GIM journals from the JCR for each year from 2000 to 2008. Total citations is the total number of times articles from a journal are cited by other publications in the given JCR year. For instance, in 2000, articles from the journal *Alternative Therapies in Health and Medicine* were cited 165 times. Immediacy index is the average number of times an article is cited in the year that it is published.³ It is believed to be a measure of the urgency of work

TABLE 1 Complementary and Alternative Medicine Journals by 2008 Impact Factor and Percent Change in Impact Factor from 2000 to 2008.

| CAM Journal* | ISSN | Country | Issues per Year | 2008 Impact Factor | Percent Change in Impact Factor from 2000 to 2008 |
|---|-----------|----------------|-----------------|--------------------|---|
| <i>Alternative Medicine Review</i> | 0360-1293 | United States | 4 | 2.81 | -- |
| <i>Integrative Cancer Therapies</i> | 1534-7354 | United States | 4 | 2.26 | -- |
| <i>Journal of Ethnopharmacology</i> | 0378-8741 | Netherlands | 18 | 2.26 | 74.6 |
| <i>Alternative Therapies in Health and Medicine</i> | 1078-6791 | United States | 6 | 2.25 | 60.9 |
| <i>Evidence-based Complementary and Alternative Medicine</i> | 1741-427X | United Kingdom | 4 | 1.95 | -- |
| <i>Complementary Therapies in Medicine</i> | 0965-2299 | United States | 6 | 1.84 | -- |
| <i>The Journal of Alternative and Complementary Medicine</i> | 1075-5535 | United States | 12 | 1.63 | 24.3 |
| <i>Forschende Komplementarmedizin</i> | 1021-7096 | Switzerland | 6 | 1.15 | 74.0 |
| <i>Journal of Manipulative and Physiological Therapeutics</i> | 0161-4754 | United States | 9 | 1.10 | 15.6 |
| <i>The American Journal of Chinese Medicine</i> | 0192-415X | Sigapore | 6 | 1.06 | 44.9 |
| <i>Homeopathy</i> | 1475-4916 | United States | 4 | 1.04 | -- |
| <i>Explore</i> | 1550-8307 | Netherlands | 6 | 0.71 | -- |
| <i>Acupuncture and Electro-Therapeutics Research</i> | 0360-1293 | United States | 4 | 0.69 | 35.8 |

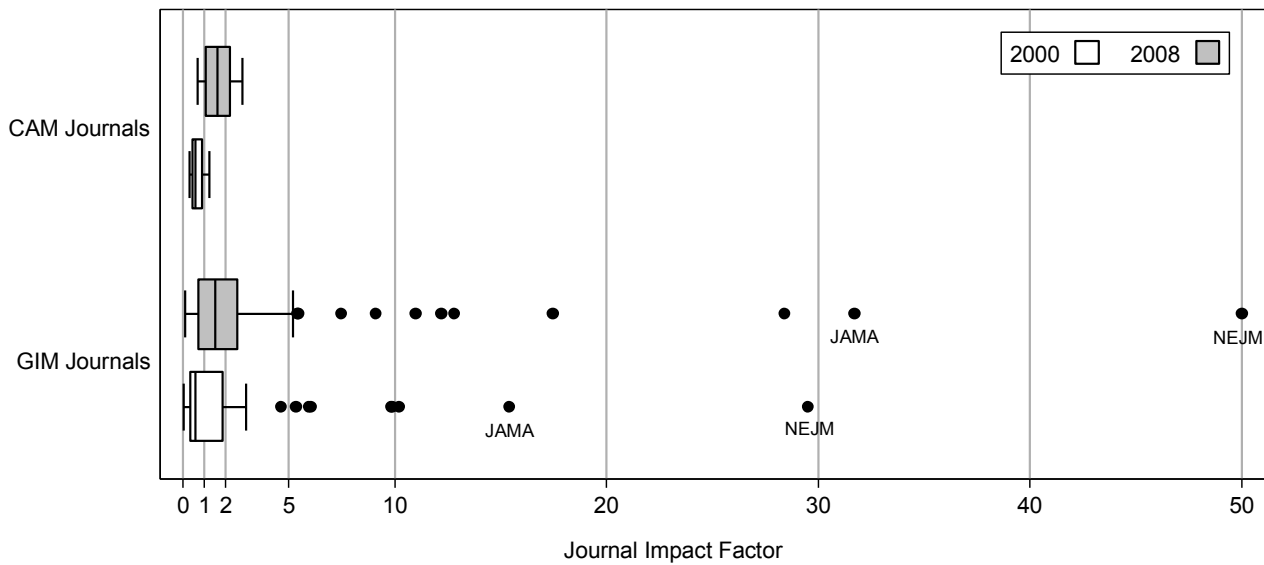
* The journal *Altex: Alternatives to Animal Experimentation* was not include in this data but is included in the Journal Citation Report® in the CAM category
Abbreviations: CAM, complementary and alternative medicine, ISSN, international standard serial number

TABLE 2 Complementary and Alternative Medicine versus General/Internal Medicine Journals in 2000 and 2008.

| | 2000 | | 2008 | | Percent Change from 2000 to 2008 | |
|----------------------------|---------------|--------------|---------------|--------------|----------------------------------|--------------|
| | CAM Journals* | GIM Journals | CAM Journals* | GIM Journals | CAM Journals* | GIM Journals |
| Total Journals | 7 | 104 | 13 | 106 | 85.7 | 1.9 |
| Total Articles | 518 | 14,055 | 1,034 | 13,812 | 99.6 | -1.7 |
| Total Articles per Journal | | | | | | |
| Mean | 74 | 135 | 80 | 130 | 7.5 | -3.6 |
| Total Cites | 3,279 | 570,161 | 19,283 | 873,621 | 488.1 | 53.2 |
| Total Cites per Journal | | | | | | |
| Mean | 468 | 5,482 | 1,483 | 8,242 | 216.7 | 50.3 |
| Impact Factor | | | | | | |
| Mean | 0.71 | 1.71 | 1.60 | 3.19 | 126.1 | 86.9 |
| Median | 0.58 | 0.59 | 1.63 | 1.52 | 179.2 | 158.5 |
| Immediacy Index | | | | | | |
| Mean | 0.15 | 0.41 | 0.24 | 0.87 | 52.7 | 110.9 |
| Median | 0.07 | 0.12 | 0.21 | 0.29 | 210.6 | 155.7 |

* The journal *Altex: Alternatives to Animal Experimentation* was not include in this data but is included in the Journal Citation Report® in the CAM category
Abbreviations: CAM, complementary and alternative medicine, GIM, general/internal medicine

FIGURE 1 The Distribution of Complementary and Alternative Medicine versus General/Internal Medicine Journal Impact Factors in 2000 and 2008.



Abbreviations: CAM, complementary and alternative medicine, GIM, general/internal medicine, JAMA, *Journal of the American Medical Association*, NEJM, *New England Journal of Medicine*

published by journals as, compared to IF, it includes only citations within the same year of publication.

ANALYSES

All descriptive analyses were conducted using STATA version 10.0 statistical software (College Station, Texas). We reported the total articles, total citations, and mean and median IF for CAM and GIM journals in 2000 and 2008 reported in the JCR. We also examined the distribution of IF among CAM and GIM journals and the change from 2000 to 2008.

RESULTS

In 2008, the journal *Alternative Medicine Review* had the highest journal IF (2.81) among CAM journals (Table 1). The journals *Journal of Ethnopharmacology*, *Alternative Therapies in Health and Medicine*, and *Forschende Komplementarmedizin* had the most significant growth in IF (between 61% and 74%) over the 9-year time span.

The total number of CAM journals in the JCR nearly doubled from 7 in 2000 to 13 in 2008, and the total number of articles published in CAM journals grew from 518 in 2000 to 1034 in 2008 (Table 2). Interestingly, the total number of CAM journal citations grew by a 488% (or 16 004 citations) whereas GIM total citations grew by 53% (or 303 460 citations) over the 9-year time span.

The mean IF of CAM journals increased 126% from 0.71 to 1.60 while the mean IF of GIM journals increased by 87%.

While the mean IF of GIM journals was higher than that of CAM journals (the mean IF of GIM journals was 3.19 compared to 1.60 for CAM journals in 2008), the median IF of GIM in both 2000 and 2008 approximated that of CAM journals. General internal medicine journals had a skewed distribution of IFs that appeared to increase from 2000 to 2008 (Figure 1).

Incrementally, number of total citations of CAM and GIM journals increased significantly from 2000 to 2008. The total citations of CAM journals grew from 3279 in 2000 to 19 283 in 2008 (488%) (Figure 2, left y-axis), whereas the total citations of GIM journals increased from 570 161 in 2000 to 873 621 (53%) (Figure 2, right y-axis). The mean increase in CAM journal citations was 2001 (19.5% per year), and the mean increase in GIM total citations was 37 933 (5.2% per year).

DISCUSSION

Main Findings

The total number of CAM publications in the JCR nearly doubled over the 9 years we examined, whereas the number of GIM publications increased by only 2%. The most dramatic growth was in the total number of CAM journal citations (488%) compared to GIM journal citations (53%). The mean IF of GIM journals was higher than CAM journals; however, the median IF of GIM journals approximated that of CAM journals. The higher mean IF of GIM was due to a small number of high impacting journals (eg, *The New England Journal of*

Medicine and the Journal of the American Medical Association) that resulted in a skewed journal IF distribution.

IMPLICATIONS

Our study reaffirms that CAM research has grown over the past 9 years as is evident by both the total number of CAM journals and their total citations as per the JCR. Considering this growth in direct and indirect expenditures related to CAM research, the outcomes of these efforts should be measured to determine the effects of ongoing CAM research on the US health care system.

In 2008, the CAM journal *Alternative Medicine Review* had the highest journal IF (2.81). Interestingly, this journal is owned by Thorne Research, Inc (Dover, Idaho), which is a large manufacturer of natural dietary supplements. Many of the articles in *Alternative Medicine Review* are review articles of natural dietary supplements. Review articles are more commonly cited,⁴ and this may account for the large number of cites and high journal IF of *Alternative Medicine Review*.

Our study begs the question: Where do we draw the line between CAM and GIM? The growing use of CAM has resulted in a large amount of CAM research, and this research is published in both CAM and GIM journals. From 1966 to 2009, there was a total of 462 000 articles published under the MEDLINE Medical Subject Heading “Complementary Therapies.”⁸

CAM researchers must choose whether to submit their research to either a CAM or GIM journal, and this is likely influenced by the researcher’s intended readership. Although competitive, high-impact GIM journals receive broad readership, and therefore CAM publications via these outlets may have a bigger impact on future health care policy and research.

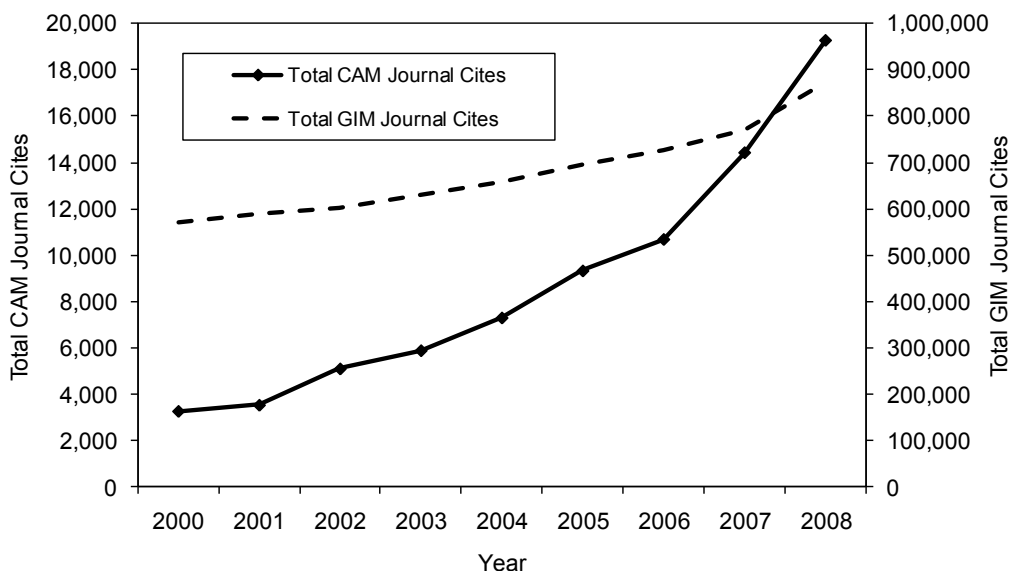
Perhaps, as CAM research becomes more mainstream, CAM and GIM publications will become even more intertwined.

STUDY LIMITATIONS

There are three specific limitations of this study that must be acknowledged. First, this study only examined CAM journals included in the JCR. Therefore, our findings likely underestimate the quantity of CAM publications. It is not uncommon for CAM articles to be published in GIM journals. Also, the JCR includes the more common CAM journals, but other non-JCR indexed CAM journals were not included in our study. For instance, the databases Manual, Alternative, and Nature Therapy Indexing System and Allied and Complementary Medicine include considerably more CAM journals than are recognized by the JCR. In MEDLINE, there are 36 CAM journals indexed, and there are 46 CAM journals in the SCImago Journal Rank and Country⁹ database. However, previous research suggests that the most influential research is conducted by a few journals in a given field.¹⁰ The JCR attempts to identify and report on only the most influential journals to capture the majority of research activity.⁷ For instance, of the 7500 journals included in the 2005 JCR, as few as 300 journals accounted for 50% of the total citations.¹¹ Nevertheless, the total number of CAM journals is significantly higher than the estimates in this report, and therefore the total CAM journal citations are likely higher as well. In addition, our analyses were subject to any inaccuracies or missing data that may have occurred in the JCR data.

Second, the data did not describe the type of journal articles published. The growing interest in CAM is evidenced by the large increase in citations and articles published. The JCR data does not describe the type of articles published, so we

FIGURE 2 Total Annual Cites for Complementary and Alternative Medicine versus General/Internal Medicine Journals, 2000 to 2008.





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were unable to determine proportion of research vs commentary/review articles published on CAM.

Third, as a measure of journal influence and quality, we used journal IF. Although journal IF is commonly used by librarians and researchers, it has specific limitations that must be considered. Journal IF has been criticized as it (1) is restricted to ISI algorithms and indexing, (2) tends to favor publications published in English, (3) does not account for negative citations, and (4) may not account accurately for citing behaviors across subject areas.³ In the future, other perhaps more accurate measures of journal quality and influence may develop; however, journal IF remains a common measurement.

Despite the inherent limitations of the JCR data, this study does provide some quantitative evidence of the increase interest in CAM in the biomedical literature and the characteristics of influential CAM publications.

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Haitian Vodou as a Health Care System: Between Magic, Religion, and Medicine

Nicolas Vonarx, PhD

Haitian vodou has been considered an African-American religion organized around a pantheon, sanctuaries, priests, fraternities, and rituals honoring the spirits (*lwa*), the dead, and the ancestors. This construction of vodou, which is predominant in the literature, is based on a substantive approach to religion. It obscures the close connections between vodou and illness and does not adequately reveal how vodou is used in the daily lives of Haitians. By adopting a microsocal perspective on vodou and focusing on the knowledge and practices of vodou practitioners, the importance of vodou's therapeutic dimension becomes clear. Indeed, I am compelled to conclude that vodou is a health care system. Grounded in 16 months' research in the Haitian countryside and using a definition of health care systems identified in the medical anthropology literature, this new

way of approaching vodou situates its religious and magical dimensions within its role as a health care system. This article deals with these different aspects, addressing the criteria that make vodou a health care system. In particular, I explore the practitioners who are recognized as healers and consulted as such; the sites where practitioners meet with the sick and treat them; the vodou theories on illness; and the curative, preventive, and care-giving practices based on those theories. This approach helps us to better understand how medicine, religion, and magic are linked in Haitian vodou and leads us back to debates about the construction of vodou, which are apparently well known in the scientific literature. All of this leads us to reflect on Western approaches to healing and caring. (*Altern Ther Health Med.* 2011;17(5):44-51.)

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Religious spaces often serve as therapeutic sites where the sick go to seek help in managing illness and other misfortunes. Research concerning the functional aspects of religions commonly refers to their therapeutic and preventive dimensions, evident in the popularity of certain pilgrimages and certain religious movements that emphasize illness management—often defined as healing religions and healing churches.¹ This functional aspect of religion is present in Haitian vodou, since its practitioners (*oungan*) are consulted as healers in the same way as are other Haitian Creole or biomedical therapists. The therapeutic dimension of vodou, however, is neglected in the literature, which focuses on vodou as an African-American religion organized around a pantheon, sanctuaries, fraternities, priests, and rituals honoring the spirits (*lwa*), the dead, and the ancestors. In the substantive approach generally taken to vodou as a religious phenomenon, one of its essential functions on the Haitian social landscape is disregarded. More specifically, by focusing unduly on the elements that make up the religion, researchers have tended to distance themselves from the field of experience and are therefore hindered in their understanding of vodou and its place in Haiti.

A microsocal approach to vodou practices and to Haitians' relationship to vodou can help to overcome the limitations and flaws of this more common approach. In adopting a microsocal perspective, the importance of vodou's therapeutic dimension becomes clear, particularly when one observes the annual rituals of vodou practitioners, collective rituals at the family home and lands (where the grandparents lived), and practices that take place at pilgrimage sites. Here, as a cult of *lwa* and ancestors, based on advantageous contracts and exchanges with such entities, vodou becomes a locus for seeing and sharing suffering, the problems of daily living, treatments, and the search for greater well-being. Such rituals are good opportunities for dealing with health and illness, since practitioners can obtain favors from invisible forces and ensure the effectiveness of practices that address a broad array of issues. Rituals are an appropriate time to plan treatment for patients, to prepare protective baths, to put the ill in contact with *lwa* (who appear through the act of possession), or to endow objects with curative or preventive powers. Even more, in this perspective, vodou can be looked upon as a health care system.

In this article, I will demonstrate the above, using data gathered during 16 months of anthropological research on vodou in Haiti. I suggest that vodou is part of the field of ethnomedicine and that it meets criteria used in medical anthropology to define traditions of care. More precisely, I describe the organization of

¹*Labitasyon* in Haitian language.

this health care system and the logic underlying that way it manages illness, emphasizing that the connections between vodou and illness are still poorly understood.

THE RELATIONSHIP BETWEEN VODOU AND ILLNESS

Health and illness are the core of Afro-Caribbean religions, particularly Cuban *Santería*,² Brazilian *Candomblé*,³ and Haitian vodou, which constitute sites where practices often involve the prevention and treatment of illness. According to Conway,⁴ Laguerre,⁵ and more recently, Brown,⁶ who has studied Haitian Vodou in the United States, illness management is the most important aspect of vodou. Researchers at KOSANBA, a North American association that studies Haitian vodou, state that the only person who has written about the medical aspects of vodou is Max Beauvoir (Bellegarde-Smith and Michel 2006),⁷ a vodou practitioner who presents vodou as an energy medicine and presents details concerning the phytotherapeutic aspects of remedies practitioners give to the sick (see Beauvoir 2006).⁸

To be fair, authors who have written about the connections between vodou and illness have suggested that vodou can be a last resort in the health-seeking process⁹ or a form of knowledge used to give meaning to illness.^{10,11} Other authors have taken a greater interest in such connections, discussing vodou in the field of mental health, particularly the pathological aspects of trance and possession¹² or the positive aspects of such phenomena.^{13,14} Vodou beliefs have also been considered as factors that predispose to mental illness,^{15,16} and its practitioners have been identified as culturally rooted therapists who may be effective where Western psychiatrists are not.^{17,18}

When all is said and done, I must agree with Bellegarde and Michel⁷ that we do not know much about vodou practices related to illness. Métraux is the only author to have provided first-hand or second-hand empirical data on the subject. Still considered to be the specialist of Haitian vodou, Métraux published a well-documented text about the “medical function” of vodou.¹⁹ It is the only ethnographic source containing details on illness categories in Haiti, their diagnosis, and their etiology with a few descriptions of therapeutic practices as well as real cases of vodou treatments. However, the observations are only a few pages long, briefly describe a treatment for someone afflicted by souls, and provide some diagnostic techniques.

The conclusions drawn by Laguerre²⁰ on the lack of understanding about vodou are still true today. Twenty years later, the same remark can be made. Although much has been written about vodou, we still know very little about how *oungan* care for the sick, the knowledge they use to cure and treat illnesses, and their practices for dealing with illness.

RESEARCH OBJECTIVES AND DATA COLLECTION

I have tried to fill these gaps and better understand the responses vodou practitioners give to those who consult them when faced by illness. My research on vodou was focused on its practitioners, sites of activity, knowledge, and practices as they appeared in illness episodes. My research objectives were to analyze

- vodou’s role within a medico-religious social landscape made up of different caregivers and therapeutic traditions;
- the supervision and treatment provided by practitioners to those seeking care; and
- how the knowledge, practices, and discourses of vodou practitioners are mobilized in illness episodes.

To do so, I spent 16 months (4 in 1998, 4 in 1999, and 8 months in 2002 and 2003) in a rural Haitian district where we gathered data using interviews and observations. In the course of fieldwork, we spent time with vodou practitioners and lived daily in the world of small farmers. I visited various places where the ill go to be treated so that we could meet care-seekers and weave a web of relations that would enable us to follow them along their therapeutic itineraries. Since my object of study was magico-religious and therefore strongly stigmatized and historically condemned in Haiti and because the practices that interested us were private and covert,²¹ I had to become close enough to both the practitioners and their patients to be able to observe practices and for people to feel free to speak.

Individual and group interviews were used to identify the different stages in people’s health-seeking process, to gain an in-depth knowledge of the practices used by vodou practitioners, to identify their discourse on illness, to grasp the dynamics and relationships between different therapists and to obtain information on the Haitian medico-religious landscape and the features of each treatment sector. Individual interviews were carried out with both sick and healthy people. I conducted 39 individual interviews with 21 vodou practitioners and met regularly with six of them. In an effort to document the Haitian medico-religious landscape, we conducted over 20 interviews with other therapists from Creole medicine, biomedicine, and healing churches. Finally, 20 interviews with individuals well acquainted with vodou (a drummer, a person who washes the dead, elders, assistants to vodou practitioners, graveyard keepers, and participants in vodou rituals) helped to fill any gaps in our understanding.

All the data gathered during the research were analyzed using NVivo software (QSR International [Americas], Inc, Cambridge, Massachusetts), which helped me to conduct a content analysis oriented by my research objectives.

FINDINGS

Data analysis was guided by the themes derived from the objectives described above. The analysis has pointed to certain content and functions used to define medical systems and ethnomedicines in the field of medical anthropology.²²⁻²⁴ By content, I refer to knowledge relating to illness, to a worldview, to preventive and therapeutic practices, to techniques, materials, skills, ways of learning, spaces of care, and therapists organized within a specific medical tradition for a group of people. By functions, I mean that the content offers a cultural construction of illness, provides elements for explaining and classifying illnesses, proposes therapeutic practices, gives indications for obtaining treatment, suggests preventive behavior, and manages death, chronic

illness, and treatment outcomes.²⁵

Identified and documented with empirical data, these functions and content clearly suggest that Haitian vodou is a health care system. I mean first that it's organized, coherent, and socially and culturally embedded in a given society. Second, it is made up of (a) practitioners recognized as healers and consulted as such; (b) treatment sites where practitioners meet with the sick, treat them, and suggest ways of dealing with their problems; and (c) practices, techniques, protocols, and specialized knowledge that are learned and shared by healers and are used to foster health, treat disease, and prevent illness. Third, vodou offers theories on illness, as a health care system does. Fourth, it plans therapeutic, preventive, and care-giving practices in keeping with those theories. And finally, it suggests behavior for preventing illness.

The Vodou Practitioner as Therapist

By emphasizing the circumstances that lead some Haitians to become vodou practitioners, I understood that they first become therapists and only later leaders in a religious cult. Many felt they were chosen or forced by circumstances to become vodou practitioners, in conjunction with an event in which they were chosen, elected, or called by *lwa*. In most cases, the event involved ending an experience with illness. Most often, it was the chosen person who fell ill and had to seek treatment. The illness was interpreted as the action of a *lwa* who was asking the sick person to make a commitment to be its servant. This was the case of Josephine, a practitioner who fell ill at the age of 12 and was told by a *lwa* who regularly possessed her grandmother that she had been chosen. After Josephine had been dressed in a black robe, offerings had been prepared, and she had been possessed by the *lwa* in question, she was healed. When she later converted to Pentecostalism, she became sick again. Although the congregation prayed for her, she tore her clothes off in public, yelled, and shouted obscenities in church. She was taken away to her home where she was delivered from her illness following a dream. In the dream, two old men asked her to build a house of worship for them. They rubbed her body with saliva and gave her a remedy. A third person who appeared in the form of an ox gave her food. When she awoke, she was healed, to the astonishment of those watching over her. She answered the call of the *lwa*, who then told her how she was to honor them and to enter into relationship with them.

The process of becoming a practitioner is complex, filled with hesitations, perpetual negotiations, and small events that most often are interpreted only in retrospect. Julio, an *oungan*, is a good example of this process.

At the age of fifteen, Julio was sick and was taken to prayer groups. He suffered from a sexually transmitted disease and a fever. One day during prayer, an old man with a white beard came to him in a dream. He led him to a mango tree and to a spring to light a candle and call a *lwa*. When he awoke, Julio remembered the details of the practice and how to appeal to the *lwa*. As soon as he told his dream to some other people, he was immediately possessed and made a divination. His relatives

asked him to stop such activities and to go to church to pray for healing. He did so until the day a *lwa* took possession of him on his way to church and led him to his family lands. His disease worsened over the course of a year, to the point that he was urinating blood and had to return to hospital. The treatment, however, was ineffective. Then, a woman appeared to him in a dream, laid her hands on him, and gave him injections. She told him that she was curing him and asked him to leave the church. He gradually got better. At the same time, a vodou practitioner asked him to become her assistant. As he was assisting her, he was possessed and later became a vodou practitioner, certain of his intimate connections to *lwa*.

Thus, Julio had to be distanced from certain religious activities and exhausted of the medical-religious resources that were morally acceptable for a Christian convert before he could answer the call of *lwa* that could heal him. He also needed the combination of revelations and unexpected encounters to guide him along the path that he was destined to follow. In this story, Julio was not responsible for the choice to become a vodou practitioner; rather it was the *lwa* who took possession of him, showed themselves, and took no account of the religious commitments of their future servant. In other words, the power of *lwa* is much stronger than the choices, ambitions, and interests of individuals. Quite simply, they cannot be resisted.

As we can see, the life trajectories of many vodou practitioners have led them through illness and healing to their calling. Practitioners state that they never decide to embrace vodou practices and that they are always influenced, indeed compelled, by outside forces to do so. Illness is therefore a very important event on their path to vodou, and healing is always the result of an acceptance of vodou, even if practitioners say that they tried to stay away from it. Healing depends on a proximity to vodou and an official commitment to the *lwa*. The involvement of the sick in operations undertaken on their behalf is an absolutely necessary condition, as it immerses the individual in a complex mechanism of actions. This personal experience is what makes a practitioner a therapist. It gives him (or her) the ability to deal with matters of illness since it is through healing that practitioners gain knowledge and commit to the *lwa*. In other words, practitioners can now do for others what they succeeded in doing for themselves by showing their skills as healers capable of treating a type of sickness and by putting their powers at the service of the community that recognizes them in this role and goes to them for that reason. Practitioners therefore appear first as therapists and later capitalize on their magico-religious knowledge through a contract, a privileged relationship, and exchanges with *lwa*. I understand now why Conway said in 1978 that "The most important aspect of Vodoun, one which underlies even its familial aspect, is the explanation and treatment of illness"²⁴ and cited Murray to assert that

The houngan has had many faces in Haitian history. But of these many faces, the houngan of . . . Kinanbwa is first and foremost a healer, and the major manifest function of the entire vodou cult in the research region is the prevention, diagnosis, and healing of illness. If

one had to sum up domestic vodou in a sentence, it would have to be described as a folk-medical system.^{4,26}

A Vodou Topography for Managing Illness

As therapists, practitioners plan a set of practices related either directly or indirectly to illness. Some of them are explicitly therapeutic or preventive. Others are intended to give the therapists medical knowledge and to maintain good relations with their invisible allies in order to fulfill the requests of both healthy and sick persons who come for consultations. All practices are carried out in places that are visited for specific reasons and compose a vodou topography. In this topography, the main sites are the practitioner's private place (*badji*), the crossroads, the graveyard, and the family home and lands, which appear regularly in illness management.

The Practitioner's *Badji*. The main site for practices is the *badji*, which is usually located in the *oungan's* yard. It is often identified by flags floating at the end of long poles or by other elements of vodou that mark the site, such as symbols of *lwa* painted on the walls, crosses in the courtyard, and tree altars for *lwa* with revealing objects on them. In the impoverished countryside, the *badji* may consist of a single room and an outdoor space defined by a leaf-covered arbor that serves as a ritual space. But the apparent simplicity of a *badji* may conceal a complex set-up and construction, either under or above ground, for entertaining *lwa* and providing an arsenal of forces needed for the practitioner's various tasks.

The public ceremonies organized annually by practitioners or at the request of *lwa* generally are held inside the *badji*, but most of all, it is in this private space that people go to consult the practitioner. The *badji* is where practitioners call on their *lwa* and interpret situations for which they are consulted. People may come for themselves or for a relative. The procedures of consultations are often the same. They begin with a call to the *lwa* with libations of *kleren*² brought by the patient and an oral request. As a result of these actions, the practitioner is possessed by a *lwa*. In some cases, a simple greeting signals the presence of the invisible entity. In other cases, the practitioner's voice changes (speaking with an accent, for instance), and he or she may enter a trance prior to becoming possessed and may make jerky movements. Once greetings have been exchanged, the reasons for the visit are discussed. This time, the *oungan* uses a support for divination, such as playing cards, a book, a hand palm, or a candle flame. Once the diagnosis has been made and the treatment has been negotiated, the first stage in the treatment is organized in the *badji*.²⁷

The Crossroad and the Graveyard. Vodou therapeutic practices may also be conducted at a crossroad, an essential place for mobilizing magical forces on account of *lwa* who reside there. Practitioners go to crossroads after dark to conduct some of their activities. A crossroad is a place for meeting with the supernatural world, an intermediary space between the visible and the invisible, a between-worlds, a passageway for all, innocuous in

the daytime yet reserved for vodou practices at night. Therapists go there to get handfuls of earth for remedies; they leave elements that can cause misfortune and send agents that can cause illness. Crossroads are the home of *lwa Mèt Kalfou* (crossroad master) who gives access to the invisible world of *lwa* and who is called on by therapists wishing to use their powers. *Mèt Kalfou* is essentially an interlocutor, a sort of "police officer," who is told of one's intentions, consulted for permission to pass, and called on to ensure the success of an undertaking.

Graveyards are also important places because of those who live there, particularly *lwa Baron Samdi*, master of the necropolis and owner of the souls of the deceased. If a person wishes to use a soul to bring sickness and death on another or to treat a person who has been affected by one, it is the *lwa Baron Samdi* to whom one must turn. As the *lwa* governing the dead, *Baron Samdi* is best for dealing with affairs connected to death since he has the last word regarding any requests or actions related to it. Graveyards and their occupants are therefore needed for treating illness, as well as for gathering materials considered by the laws of sympathetic magic to have healing properties that may be used to prepare remedies. Lastly, graveyards are used to prevent misfortunes by making offerings to the dead so that they not trouble the lives of the living.

The Family Home and Lands (*Labitasyon*). As in the places mentioned above, vodou practices related to illness may be carried out at the family home and lands because, as private places, they contain not only houses and granaries but also the invisible. *Lwa* live in certain trees, springs, pools, and all entrances. Along with ancestors who lived in the dwelling, they can influence the fate and daily lives of the inhabitants and their descendants, and they can bring either illness or healing. In order to control their influence or to solve a problem that the practitioner has identified as being the action of family *lwa* or disgruntled ancestors, family members take part in symbolic exchanges, create ties, and maintain a space for worship at the family home and lands, witnessing a family dimension of vodou discussed by Herskovits,²⁸ Simpson,²⁹ Métraux,³⁰ and Lowenthal.³¹ Good health and illness are therefore evidence of this transgenerational mechanism for mediating relations, which shifts according to a variety of factors (social, economic, and religious) and comes into play almost exclusively in the context of illness.

Theories Regarding Illness and Therapies

When a sick person consults a vodou practitioner in his or her *badji*, together they identify the problem to be addressed. The therapist formulates an explanatory scenario for the illness from among a repertory of common scenarios that refer to two levels of causality supporting the vodou explanatory model for illness.

The Role of Ancestors and *Lwa* in the Origin of Illness. In the first level of causality, the sick are responsible for their own afflictions. Illness is embedded in an order of inherited sociocultural values that impose rules, obligations, and rituals for *lwa* and ancestors. When people do not respect the order and its implications, they are punished and afflicted with disease. There

²⁶Local alcohol made from distilled sugarcane

are two types of cases. In the first, the sick person has neglected his or her responsibilities towards the ancestors and the family *lwa*. He or she is guilty of neglecting or avoiding the relations to which all Haitians are normally subject. The cult of the ancestors and *lwa* who reside at the family home and lands is implicated in such cases. Illness is the consequence of a wrongdoing and cannot be remedied without the assistance of those who caused it. In other words, the family *lwa* and the ancestors are the cause of the affliction; it is the result of a failure to observe the proper devotions and rituals in their honour, and the sick are the authors of their own fate when they are mature enough (in age and financially) to pay their family debt.

In order to be cured, the sick must negotiate their recovery with their *lwa* and ancestors, relations must be smoothed over, or they must attend to their ties to them. In addition to natural remedies for treating the symptoms, the treatment consists in reintegrating the sick within a socio-family and symbolic framework where they are under obligation to these entities inherited from a ritual tradition. The practitioner's therapy is clearly determined by the origin of the illness. The protagonists first call on the *lwa* and the ancestors, asking them for healing. They emphasize the sick person's commitment and complete devotion, they make a request, and then they set the conditions of a contract that each party agrees to honor. Once the patient has been healed, a service is conducted in the dwelling, characterizing vodou as a cult of *lwa* and ancestors. A ritual performance is organized by the sick and his or her relatives around a propitiatory ritual with a ceremony, pledges of fidelity, prayers, libations, offerings, and entertainment (dance, music, songs, drink).

The second case refers to a *lwa* who imposes a particular type of relationship on an individual. The *lwa* controls that person's fate or well-being and makes his whims known by causing illness. Here too neglect may be part of the cause in cases of people who have not taken care of a *lwa* that was given to them as a master. The *lwa* may have demands to which the chosen person has lent a deaf ear, and they use misfortune to remind him or her of their expectations. This is often said to be the case when illness makes pregnancies difficult or impossible or when it disturbs gender relations, love relations, or sexual relations (lack of pleasure or impotence for example). Illnesses in these areas of life often draw connections between individual responsibility and obligations and the expectations of personal *lwa*.

In treating such problems, the therapist addresses the origin of the illness by creating a relational mechanism for satisfying the *lwa* and involving the sick person. The simplest way to involve patients is to have them wear an object, clothing, a ring, or a necklace (first endowed with powers) that materializes their relationship to their *lwa*. This intimate connection is a less costly variant of the mystical marriage that vodou practitioners contract with *lwa*, which brings them socioeconomic benefits and medical knowledge. Another treatment option is to entertain the *lwa* in a reserved place. A bedroom may be set up or a house built or the *lwa* may be placed in a small buffet with various objects such as perfumes, drinks, and scarves that show the host's attention and

caring. The marriage is transformed into an individual worship cult in which two beings are united and the *lwa* is humanized. The therapist draws inspiration from social conventions and love between humans. The practitioner is guided by the models of marriage and commitment that exist in Haiti: on one hand, official weddings celebrated at church, which are simplified by keeping only the symbol of the ring or another object that has been blessed; on the other hand, a replica of customary marriage (*plajaj*) is proposed, consisting in a relationship that is not formalized by a religious or civil ritual or a less formal union in which the *lwa* is moved into the home and taken care of as one would build a house for a woman, clothe her, feed her, and spoil her.

Magic and Witchcraft in Explaining Illness. In the second level of causality, illness is caused by a third party who uses witchcraft to attack the sick person for personal reasons. In this category, the sick person is the victim of magical practices at the hands of his or her relatives or contemporaries. In this level of causality, illness scenarios mainly refer to the cause and the agent of the illness. There are three common examples of such attacks. Either a soul (*nàm*) has been directed at the victim, a *lwa* was sent to strike, or a child was attacked at night by a person in the form of an insect or an animal, a sort of vampire referred to as a *lougarou*.

In fact, there isn't a direct and strict connection between a type of illness and certain signs/symptoms in the diagnoses of vodou practitioners. However some indications can be considered to pronounce the diagnosis. Indeed, a soul can cause pain, fever, or other somatic symptoms (vomiting or diarrhea for example). These symptoms may linger, vary in intensity, and move around in the body. These variations and movements prove the presence of a dynamic and external agent in the body. Sometimes the clinical profile shows a personality and behavioral disturbances. Some souls can also render the person mute, isolated, apathetic, or agitated and prevent him from eating. In this case, one considers the sick person's spirit overpowered by an agent who disorganizes his personality and relationships with others.

In an illness caused by a *lwa* attack, the victim is often in poor physical condition because a *lwa* strikes with great intensity. It is not unusual for the sick person to be bed-ridden and to have visions of an animal coming to attack them that others cannot see. Finally, the *lougaou* may provoke diarrhea or vomiting and cause weight loss in a child, preventing him from growing. Its actions are recognized through nocturnal spasms, agitation, and nightmares.

Let us take as an example a soul (or souls) sent to attack a person. This involves the intrusion of a vital principle into a body where it creates disorder, symptoms, and visible or invisible physical signs. These agents do not necessarily appear in the same form in all victims. In some, they may cause pain, in others fever, and so on. They may cause behavioral disorders, loss of speech, apathy, or agitation. The diagnosis is an attack by an "evil spirit" or the soul of a dead person that is causing personality disorders. The therapist may call these *maladi movès èspri* (evil spirit sickness), *maladi zonbi* (zombie sickness), or *maladi kou de zonbi* (zombie attack sickness).

In addition to identifying the agent during consultation, the therapist suggests the causal mechanisms, positing that the victim has a *kou de poud* (struck with powder) or a *kou de zombi* (struck by the soul of a zombie). No other details are given because everyone knows that the souls of the dead are sent through practices carried out at crossroads and in graveyards with the help of *lwa Baron Samdi* and his acolytes for using an *espri zombi* (zombie spirit). Souls can also reach their target through direct contact: they are placed on the ground, on the road, in front of a door, at a crossroad, or elsewhere, in the form of a powder or a carefully prepared liquid. Vodou practitioners and those who wash the dead confirm that these morbid concoctions are made by grinding the dried bones or other parts of dead animals, insects, men, or children. Dangerous liquids such as a dead person's bathwater, a corpse's digestive excretions (*bav de mò*, or dead person's spit), and other liquids in which organisms have macerated are added to these powders. In such preparations, the law of sympathetic contiguity makes it possible to know what the specific properties of the preparation are, an illness or death, depending on the maker's intentions. For instance, a dead person's clothing, his last bathwater, or any part of his body that has been ground to a powder brings death. In short, elements close to death or to a dead person acquired from graveyards using specific means can materialize souls and be used to send illnesses.

To treat such afflictions, the sickness must be eliminated and similar states prevented. This involves a series of complex operations aimed at diverting what has been directed at the sick person, at identifying, controlling, and returning the evil agents in the crossroad and then protecting the victim from similar attacks. I have explained elsewhere the phases and sequences that respond to these objectives,²¹ which are accompanied by other treatments that deal with the physical environment and a soiled body, suffering and permeable to such agents (massage, syrup, tea, decoctions, or purgatives in particular). The body is cleaned and endowed with new properties that encourage the souls to leave and prevent them from entering anew. The whole process is organized by a therapist who visits the vodou topography for the symbolic characteristics and powers discussed above. It consists in a series of complex procedures carried out in a magical atmosphere in which the laws of sympathetic magic govern the quality and aims of the gestures, bestow each tool with specific properties, and convey representations that give meaning to the whole.

ON THE VODOU HEALTH CARE SYSTEM

Given the definition of a health care system presented above based on specific criteria, these results confirm that vodou is indeed a health care system. They show why vodou practitioners must be considered therapists and describe a vodou topography used for managing illness. The results describe vodou theories on illness and show that illness explanations are grounded in a Haitian ontology. That ontology describes the place of *lwa* and ancestors in human affairs and specifies the nature and quality of

the relationships that Haitians must maintain with them. It encompasses a worldview, a way of living, and a way of being in the world. It also refers to a collectively shared definition of reality and of social relations imbued with danger, spitefulness, envy, and jealousy, which prompt Haitians to attack those close to them by consulting the vodou practitioner. This definition of reality shapes day-to-day experiences, justifies how misfortunes are interpreted, and transforms the sick into victims and Haitians into vulnerable people. The Haitian ontology circumscribes the field of what is real and possible. It supports and renders intelligible vodou perspectives on illness and gives credence to the main explanations found in the two levels of causality presented above (that is, individual wrongdoing or an attack by an outside agent). Because Haitian ontology is part and parcel of Haitian culture and society, the vodou health care system is very well integrated in Haiti through the overarching ontology.

The therapists' practices described briefly here draw together all of the elements of vodou medicine: its specialized therapists, the places in which it is practiced, and its techniques, procedures, complexity, and materials.²⁷ Therapists' practices are seen to be closely linked to their explanatory knowledge of illness and other associated knowledge. In other words, both preventive¹ and treatment practices are organized in continuity and correspondence with the explanatory scenarios identified during consultations.

As a result, it is not surprising to find that the magical and religious poles that orient the different explanations for illness also orient the content and quality of care-giving practices. In following the dominant logics of these two poles, the therapist relies on specific knowledge. Close to the religious pole, the origin of the illness is emphasized. The main meaning given to the illness will therefore focus on the sick person's detachment from his family group, his paternal and maternal dwellings, his *lwa*, and his ancestors. The therapist will therefore pay attention to both the individual and the society, the place of the sick person in relationship to an inherited sociocultural order. The sick person's behavior is assessed against an ethical code that structures the connections between humans, *lwa*, and ancestors; that refers to the uniqueness and identity of Haitian society; and that prescribes a way of being in the world and of interacting with other generations. The vodou therapist is therefore specialized in religion and ritual whose purpose is at once to provide care, to treat, and to prevent. At this pole, his knowledge of illness contains a strongly religious dimension in explaining illness.

Closer to the magical pole, focusing on the agents and mechanisms underlying the illness, therapists concentrate on interpersonal relations, the social order, ways of being and of entering into relationship, social justice, behavior, and social prohibitions. Here the therapist is specialized in magic for caring, treating, and preventing illness. All of the classic elements of magic admirably presented by Mauss³² come into play in manag-

In the interest of brevity, I have not discussed the subject of preventive practices, of which there are many, just as complex as vodou treatments. For more detail, see Vonarx, 2005.²⁷

ing illness: the spatio-temporal conditions surrounding therapeutic practice (clearly revealed by the properties of vodou topography); the therapist's incantations in the form of prayers, praise for *lwa*, promises, and thanksgiving; the laws of contiguity and similarity that guide the therapist's gestures, define the properties of the materials to be used for preparing remedies, and validate the connections between the therapist's gestures and the desired effects.

CONCLUSION

These research results make it clear that vodou's connections to illness go beyond a care-giving dimension identified for most religions. Instead, illness management is at the heart of the form of vodou found in the Haitian countryside where it is a health care system grounded in a unique ontology. What is more, there is a magical dimension to the vodou health care system in cases where illness is caused by witchcraft and the therapist's role is therefore to counter the attack by dealing with the pathogenic causal agent central to the explanation for the illness. There is a religious dimension to the vodou health care system in cases where the origin for the illness, the world order, and a way of living enter into the therapist's explanation for the illness, and a relational balance must therefore be reestablished with the ancestors and *lwa*. In such cases, the remedy is relationship, and vodou aims to reintegrate the sick person into a network of socio-symbolic relations responsible for illness, well-being, and quality of life. The vodou health care system is combined with an individual and family cult of ancestor and *lwa* worship, which the therapist organizes to smooth over disturbed relationships.

These magical and religious dimensions draw attention to the many skills of vodou practitioners who, in the end, focus on ways of living, the various dimensions of existence, the sick person's physical and social environment, and to a physical body that has become fragile and vulnerable. These aspects are therefore closely related to the medical dimension of vodou, as is still the case in Haiti in Protestant and Pentecostal churches.^{33,34} They are also encountered in medical practices that consist in having a sick person join a self-help or prayer community or enter into a specific relation with invisible, nonhuman beings (God, divinities, the Holy Spirit, or others) or with various material or immaterial elements of an environment. Medical practices composed of trances and possession rituals (as in African medical and religious traditions); those insisting on close links with the natural world, its components, its visible and invisible powers (as often found in shamanic practices); those inviting the sick person to have a spiritual/religious experience, a transformation, or discovery of one's self or one's place in the world (such as in New Age practices) are based on the idea that developing and taking care of relationships lead to better health and cure. Symbolic and supported by a certain idea of the reality, these relationships become prominent as soon as allusions to cosmology, the universe, the world, and a sacred nature are present. Moreover, the prominence of the relationships in these types of medicine and therapy testifies to the impossibility of adopting a reductionist approach to the problem,

to the necessity of remaining open minded about the sick person's universe and way of being, and to the search for a relational equilibrium indicated by a world's ontology.

Beyond its ethnographic contribution to a better understanding of vodou, this article shows how closely the magico-religious and medical fields are intertwined in dealing with suffering that is not merely physical. It reminds us that it is arbitrary to locate vodou in a single social field, for vodou is a total social phenomenon from which different versions can be drawn, depending on the discipline or subdiscipline to which researchers belong. But above all, this article insists that our knowledge of vodou be rooted in the everyday reality of Haitians and that a microsocial approach be taken to the practices and knowledge of vodou practitioners at a time when anthropological fieldwork is difficult and completely outmoded in Haiti.²¹ In my view, this would ensure that the knowledge produced better reflect Haitians' relationship to vodou and its practitioners and would enable us to challenge what we think we know on the subject.

Furthermore, this analysis of the connections between medicine and religion within vodou can help to inform health care practices in the West. Of course, in treating Haitian immigrants, the importance of such considerations cannot be over-emphasized. The vodou case underlines the fact that a treatment is relevant only insofar as it is in keeping with the sufferer's system of representations and values because it is that system which structures experience and helps the sufferer to define the meaning of life, to reflect on the meaning of events (including illness), to see himself as either sick or healthy, and to take steps toward greater well-being. In summary, practitioners must not respond solely to a biomedical ontology limited to a material and visible version of the person (essentially anatomical and biological) and his relationship to an immediate physical environment (made up of pathogenic agents, for example). What vodou teaches us is that illness is also an issue of troubled, inadequate and unacceptable relationships to the world, which the sick person and his social group refuse (based on individually adopted norms, representations, and values). Thus, there is a symbolic dimension to illness that practitioners need to be attentive to and to decode in their roles as caregivers. This will help them to identify (1) how illness is understood and what dimensions of life that meaning reveals and is tied to; (2) what sources of suffering an understanding of illness brings to light, what dimensions of life are affected by illness, and which ones need to be attended to in taking care of the person who is ill; (3) which caregivers are best able to offer assistance that is coherent with the person's understanding of his problem and with what he considers meaningful (both in the causes and the manifestations of that problem).

Of course, attentiveness to meaning and to different layers of logic is more complex in societies where systems of meaning are more diverse and individualized and where caregivers often do not share the same knowledge as their patients. Yet it is essential in providing the best possible care, particularly among people whose representations and values are very different (migrants with different cultural origins) who are seeking holistic

approaches to health care and/or who explicitly turn to alternative and complementary spaces, medicines, and treatment that have a spiritual and/or religious content.

In this case, the “lessons” flow in the opposite direction: from Haiti to the West. We are forced to question the separation between the official field of the medical and the religious in the West and to consider what has been lost in this separation (in both the supply and the demand for health care). We are also asked to define alternative and contemporary forms of health care that might fill the gap and respond to the expectations of those dealing with illness while also addressing the complexity of their illness experience.

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Prospective clinical trials with synthetic and plant-based cannabinoids are consolidating the evidence of cannabis's role in the management of some serious chronic or debilitating medical conditions. At present, there are different cannabinoid medicinal products approved for human use. Although these drugs can be used under the supervision of health care professionals, patients continue to obtain cannabis on the black market for self-medication.¹

Several population-based surveys (from Canada,² the United States,³ Germany,⁴ Australia,⁵ The Netherlands,⁶ and the United Kingdom⁷) have reported subjective improvements with cannabis use in a variety of medical conditions. However, there is little information about its use in Spain. Medical use of cannabis was illegal in Spain until last July 2010 and is only available as a foreign drug and for compassionate use (a method of providing experimental therapeutics prior to final approval from the official medicines agency for use in humans; this procedure is used with very sick individuals who have no other treatment options). In January 2006, the Department of Health Government of Catalonia (one of the autonomous communities of the Spanish state) in collaboration with the Spanish Ministry of Health launched a pilot program using a cannabis-based medicine (Sativex, GW Pharmaceuticals, Wiltshire, United Kingdom). The purpose was to evaluate potential benefits in patients who had failed previously with conventional treatments. After this program, the number of multiple sclerosis (MS) patients suffering unbearable pain decreased from 65.9% to 35%, and the number of MS patients suffering continual spasticity also decreased from 67.9% to 51.9%. The proportion of patients with severe neuropathic pain decreased from 84% to 72%. The incidence of nausea associated with chemotherapy decreased in 20 out of 31 patients who were undergoing chemotherapy-related nausea (60.6%). In addition, 21 out of 30

patients suffering from anorexia associated with acquired immune deficiency syndrome (AIDS)—cachexia (58.3%) regained their appetites.⁸ The present exploratory study on the views of cannabis users with different medical conditions seeks to gain more information about the reality of the medicinal use of cannabis in Spain.

METHODS

A cross-sectional population-based survey design was used with a structured questionnaire about the medical use of cannabis. This included a total of 10 questions on demographic characteristics of users and other aspects related to the actual pattern of cannabis use: specifically, diseases associated with the medical use of cannabis, reasons for using, beneficial and adverse effects perceived by the patients, mode of administration, duration of use, who recommended the use, and sources for obtaining cannabis. The questionnaire was randomly distributed to 2250 patients (95% level of confidence and a margin of error of 0.019) from 30 different patient support groups around Spain and was performed over a period of 6 months via mail surveys. Medical conditions most represented were breast cancer, human immunodeficiency virus (HIV)/AIDS, MS, and fibromyalgia. Confidentiality and anonymity of the information was maintained. The final sample consists of 130 patients who used cannabis for medical purposes. We performed a descriptive statistical analysis of the data using SPSS version 12 (SPSS, Chicago, Illinois).

RESULTS

Of the 2250 questionnaires distributed, 5.8% (n = 130) were returned. The average age of responders was 45 years (standard deviation 22), and 64% (n = 83) were female. Eighty-one percent (n = 105) lived in urban areas of Spain. Catalonia (northeastern Spain) had a total of 70 responses (53.8%), followed by the Basque country (northern Spain) with 43 (33.1%), and 17 (13.1%) in the rest of the country. The main diseases associated with the medical use of cannabis were breast cancer (52.3%), MS (9.2%), HIV/AIDS (9.2%), fibromyalgia (7.7%), and other conditions (13.1%) such as nononcologic pain. This question was not answered by 8.5% of responders.

The main reasons participants used cannabis medicinally were nausea relief (47.7%), promotion of sleep (47.7%), pain relief (44.6%), vomiting relief (41.5%), relaxation (38.5%), appetite stimulation (35.4%), and as an emotional coping mechanism (13.1%). Perceived effects of cannabis use were promotion of sleep (56.9%),

nausea relief (47.7%), pain relief (46.9%), appetite stimulation (46.2%), vomiting relief (43.8%), relaxation (36.9%), and ability to cope emotionally (6.2%). Adverse effects reported, in descending order of frequency, included dry mouth (44.6%), emotional changes (22.3%), memory problems (22.3%), red eyes (21.5%), cardiac arrhythmias (8.5%), decrease in blood pressure (5.4%), decrease in blood glucose (1.5%), and gastric problems (1.5%).

Regarding duration of cannabis use, 28 (21.5%) subjects reported use for over 2 years, 6 (4.9%) from 1 to 2 years, and 36 (27.7%) from 6 to 12 months. Additionally, 34 subjects (26.2%) indicated use for 3 to 6 months, 13 (9.8%) 1 to 3 months, and another 13 (9.8%) for less than 1 month. Most patients began using cannabis approximately 6 to 9 months after diagnosis of their primary condition.

The most commonly reported mode of administration/use of cannabis was smoking (69.2%) followed by oral administration (65.6%): specifically, food preparations (23.1%), infusion (16.9%), oil (14.6%), capsules of the plant (9.2%), and nabilone capsules (0.8%). Very few individuals reported use via inhalation (5.4%). The Table shows the beneficial and adverse effects perceived by patients based on the mode of administration of cannabis.

The majority of patients used cannabis on their own initiative (63.1%), followed by 17.7% that received suggestions from friends or relatives. Approximately one in every 10 patients reported that they took the advice of their doctor (13.1%). Less reported was recommendation from the media (7.7%) and from different patient support groups (6.9%).

Most patients reported their source of cannabis as being their family and friends (32%) or from support groups related to the study of cannabis (31%). Others reported their source as the black

market (24%) or by growing the plant in their own homes (13%).

COMMENTS

Several limitations of the study are mentioned. The results may not be representative of the Spanish population's use of cannabis medicinally. It would exclude those patients who were not members of support groups (the original selected patient population). Patients who volunteered information were most likely those who experienced positive benefits from using cannabis. Patients may have been discouraged from volunteering information as cannabis use was illegal in Spain at that time (response rate <6%).

The mean age of responders was 45 years,^{3,5,7} with a higher representation of women (64%)⁶ compared to previous studies.^{2,5,7} This is most likely because our study included the use of cannabis for breast cancer symptom relief, since various organizations of women affected by this type of cancer have exerted heavy pressure on the media. Most patients live in urban areas (81%), which is where patient support groups are located. These support groups consist of individuals who are experiencing symptoms similar to the patients in our study, which therefore could have influenced their decision to use cannabis.³

Most patients have used cannabis for medicinally documented reasons, with major mode of administration being smoking.^{2,5,7} Recently, the American College of Physicians submitted a position paper indicating the need for additional research to clarify the therapeutic value of cannabinoids and to determine optimal routes of administration.

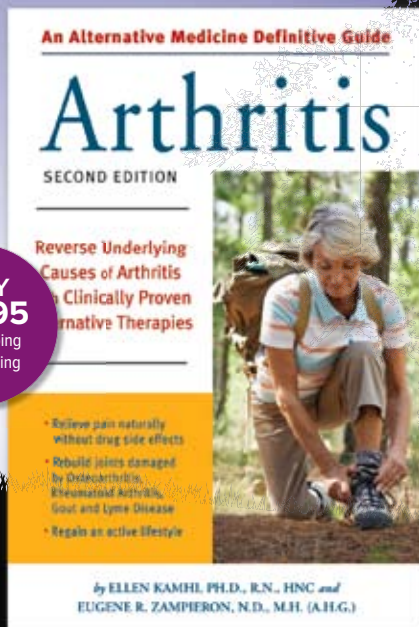
Many users reported cannabis to be effective for a range of symptoms. Perceived symptom relief was very high among patients in our study (around 100%), except for ability to cope emotionally (47.1%). The main negative effect was dry mouth,

TABLE Beneficial and Adverse Effects Perceived by Patients Related to the Mode of Cannabis Use

| Effects Perceived by Patients | Mode of Cannabis Administration | | | | | | |
|-------------------------------|---------------------------------|-------------------------|-----------------|------------|------------------------------|------------------|----------------|
| | Smoking (n=90) | Food preparation (n=30) | Infusion (n=22) | Oil (n=19) | Capsules of the plant (n=12) | Inhalation (n=7) | Nabilone (n=1) |
| Beneficial effects, n | | | | | | | |
| Pain relief | 48 | 16 | 11 | 10 | 5 | 3 | 1 |
| Nausea relief | 42 | 16 | 13 | 10 | 8 | 3 | 0 |
| Sleep promotion | 60 | 14 | 12 | 9 | 8 | 4 | 0 |
| Appetite stimulation | 50 | 13 | 7 | 6 | 5 | 2 | 0 |
| Vomiting relief | 36 | 14 | 13 | 9 | 6 | 5 | 0 |
| Relaxation | 38 | 13 | 10 | 8 | 4 | 3 | 0 |
| Ability to cope emotionally | 0 | 3 | 1 | 3 | 0 | 0 | 0 |
| Adverse effects, n | | | | | | | |
| Dry mouth | 46 | 9 | 9 | 6 | 7 | 2 | 0 |
| Red eyes | 24 | 6 | 4 | 4 | 4 | 2 | 0 |
| Decrease in BP | 5 | 0 | 2 | 1 | 1 | 0 | 0 |
| Decrease in BG | 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| Memory problems | 26 | 5 | 2 | 4 | 2 | 1 | 0 |
| Gastric problems | 1 | 0 | 0 | 1 | 1 | 0 | 1 |
| Emotional changes | 20 | 7 | 2 | 4 | 5 | 4 | 0 |
| Cardiac arrhythmias | 9 | 1 | 1 | 1 | 2 | 1 | 0 |

Abbreviations: BP, blood pressure; BG, blood glucose.

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followed by memory problems and changes in emotional state. These adverse effects were present in people who used cannabis daily and for a period exceeding 6 months. Beneficial effects and remaining adverse effects were somewhat different based on the mode of administration used. More high-quality trials are necessary to establish the safety profile of long-term use with cannabis.^{1,8}

Long-term use was found in this study as in others.^{3,5} The late onset of cannabis use (6-9 months) may be because patients tended to use cannabis after primary treatments failed or if they could not tolerate those treatments.⁸

Of the entire Spanish sample (n = 130), only 13% of patients said that their doctors had recommended the use of cannabis. A high proportion of Spanish patients use cannabis without the recommendation of a doctor (more than 75%), so it is necessary to provide information for these patients to assist in their decisions about treatment.⁸ In a study performed in the United Kingdom of 947 users, approximately 16% of patients said their doctors recommended use.⁷ In the study performed in Germany with 165 respondents, doctors were willing to prescribe delta-9-tetrahydrocannabinol to 54.8% of the patients who requested it.⁴ Most Australian participants had regular doctors and almost all had informed their clinicians of their therapeutic use.⁵ Ogborne et al (2000)² reported that most Canadians had told their health care professionals about using cannabis for medical purposes and received positive reactions.

Sources for obtaining cannabis were very different and reflect concerns about quality and dosing adjustments.^{1,2,5} A single origin of the plant with a homogenization and control of active ingredients will provide an accurate dose and schedule of administration appropriate for patients. There is still a need for further investigation of different dosage forms for cannabis-based medications.^{1,7}

In Spain, it is estimated that a high number of people are using cannabis medicinally without the supervision of a health care professional. It is necessary to establish clinical and administrative protocols to improve this situation in Spain.

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Martha Stark, MD: “What Doesn’t Kill You Makes You Stronger”

Interview by Karen Burnett and Suzanne Snyder • Photography by Mark Karlsberg

Martha Stark, MD, a graduate of Harvard Medical School and the Boston Psychoanalytic Institute, is an adult and child holistic psychiatrist/psychoanalyst with a faculty appointment at Harvard Medical School and in private practice in Boston, Massachusetts.

Dr Stark is clinical instructor in psychiatry at Harvard Medical School and a teaching and supervising analyst at the Massachusetts Institute for Psychoanalysis. In addition, she is adjunct faculty at the Center for Psychoanalytic Studies at Massachusetts General Hospital (Harvard Medical School), serves on the faculty of the continuing education program in the Department of Psychiatry at the Beth Israel Deaconess Medical Center (Harvard Medical School), and is adjunct faculty at both the Massachusetts School of Professional Psychology and the Smith College School for Social Work. Dr Stark is the author of award-winning books on psychoanalytic theory and technique: Working with Resistance; A Primer on Working With Resistance and Modes of Therapeutic Action: Enhancement of Knowledge, Provision of Experience, and Engagement in Relationship. She is currently at work on a book entitled Relentless Hope: The Refusal to Grieve.

Over the past 15 years, Dr Stark has adopted a more holistic approach to the mental and physical well-being of her patients. Her particular interests have become the mind-body connection, the body's capacity to process and integrate the impact of environmental challenge, and the body's connective tissue matrix as a highly ordered array of molecules with the semiconducting properties of a liquid crystal. Additionally, she has particular expertise in the maintenance of an environmentally safe, chemical-free lifestyle.

Dr Stark has presented her ideas at various energy medicine, environmental medicine, and functional medicine conferences. She is on the Health and Medical Advisory Board for The Housekeeping Channel and is a founding member (and Secretary) of the Environmental Health Research Foundation. Dr Stark is on the editorial board of the Journal of the American Association of Integrative Medicine as well as the Journal of Clinical Toxicology. She recently became a member of the editorial board of Alternative Therapies in Health and Medicine. (Altern Ther Health Med. 2011;17(4):57-65)

Opposite: Martha Stark, MD, shown here at her office in Newton, Massachusetts, believes that life, if done right, is a never-ending journey of discovery and evolution.

ATHM: Please tell us a little bit about your background and schooling.

Dr Stark: I did my undergraduate studies at Harvard University, where I majored in pure mathematics and studied number theory and topology. The courses were extraordinarily demanding, but the concepts, though elegant and compelling, were so much at a remove from my life that now, these decades later, all I really remember from those years was my fascination with the Mobius strip. The Mobius strip is a topological object that is created by taking a paper strip and giving it a half-twist and then joining the ends of the strip together to form a loop—such that if a bug were to crawl along the length of this strip, it would return to its starting point having traversed every part of the strip without having once crossed an edge. To this day, I find the Mobius strip and its properties breathtakingly intriguing.

I think it was from my dad that I inherited my capacity for analytic thinking and my love of games and puzzles. Dad was both a celebrated chess master—he played on the Harvard Chess Team that beat out Yale 4 years running—and a life master at bridge: the most highly sought level of bridge achievement.

Dad and I loved solving mathematical problems together. One of our favorites was the classic 12-ball problem. All but one of the 12 balls are of equal weight. You do not know whether the “oddball” is lighter or heavier than the other 11 balls. You are given a set of scales—a simple balance—but allowed only three weighings. You must then determine which ball is the oddball and whether it is lighter or heavier than the other balls. Dad and I worked long and hard on that one—as we did on Rubik’s cube.

A particularly enjoyable pastime for Dad and me was the Chinese ring puzzle that we played for more than 50 years. It is a famous mechanical puzzle that requires 86 steps to remove the interlocking metal rings from the horizontal metal loop and 86 steps in reverse order to put them back on. All I knew how to do was to take the rings off; all Dad knew how to do was to put them back on. And so, for more than half a century, Dad and I would pass this little puzzle back and forth to each other, sometimes many times over the course of a day. We never tired of this delightful routine.

From my mom, I inherited my enjoyment of talking to people and learning about them, their lives, and what mattered to them. Wherever we would go, Mom would engage people in

these amazing conversations. People who came over to our house would often end up sitting with Mom on our back porch. I would settle into a little wooden rocking chair that was my favorite place to sit; it was situated unobtrusively in the corner of the porch, so that I could be a part of it all but still apart from it, both participant and observer. I spent many a wonderful summer afternoon on that back porch, listening to Mom and her friends talking and talking and talking. As the fascinating stories of their lives unfolded, I would concentrate intently, in awe of the fact that there could be so many different people in the world with so many different stories to tell.

So I grew up with these two parts of me: a part of me like my dad, very analytical, logical, interested in numbers and games, and another part of me like my mom, more intuitive, attuned to, and interested in people.

But once I began my studies at Harvard and found that the abstract mathematical concepts to which I was being exposed were unrelated to what was going on in my real life, I decided to shift my focus. I was in college during the late '60s, an exciting but anguished coming-of-age time for me and my generation, and my friends and I were struggling into the wee hours of the morning to make sense of it all.

I decided to shift from the more abstract realm of pure mathematics to the more people-oriented world of medicine, a challenging, more real-life field of study that I knew would be both intellectually stimulating and emotionally gratifying—and would engage my passion. I wanted to feel that I was doing something with my life, that I was making a contribution, that I was making a difference in people's lives.

So after I completed my medical training at Harvard Medical School, I went on to do a 3-year residency in adult psychiatry, followed by a 2-year fellowship in child psychiatry; then, after completing an intensive psychoanalytic training program, I went on to become a psychoanalyst.

It has been said that the difference between a job and a career is the following: When you have a job, the hours in the day never pass quickly enough; when you have a career, there are never enough hours in the day. I loved the practice of psychiatry and psychoanalysis and considered myself blessed to be in the position of being invited into my patients' inner worlds and allowed to accompany them on their journeys from entrenchment in dysfunctional patterns and relationships to embracing more functional ways of being and relating.

ATHM: What kinds of models have you developed to help psychoanalysts lead their patients on journeys to healthier functioning lives?

Dr Stark: As a psychoanalyst, I have always been interested in understanding what exactly it is that enables patients to heal their psychological scars. I conceptualize these psychic scars as the internal price they have paid for early-on experiences, usually at the hands of their parents, that were never fully processed and integrated. Psychodynamic psychotherapy, albeit belatedly, offers such patients the opportunity to process and integrate these unmastered emotional experiences.

Based on both my years of clinical experience as a psychoanalyst and a careful review of the psychoanalytic literature, I have distilled out three relatively distinct modes of therapeutic action: knowledge, experience, and relationship—modes that are mutually enhancing, not mutually exclusive. I have written about these three modes in several award-winning textbooks—it is a conceptual paradigm that is now being taught in a number of psychodynamic training programs around the country.

Model 1, enhancement of knowledge, is the interpretive perspective of classic psychoanalysis, a drive-defense model that focuses on the patient's traumatically frustrated infantile drives and her self-protective defenses. This model offers the neurotically conflicted patient an opportunity to gain greater self-awareness and insight

into her internal workings so that she can resolve unmastered intrapsychic conflicts and move toward greater self-actualization, now freed up to direct her passions toward the pursuit of achievable dreams.

Model 2, provision of corrective experience, is a more contemporary perspective, one that focuses on the patient's psychological deficiencies. These psychic scars are generally thought to be the result of traumatic early-on "absence of good" in the form of deprivation and neglect—internally recorded and structuralized as an unrelenting need for a good parent in the here and now. This deficiency-compensation perspective offers the patient an opportunity, in the context of the current relationship with her therapist, to grieve traumatic parental failures in the past and to experience symbolic restitution for those failures in the present. As the patient makes her peace with the heartbreaking reality that the people in her world were not, and will never be, all that she would have wanted them to be, she evolves to a place of

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greater acceptance and inner tranquility.

Model 3, engagement in authentic relationship, is another contemporary perspective, one that focuses on the patient's psychological toxicities. These psychic scars are generally thought to be the result of early-on "presence of bad" in the form of trauma and abuse—internally recorded and structuralized as dysfunctional relational patterns. Such a patient will come to assume a stance in relation to her therapist that is best described by the late Warren Zevon in a song entitled "If You Won't Leave Me, I'll Find Someone Who Will." This third model of therapeutic action offers the patient a stage upon which to play out, unwittingly and symbolically, her unresolved childhood dramas—but ultimately to encounter a different response this time, a different outcome because the therapist will be able to facilitate resolution by bringing to bear her own, more evolved capacity to process and integrate on behalf of a patient who truly does not know how. As the patient, taking the therapist's lead, begins to recognize and to deal with her unconscious compulsive repetitions at the intimate edge of her relationships, she will evolve to a place of greater responsibility for her actions.

In all three models, the therapist, ever attuned to the patient's capacity to tolerate stress, offers, in an ongoing fashion, an optimal balance of challenge and support—alternately challenging when possible and supporting when necessary—such that an optimal level of anxiety will be generated in the patient, anxiety that will then provide the impetus for the patient to evolve to a higher level of awareness, acceptance, and accountability—a higher level of order, complexity, and integration.

In essence, the psychotherapeutic process transforms resistance into awareness, which is Model 1; relentless hope and refusal to grieve into acceptance, Model 2; and reenactment into accountability, Model 3. Growing up, which is the task of the child, and getting better, which is the task of the patient, are all about this ongoing evolution to greater awareness, acceptance, and accountability. More specifically, maturity involves developing the capacity to know and accept the self, including one's psychic scars, to know and accept others, including their psychic scars, and to take responsibility for what one delivers of oneself into relationship and, more generally, into one's life.

ATHM: Do your models work with everyone?

Dr Stark: Because I always loved a challenge, over time I became the go-to psychiatrist for patients who were particularly "stuck" in their life and/or their psychotherapy. I especially enjoyed the challenge of doing consultations on "difficult" patients, and I ultimately wrote several psychoanalytic textbooks on working with these so-called "resistant" patients.

But I also began to recognize, to my great dismay, that the more traditional approach to working with these "psychiatric" patients was not always effective; I began to let myself know that some of the psychiatric patients coming our way, despite our best efforts, were still struggling in their lives and unable to move forward. It was upsetting for me that some of my patients were simply not getting better.

ATHM: How did you handle this roadblock?

Dr Stark: Well, I have always been guided by Thomas Edison's "There's always a better way. Find it!" And so, determined to find a better, more effective way, I began, slowly but steadily, to broaden my approach by expanding my horizons to include a more thoroughgoing appreciation for the complex interplay between mind and body. I immersed myself in some of the more "alternative" literature and sought out mentors around the country in environmental medicine, functional medicine, complementary and alternative medicine, bioregulatory medicine, and energy medicine.

ATHM: Did you have any mentors at the time?

Dr Stark: Most influential for me has been my relationship with Dr William J. Rea, author of the definitive four-volume set on chemical sensitivity and an exceptionally gifted and intuitive environmental physician with vast experience and knowledge; I have had the incredible privilege of calling him my mentor and, now, my dear friend. I have also been blessed by my deep friendship with Dr Doris Rapp, an internationally acclaimed pediatrician and award-winning environmental physician; she has more wisdom, more heart, more soul, and more compassion than anybody I have ever had the pleasure and privilege of knowing.



ATHM: Did the realization that some patients were not improving lead you to an interest in a more holistic approach to treatment?

Dr Stark: As I have gradually deepened my understanding of psychiatric illness, my approach, of necessity, has become much more holistic. A more holistic approach takes into consideration not only the system's parts but also the system as a whole.

To demonstrate the limitations of a reductionist approach and to highlight the need for a systemic, or holistic, approach to complement it, I offer the following: Most psychopharmacologists believe that aberrant feelings speak to abnormal or imbalanced levels of neurotransmitters in the brain. Regulation of mood therefore can be achieved, they reason, by specifically targeting, with drugs, the levels of these chemical mediators. Indeed, psychotropic medications, from antidepressants to antipsychotics, do just this.

I have now come to understand why so many psychiatric patients fail to benefit from psychopharmacologic intervention. So-called "treatment resistance" speaks perhaps to this reductionism—this too-narrow-a-focus upon imbalanced neurotransmitter levels and this too-limited-a-perspective that fails to consider not only the underlying causes of these chemical imbalances but also the roles played by numerous other interdependent factors contributing to the overall clinical picture.

Unfortunately, only a small percentage of psychopharmacologists are beginning to espouse a more holistic approach, one that is both broader-based and more medicalized, one that appreciates the multiplicity of factors involved in the regulation of mood and therefore takes into account the numbers of factors, both environmental and genetic, that contribute to mental illness.

I can understand the difficulty that my psychiatric colleagues have in expanding their horizons to include a more holistic approach because all of this flies in the face of the more traditional approach that we were taught during our years and years of medical training. But as I have developed an ever keener appreciation for the intimate and precise relationship between the health and vitality of the mind and that of the body, I have come to appreciate ever more profoundly the mind-body connection

and the importance of adopting a more holistic approach.

Accordingly, I have broadened my psychotherapeutic paradigm to include not just enhancement of knowledge "within," which speaks to the cognitive component; provision of corrective experience "for," which speaks to the emotional component; and engagement in authentic relationship "with," which speaks to the relational component, but facilitation of flow "throughout," which speaks to the mind-body connection. My recently created Model 4 is a holistic approach that is attuned to the complex interconnectedness of mind and body and to the flow of information and energy through the extensive network of channels constituting what I describe as the MindBodyMatrix.

Information is conducted along these channels in much the way that a telephone line conducts information, and energy is transmitted in much the way that a toaster wire transmits energy.

ATHM: Can you describe more specifically the MindBodyMatrix?

Dr Stark: I am referring to the high-speed, body-wide information and energy dissemination system responsible for maintenance of homeostatic balance and described in the literature as the ground regulation system, the extracellular matrix, the connective tissue matrix, or, simply, the living matrix.

As I understand it from the writings of Albert Szent-Gyorgyi, Hartmut Heine, Alfred Pischinger, Fritz-Albert Popp, and Mae-Wan Ho, the living matrix is a vast interconnected network of molecules

within which all the body's cells, tissues, and organs are embedded and through which the flow of life takes place. More specifically, it is comprised of a continuous meshwork of collagen fibrils and an amorphous colloidal ground substance in precise and intimate relationship with organized layers of electrically charged water.

Because this matrix is a highly ordered array of molecules densely packed and tightly organized in a crystal-like lattice structure, it has the semiconducting properties of a liquid crystal, which makes it an ideal candidate for the high-speed propagation of regulatory information and vibratory energy throughout the entire body. Over time, I have come to appreciate



that this intricate regulatory web composed of complex and interwoven pathways constitutes a body consciousness working in tandem with the brain consciousness of the nervous system.

I now complement my practice of psychiatry and psychoanalysis with a more holistic approach, one that deeply appreciates the complex interplay between the myriad of risk factors and environmental stressors that are an integral part of our everyday experience. Over the years I have also come to recognize, on ever more profound levels, that psychiatric and medical symptoms are but the outward manifestation of underlying vulnerability, dysfunction, imbalance, blockage, hypersensitivity. My focus now has become to ferret out “hidden causes” and the contribution of environmental and genetic factors to a person’s mental and physical well-being.

I have also increasingly come to appreciate how important it is that the MindBodyMatrix have the capacity to process and integrate the potentially devastating impact of the myriad of environmental stressors to which it is being continuously exposed—stressors that take the form of both “too much bad” and “too little good.”

The ultimate goal is to lighten the load to correct for toxicities, replenish the reserves to correct for deficiencies, and facilitate the flow to restore the system’s intrinsic orderedness and natural biorhythms. Challenging, when possible, and supporting, when necessary, to jumpstart the system’s innate ability to renew itself. Therapeutic induction of healing cycles of disruption and repair, defensive collapse and adaptive reconstitution at ever higher levels of integration, balance, and harmony.

ATHM: What are some examples of the kinds of environmental stressors that might cause problems for people?

Dr Stark: Environmental challenge will take the form of both toxicity—too much bad—and deficiency—not enough good. Too much rejection by the caregiver, not enough love and support. Too much oxidative stress from electron-scavenging free radicals, not enough neutralizing antioxidants. Too much criticism, not enough acceptance. Too many antibiotics altering the balance of healthy flora in the gastrointestinal tract, not enough probiotics, or beneficial bacteria, to restore that balance. Too many anxiety-provoking interpretations, not enough anxiety-assuaging empathic interventions.

ATHM: And how would you describe the healing cycles of disruption and repair?

Dr Stark: I use the sand pile model—developed by chaos theorists—as a visual metaphor for the cumulative impact, over time, of environmental stressors on an open system. Amazingly enough, the grains of sand being steadily added to the gradually evolving sand pile are the occasion for both its disruption and its repair. Not only do the grains of sand being added precipitate partial collapse of the sand pile but also they become the means by which the sand pile is able to build itself back up—each time

at a new homeostatic set point.

So, too, the MindBodyMatrix is continuously refashioning itself at ever higher levels of complexity and adaptive capacity—not just in spite of “stressful” input from the outside but by way of that input.

More specifically, with respect to the paradoxical impact of environmental stressors on the living system, the noted 16th-century Swiss physician Paracelsus is reputed to have said that the difference between a poison and a medication is the dosage thereof. And, I would add, the system’s capacity—a function of its underlying resilience—to process, integrate, and adapt to the impact of that stressor.

In other words, stressful input is inherently neither bad nor good. Rather, the dosage of the stressor, the underlying adaptability of the system, and the intimate edge between stressor and system will determine whether the system, in response to the environmental input, devolves to greater disorganization or evolves to more complex levels of organization and dynamic balance.

ATHM: Is this a new concept?

Dr Stark: The evolution of this sand pile, governed by some complex mathematical formulas, has long fascinated chaos theorists, but the sand pile model, though well known in many academic circles, is rarely applied to living systems. I believe, however, that the sand pile model is a wonderful visual metaphor for the evolution of the living system because it offers a dramatic depiction of the paradoxical impact of stress on a complex adaptive system.

ATHM: Whose writings have informed your understanding of the impact of stress on the body?

Dr Stark: Actually, it is Walter B. Cannon, author of the 1932 groundbreaking volume *The Wisdom of the Body*, and Hans Selye, author of the 1956 classic *The Stress of Life*, who are credited with highlighting both how crucial it is that the body be able to preserve the constancy of its internal environment and that the body, when challenged, be able, by virtue of its innate wisdom, to adapt by mobilizing its resources in the interest of restoring homeostatic balance.

ATHM: Isn’t that ability to adapt the hallmark of a system’s resilience?

Dr Stark: Exactly! In fact, my particular interest has long been in the resilience of the MindBodyMatrix, by which I mean the ability of the living system to restore its homeostatic, or, perhaps more accurately, allostatic, balance in the face of environmental challenge. As you suggested, the hallmark of a system’s resilience is its capacity to self-regulate, that is, to maintain—or, if lost, to recover—its balance in the face of ongoing environmental perturbation.

In essence, resilience speaks to the compelling idea that a living system must be able to adjust to instability continuously. It will be able to preserve its stability only by way of ongoing

adjustment to instability. In 1965, two obstetricians made an intriguing discovery about the paradoxical relationship between fetal mortality and the regularity of the fetal heart rate. They observed that the more metronome-like the heartbeat, the less likely the fetus would be to survive, but that the greater the heart rate variability—that is, the more variable the heart’s beat-to-beat intervals—the more likely the fetus would be to thrive. In other words, longevity is directly proportional to heart rate variability.

More generally, it would seem that a system’s health, both psychological and physiological, is a story about its capacity continuously to process and adjust to the impact of ongoing environmental perturbation and adaptively to reorganize at ever higher levels of order, complexity, and integration.

ATHM: That makes sense.

Dr Stark: Stressful stuff happens all the time. But it will be how well the MindBodyMatrix is able to process and integrate its impact—psychologically, physiologically, and energetically—that will make of it either a growth-disrupting event or a growth-promoting opportunity. In other words, it will be how well the MindBodyMatrix is able to manage the cumulative impact, over time, of environmental stressors that will either hasten a compromised system’s deterioration or support a more resilient system’s evolution toward increasing complexity.

So whether the primary target is mind or body and the clinical manifestation, therefore, psychiatric or medical, the critical issue will be the ability of the MindBodyMatrix to handle stress through adaptation.

ATHM: How do you conceptualize the impact of stress on this MindBodyMatrix?

Dr Stark: I find it clinically useful to think in terms of stress as impacting the MindBodyMatrix in three ways.

Too much stress—traumatic stress—will be too overwhelming for the system to process and integrate, triggering instead cataclysmic breakdown. Too little stress will provide too little impetus for transformation and growth, serving instead simply to reinforce the status quo of the system.

But just the right amount of stress—“optimal stress”—will offer just the right combination of challenge and support needed ultimately to induce, after initial disruption, subsequent reconstitution of the system at a higher level of complex orderedness and integrated coherence. The system will therefore have been able not only to manage the impact of the stressful input but also to benefit from that impact by virtue of its ability to adapt.

In other words, if the interface between stressor and system is such that the stressor is able to provoke recovery within the system, then what would have been poison becomes medication, what would have constituted toxic input becomes therapeutic input, what would have been deemed traumatic stress becomes optimal stress, and what would have overwhelmed becomes transformative. What doesn’t kill you makes you stron-

ger. I’m speaking here to the therapeutic use of stress to provoke recovery by activating the body’s innate ability to heal itself.

ATHM: What are some examples of how we stress the body in order to activate its innate ability to heal itself?

Dr Stark: All manner of mild aggravations will stimulate the body’s ability to self-heal. For example, every-other-day workouts will create microtears that the body will be able to repair on those alternate days when the body is at rest. Debridement of wounds is thought to accelerate healing by creating minor irritation to the area, thereby prompting the body to repair itself. Pin-firing partially healed tendons of injured race horses is used by some veterinarians and has been approved since 2006 as an acceptable form of therapy in cases refractory to conventional treatment. Pin-firing involves inserting a small, red-hot probe into an 80% healed tendon, which will superimpose an acute injury on top of a chronic one, which will activate the body’s innate ability to heal itself.

Obviously, we all know about the use of vaccines, hopefully contaminant-free, to promote the body’s resistance to subsequent exposures. And homeopathic remedies, by offering minute potentized doses of the toxin, can be used to activate the body’s ability to heal itself. More generally, intermittent exposures to small doses of toxins will prompt the body to adapt—as long as the dose does not overwhelm the system’s adaptive capacity.

Along these lines, a little known remedy for the temporary relief of depression is mild sleep deprivation. Neuroscientists don’t really know how to explain the mystery of why depriving yourself of half a night’s sleep once a week, preferably the second half of the night, should have such a beneficial effect on depression, but Leibenluft hypothesizes that interrupting normal sleep patterns may “resynchronize disturbed circadian rhythms”—disruption/repair, producing often a rapid and sustained, even if temporary, recovery from depression.

And fasting even one day a week can so significantly reduce the total body burden, the total stress on the system, that mental clarity and focus can be improved dramatically—at least temporarily—and a sense of overall well-being restored. In fact, doing a water fast once a week for 36 hours—say, from after dinner on Monday evening at 8 PM, all day Tuesday, until before breakfast on Wednesday morning at 8 AM—is an extraordinarily effective optimal stressor. Digesting takes a lot of work. Fasting frees up all the energy that would otherwise have been consumed in the digestive process, and that freed-up energy can then be redirected to other regulatory systems in the body, especially the nervous system for clearer thinking, the endocrine system to support hormonal balance, and the immune system for accelerated self-healing. When we are sick, we lose our appetite; this loss of appetite is an adaptive response to illness because it enables us to redirect our energies away from the digestive process to the immune system and the processes of self-repair. Even animals instinctively fast when they are sick or injured, which accelerates their rate of recovery.

When a person fasts, the body must turn to its fat reserves to get energy. As the fat cells are broken down, the lipophilic, or fat-loving, environmental toxins that had been sequestered there are released from their hiding places and eliminated by way of either the digestive system, the respiratory system, or the skin. This is detoxification. As the total body burden is gradually reduced, particularly by way of a series of fasts, the functionality of every cell is optimized. Finally, during a fast, the body undergoes first a tearing down and then a rebuilding of its cells and tissues. For this reason, fasting is well known for its ability to rejuvenate the body and give it a more youthful tone. Such is the power of a carefully designed fast, which serves as an optimal stressor, as a catalyst inducing healing cycles of breakdown and repair, deconstruction and reconstruction at ever higher levels of functionality and adaptive capacity.

And with respect to aerobic exercise: In 1999, a team of researchers at the Duke University Medical Center demonstrated that for the middle aged and the elderly, aerobic exercise is at least as effective as medication in treating major depression. But, interestingly, they discovered an additional benefit as well—namely, improved cognitive ability, particularly in the frontal and prefrontal regions of the brain. In addition, it is said that if you are willing to carve out 40 minutes of time during your day for an aerobic workout, then you will be able to get by on 40 fewer minutes of sleep the next night.

ATHM: So you're speaking about the use of optimal challenge, or optimal stress, to provoke recovery by triggering the body's innate ability to heal itself. How does this manifest in the psychotherapeutic realm?

Dr Stark: Psychotherapists are ever busy formulating interventions that will either challenge or support—that is, challenge the patient by directing her attention to where, in the moment, she isn't—but where the therapist hopes the patient will go—or support the patient by resonating with where, in the moment, the patient is—and where the patient would seem to need to be.

Based on the therapist's moment-by-moment assessment of what the patient can tolerate, the therapist will therefore either challenge, by way of anxiety-provoking interpretive statements

that call into question the defenses to which the patient has long clung in order to preserve her homeostatic balance, or support, by way of anxiety-assuaging empathic statements that honor these self-protective defenses—a therapeutic stance often referred to as “going with the resistance.”

Interventions that challenge will increase the patient's anxiety; interventions that support will decrease it. And if the therapist's interventions make the patient too anxious, the patient may get defensive, resort to shutting down, and then be unable to take in or benefit from the therapist's input. But if the therapist's interventions elicit anxiety that is more manageable, the patient may be able to process and integrate the therapist's input and adapt to it by ultimately reconstituting at a higher level of complex understanding and emotional maturity.

And so it is that the therapist, in order to maximize the therapeutic potential of every moment, offers, in an ongoing fashion, an optimal balance between challenge and support—alternately challenging, when possible, and supporting, when necessary—in order to provoke an optimal level of anxiety in the patient, anxiety that will then provide the impetus for the patient to evolve, by way of cycles of disruption and repair, to ever higher levels of awareness, acceptance, and accountability.

In essence, psychotherapy affords the patient an opportunity, often long after the fact, to process, integrate, and adapt to experience that had once been overwhelming—and therefore defended against—but that can now, with enough support from the outside, be detoxified and

assimilated. In summary, psychotherapy is a story about the belated processing of unmastered experience and, in the face of optimal challenge, adaptive reconstitution at ever higher levels of awareness, acceptance, and accountability.

ATHM: Yes, and some patients can handle more challenge than others.

Dr Stark: Absolutely. We speak of psychiatric disorders and diseases and of medical disorders and diseases. But whether the primary involvement is of mind or body, I believe that “dis-order”—that is, disrupted orderedness within the MindBodyMatrix—and “dis-



ease”—that is, disrupted ease of flow within the MindBodyMatrix—are implicated in the generation of both psychiatric and medical problems. The journey from disorder and disease to health and vitality—from illness to wellness—requires that the infrastructure of the MindBodyMatrix be both “ordered” and “fluid.” The more ordered the crystalline matrix, the more fluid will be its flow. The more fluid its flow, the better able it will be to process and integrate the impact of environmental stressors—in essence, the better able it will be to cope with stress.

So bad health is a story about dis-order and dis-ease, and good health is a story about orderedness and ease of flow. To optimize the ease of flow of information and energy, just for starters, the matrix should be kept as uncongested, well-hydrated, nutrient-rich, well-oxygenated, alkaline, electron-rich, energetically unblocked, well-balanced, relaxed, structurally aligned, aerobically exercised, well-rested, and unencumbered by disruptive “imprinting” of psychological trauma and emotional deprivation as possible.

More specifically, because dis-order and dis-ease are occasioned by the cumulative impact of both presence of bad—toxicity—and absence of good—deficiency—therapeutic interventions must aim to detoxify in order to lighten the load and supplement in order to replenish the reserves, all with an eye to restoring the ease of flow of information and energy through the matrix; that is, to restoring the system’s capacity to process and integrate the impact of environmental impingement and adaptively to reconstitute at a higher level. In other words, all with an eye to reinforcing the system’s capacity to tolerate the stress of life.

Treatment modalities must either eliminate bad or supplement with good or, as is true for some treatments, do both.

ATHM: What are some of the other therapeutic interventions that you might resort to in order to restore the resilience of a compromised MindBodyMatrix?

Dr Stark: Obviously, interventions are customized to accommodate each patient’s needs. But in order to lighten the total body load and replenish the total body reserves, any of the following are options: infrared saunas, deep tissue massage, lymphatic drainage, the chi machine, craniosacral therapy, Reiki, shiatsu,

frequency-specific microcurrent, traditional Chinese medicine, including acupuncture, therapeutic touch, chiropractic, detox foot pads, ionic foot baths, cholestyramine, neti pot, colonics, love, support, probiotics, prebiotics, organic food, antioxidants, nutritional supplementation, phytonutrients, adaptogens, herbal medicine, spirulina and chlorella, alkaline water, restful sleep, light box, earthing, neodymium magnets, low-level laser therapy, sensorimotor psychotherapy, eye movement desensitization and reprocessing, psychomotor psychotherapy, somatic experiencing, yoga, and aerobic exercise—to name a few.

ATHM: Have you broadened your focus to include the impact of stress on both the mind and the body?

Dr Stark: Yes, in fact, I now describe my practice as “synergy health for mind and body.” I offer comprehensive consultation and strategic solutions for persistent psychiatric and medical problems. My expertise is in working with those who have already consulted numerous health care specialists but suffer still and are desperate for answers and relief.

Over the years, I have acquired a broad-based understanding of the multiplicity of factors that have an impact on the health and vitality of the MindBodyMatrix. As a result, my goal, as a holistic consultant, is to design treatments that offer just the right balance of challenge and support to provoke recovery by fueling recursive cycles of disruption and repair, defensive collapse and adaptive reordering of the MindBodyMatrix at ever high-

er levels of “synergy”—the rhythms of mind and body now synchronized and in harmonic resonance. In essence, my objective is to create individualized treatments that are specifically designed to restore the resilience of a compromised matrix by revitalizing its capacity to cope with stress.

ATHM: How would summarize your thoughts about the impact of stress on the living system?

Dr Stark: Stressful stuff happens. But whether the primary target is the mind or the body, the critical issue will be the ability of the living matrix to process and integrate the impact of that environmental perturbation so that balance and harmony can be

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ATHM: It seems that you are finding a “better way,” as Edison said, to understand the process by which people get from point A to point B, namely, that it is rarely a linear process but rather an unpredictable process that involves a series of stops and starts, destabilizations and fortifications. It is almost never an easy progression because it usually involves some kind of challenge to the status quo and then a reorganizing at a higher level of functionality. Do I have that right?

Dr Stark: Absolutely. In finding the world of integrative medicine, I have indeed found a better way—way better and way more satisfying than I could ever have imagined possible. In my work with patients who have long suffered from chronic health problems, both mental and physical, I now have a breadth and depth of understanding that has been hard earned but totally worth the struggle.

I guess you could say that my own journey in the health care field has been characterized by a series of disruptions, when I have felt, at times, overwhelmed by the abundance of material that I have yet to master, and repairs, when suddenly I have had an insight and things have come together for me in a flash—with reconstitution at ever higher levels of complex understanding. The journey has not been easy, and, quite frankly, the more traditional medical circles in which I sometimes travel have not always offered much support for the holistic approach that I have adopted. But even so, the journey has been an exhilarating one—and one that was well worth the effort. As Ernest Hemingway said, “The world breaks everyone; but, in the end, people are stronger at the broken places.”

And I'm not done yet. As noted earlier, my Model 4 is about facilitation of flow throughout, but my Model 5—only in its early stages of development—is about expansion of consciousness beyond (which introduces the spiritual realm). I very much look forward to this next decade. I believe that life, if done right, is a never-ending journey of discovery and evolution.

ATHM: Please tell us a bit about the book you're writing. It seems to be a bit of a departure from the other books you've authored.

Dr Stark: I actually have two books that I'm working on right now: *Relentless Hope: The Refusal to Grieve*, which is almost completed, and *Optimal Stress: Stronger at the Broken Places*, which is halfway done. The first book suggests that hope is not always good, and the second book suggests that stress is not always bad.

With respect to relentless hope, I have found it to be an

extraordinarily useful clinical concept, especially with respect to psychiatric patients who are “relentlessly self-sabotaging.” In my book, I develop the idea that relentless hope is a defense to which the patient clings in order not to have to face the pain of her disappointment in the other, the hope a defense ultimately against grieving. The patient's refusal to deal with the pain of her grief about the other fuels the relentlessness with which she pursues it—both the relentlessness of her hope that she might yet be able to make the other over into what she would want it to be and the relentlessness of the outrage she experiences in those moments of dawning recognition that, despite her best efforts and most fervent desire, she might never be able to make that actually happen.

In truth, relentless hope is a defense to which many of us cling, to varying degrees, in order not to have to confront certain intolerably painful realities in our lives.

I believe that growing up and getting better have to do with making your peace with the disappointment and the pain that come with the recognition of just how imperfect, just how flawed, and just how immutable the people in your world—and you yourself—really are.

Perhaps it could be said that maturity involves transforming the need to have the important people in your world be other than who they are into the capacity to accept them as they are—it involves transforming relentlessness—a defense—into acceptance—an adaptation. It could therefore be said that maturity is an adaptation to the impact of painful truths: it requires the acceptance of realities that sober and sadden.

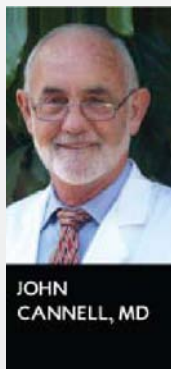
So when a patient is caught up in the throes of needing the important people in her world to be other than who they are, the therapeutic goal will be to transform infantile need into mature capacity, namely, the patient's relentless need to pursue the unyielding other into a healthy capacity to relent, accept, forgive, and let go. And it will be by way of grieving that need is transformed into capacity—infantile need into mature capacity and realistic hope. In fact, Harold Searles has suggested that realistic hope arises in the context of surviving disappointment.

I am here reminded of a *New Yorker* cartoon in which a gentleman, seated at a table in a restaurant by the name of The Disillusionment Cafe, is awaiting the arrival of his order. His waiter returns to the table and announces, “Your order is not ready, nor will it ever be.”

Karen Burnett is a freelance journalist in Groton, Massachusetts. Suzanne Snyder is managing editor of Alternative Therapies in Health and Medicine.



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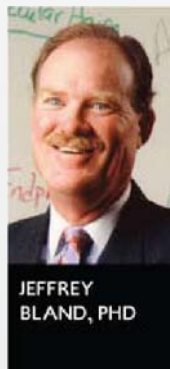
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2011-2012 CONFERENCE CALENDAR

66th World Homeopathic Congress of LMHI

December 1-4, 2011—Sirifort Auditorium, New Delhi, India

Carrying on with the tradition of LIGA meets, the upcoming one in India also promises a lot of learning and awareness about homeopathy and how it can make a difference in the public health scenario. It has always been an endeavour of LHMI to promote scientific, literary and genuine work in homeopathy. The Congress will provide you an opportunity to share your clinical experiences and deliberate on the latest scientific research in the field of homeopathic medicine in India, a hub of homeopathic activities. For more information, please visit <http://www.liga2011.in/home.aspx>.

19th Annual World Congress on Anti-Aging Medicine and Biomedical Technologies

December 8-10, 2011—The Venetian & Palazzo Resorts, Las Vegas, Nevada

Whether you are involved in the anti-aging movement or not, it's a given that people are living longer. By limiting illness and disability in the latter stages of life, anti-aging medicine can make a quantum leap in people's enjoyment of their later years. Seek the latest cutting edge diagnostic and treatment technologies in this competitive medical arena. Don't miss out—find the solutions to building your patient base and improving your practice at the 19th Annual World Congress On Anti-Aging Medicine & Regenerative Biomedical Technologies 2011. For more information, visit <http://www.worldhealth.net/las-vegas-2011-anti-aging-conference/attendee-info-2011/?expanddiv=attendeeinfo>.

2011 Specialty Conference for Primary Care NPs

December 8-11, 2011—Crystal Gateway Marriott, Arlington, Virginia

The American Academy of Nurse Practitioners (AANP) cordially invites you to spend the weekend in a focused clinical update. Arrive a day early to take advantage of the additional Legislative Day opportunity to visit with Congressional members and their key legislative staff! The specialty conference is for the experienced primary care nurse practitioner who is seeking an intensive update in one of the following clinical areas: cardiology, dermatology or orthopedics. From Friday morning's skill workshop through Sunday midday, attendees spend the weekend immersed in an evidence-based, state-of-the-science, primary-care focused conference in one of these three clinical areas. For more information, visit <http://www.aanp.org/AANPCMS2/Conferences/SpecialtyConference/>.

9th Annual Natural Supplements: An Evidence-Based Update

January 19-22, 2012—Hilton San Diego Bayfront, San Diego, California

During this informative and comprehensive CME conference, renowned faculty will present a concise, clinically relevant overview of the latest information on natural supplements and nutritional medicine with an emphasis on disease states. This course provides practical information for health care professionals who make nutritional recommendations or manage dietary supplement use. For more information, go to www.scrippsintegratiemedicine.org.

Melanoma 2012: Annual Cutaneous Malignancy Update **January 21-22, 2012—Hilton San Diego Bayfront, San Diego, California**

As the incidence of melanoma continues to rise rapidly in the United States and around the world, the need to educate clinicians from various specialties on the disease also increases. During this course nationally recognized experts will present information on prevention, risk assessment, early detection, genetic factors, and current and future treatment choices for melanoma patients. Issues concerning surgical management, adjuvant therapy, advanced disease therapy, and personalizing the course of treatment for individual patients will also be discussed. This course is designed to provide information that will help clinicians in their decision making regarding these difficult patient problems. The course will be taught by a wide range of experts as this most serious of skin cancers will require multidisciplinary efforts to conquer. See <http://www.scripps.org/events/melanoma-annual-cutaneous-malignancy-update> for more information.

Bioidentical Hormone Therapy-Evidence Based Training **January 27-29, 2012-Hilton Garden Inn, Salt Lake City, Utah**

This course features Dr. Neal Rouzier, a renowned leader and expert in the field of Bioidentical Hormone Replacement, with over 15 years of experience as an educator and practicing physician. This course is entirely evidence based, which enables Health Care Practitioners to strengthen the integrity of their practice in a growing industry. CME credits available. Choose from three course dates including June 1-3, 2012, and August 19-21, 2012. For more information, go to <http://worldlinkmedical.com/>.

Advanced Mind-Body Training Program: Integrating Mind-Body Medicine into Clinical Practice, Medical Education, and Trauma Healing

January 2-February 1, 2012—Hyatt Crystal City, Washington, DC
Over the course of this training you will practice leading Mind-Body Skills Groups, be supported with individualized and interactive supervision by senior faculty, and receive guidance on creating and integrating the mind-body approach into individual as well as group work. In addition, we will guide you as you take the next steps in creating your own personally fulfilling and economically viable programs of mind-body and integrative medicine. We will help you to make your program work within institutions—hospitals, professional schools, private practices, and bureaucracies—and we will show you how you can create independent practices and teaching programs that are unique to your talents and abilities.

For more information, visit www.cmbm.org.

Melanoma 2012: 22nd Annual Cutaneous Malignancy Update **January 21-22, 2012—Hilton San Diego Bayfront, San Diego, California**

As the incidence of melanoma continues to rise rapidly in the United States and around the world, the need to educate clinicians from various specialties on the disease also increases. During this course nationally recognized experts will present information on prevention, risk assessment, early detection, genetic factors, and current and future treatment choices for melanoma patients. Issues concerning surgical management, adjuvant therapy, advanced disease therapy, and personalizing the course of treatment for individual patients will also be discussed. This course is designed to provide information that will help clinicians in their decision making regarding these difficult patient problems. The course will be taught by a wide range of experts as this most serious of skin cancers will require multidisciplinary efforts to conquer. For more information, go to <http://www.scripps.org/events/melanoma-2012>.

Integrative Healthcare Symposium

Pre-Conference: February 8

Conference: February 9-11

Exhibits: February 10-11, 2012, Hilton New York, New York

Hear from nationally recognized practitioners and experts in the fields of: women's health, environmental health, mind-body medicine, functional medicine, homeopathy, and more on topics such as nutrition, integrative cardiology, hormones, pain management, and the mind-body spirit. Speakers include Jeffrey S. Bland, PhD, FACN, FACB, Dean Ornish, MD, Joan Boysencko, PhD, Erminia Guarneri, MD, FACC, and many more. For more information, please go to www.ihSYMposium.com.

The Institute for Functional Medicine, Advanced Practice Module—Re-establishing Balance in the Hypothalamic Pituitary, Adrenal, Thyroid and Gonadal Axis

February 24-26, 2012—JW Marriot, New Orleans, Louisiana

Hormone replacement therapy (HRT) remains a controversial area in medicine. The functional medicine paradigm uniquely looks at the larger picture of HRT, especially what one needs to do before considering HRT. This Advanced Practice Module focuses on how stress is a key component in hormone dysfunction. Attendees will learn through workshops, lectures, and experiential sessions how to address stress in everyday life and thus better understand and treat hormonal dysfunction. For more information, visit www.functionalmedicine.org or call (800) 228.0622.

2012 North American Research Conference on Complementary and Integrative Medicine

May 15-18, 2012—Marriott Downtown Waterfront, Portland, Oregon

The North American Research Conference on Complementary and Integrative Medicine will represent the third occasion that the 44 Consortium of Academic Health Centers for Integrative Medicine along with other leading national and international CAM networks and organizations are invited to come together to meet and share their research. For updates, e-mail ingo@imconsortium-conference.org or go to www.imconsortium-conference.org.

Third International Fascia Research Congress

March 28-30, 2012—Sheraton Wall Centre Hotel, Vancouver, British Columbia, Canada

The principal focus of the conferences is the presentation of the latest and best scientific research findings on the human fasciae in all its forms and functions. More than 1,000 participants from around the world are expected to attend the 2012 conference. The 2012 International Fascia Congress will focus on the latest and best research on the human fasciae. Additionally, in recognition of the interests of clinicians in gaining insights that will bear on practical applications, the program will be designed to include more presentation time given to relating the research findings to clinical issues. For more information, go to <http://www.fasciacongress.org/2012/>.

17th Annual Primary Care in Paradise

April 2-5, 2012—Kauai Marriott Resort and Beach Club, Lihue, Kauai, Hawaii

Primary care physicians are often the first medical practitioners contacted by a patient. Therefore, primary care physicians require a distinct approach and special skills in eliciting concerns, focusing key issues, negotiating plans, and helping solve problems. This CME conference educates and promotes improved patient outcomes in a broad range of therapeutic areas commonly encountered in primary care. For more information, including registration details, please visit <http://www.scripps.org/events/primary-care-in-paradise>.

9th Annual Nutrition and Health Conference: State of the Science and Clinical Applications

April 15-18, 2012—Westin Boston Waterfront, Boston, Massachusetts

This conference assembles internationally-recognized researchers, clinicians, educators, and chefs, all of whose work focuses on the interface between nutrition and healthful living. You'll leave understanding the links between nutrition, disease, and health to better advise patients on nutritional recommendations that improve their conditions. In addition, you'll taste delicious and healthful meals developed by Andrew Weil's personal chef based on dietary recommendations and anti-inflammatory guidelines, earn credit for your professional development, and learn alongside like-minded professionals. For more information, visit www.nutritionandhealthconf.org.

9th Annual National Ayurvedic Medical Association Conference (NAMA): Healing People, Healing Communities

April 19-22, 2012—Hyatt Regency Hotel, Bellvue, Washington

Join the National Ayurvedic Medical Association, its Board of Directors, Advisors, Members and friends for a weekend of exploration and deeper journey into the wisdom of Ayurveda. This is an excellent opportunity for us to come together in community to learn and celebrate! Included in this conference: clinical practice presentations; 3 continuing education Practicum for Practitioners and advanced students, presentations on Ayurveda's integration with Yoga, Vastu, and Jyotish; well-known presenters in the Ayurvedic community; products, services, and information from sponsors and exhibitors throughout the conference. For more information, visit <http://www.cvent.com/events/9th-annual-nama-conference-attendee-registration/event-summary-458bc21ee2e84727a05232ae232b7874.aspx>.

International Postgraduate Course in Anthroposophic Medicine

May 4-11, 2012—Rudolf Steiner College, Fair Oaks, California

Come and learn about anthroposophic medicine and nursing—a comprehensive integrative approach, 90 years old and always new. This year's clinical course includes; workshops in pediatric constitutional treatment; a certification course in anthroposophic nursing; an international faculty with Michaela Glockler, Albert Schmidli, Ursula Flatters, Mark Kamslet, Alicia Landman, Adam Blanning, Christoph con Dach, and more. For more information, please contact paamdrscourse@anthroposophy.org or go to <http://www.paam.net/training/annual-training-week-for-doctors.html>.

To add a listing to our conference calendar, please send an e-mail to ATHM@innovationhm.com.

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Do You Have Patients With Cancer Who Have Become Untreatable?

Saving Sonia

On December 27, 2010, Sonia went to a prominent hospital in Scottsdale, Arizona unable to keep anything down, vomiting around the clock. After many tests, Sonia was told she had ovarian cancer. Advanced ovarian cancer. Explorative surgery was attempted, but when the surgeon opened her up he closed her right back up and told the family: "I couldn't tell one organ from another".

In February Sonia started chemotherapy. Her hair fell out, she continued to vomit.

In April, after two months of chemotherapy, Sonia was told the treatment was not working. Her CA-125 ovarian cancer marker had only gone up — not down. They sent her home to die.

Sonia could still keep nothing down.

After two months of lying in bed, vomiting five times a day, waiting to die, Sonia learned of Dr. Knouse through a friend. Sonia was told Dr. Knouse was not afraid to treat a cancer victim sent home to die, and that he did not use chemotherapy. Sonia learned Dr. Knouse had previous patients who also had been sent home to die, who were now healthy and happy.

On June 15, Sonia started treatment under the direction of Dr. Knouse in the comfort of her own home.

She stopped vomiting. Her CA-125 dropped like a stone.

Other markers, such as Sed-Rate and C-Reactive Protein — markers for inflammation caused by her cancer — dropped from Too High To Measure to Normal.

She lost pounds of tumor in weeks.

She started eating.



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On July 11th, Sonia started taking walks in the sun.

Started playing with her two pugs in the backyard. Started puttering in her garden with her daughter. If you would like to know how Sonia is doing now and how you could either refer or consult with us, please call.

The Knouse Program, Payson, AZ

The difference happens here.

Phone: 888.554.8626 Email: thedifference@knouseprogram.com



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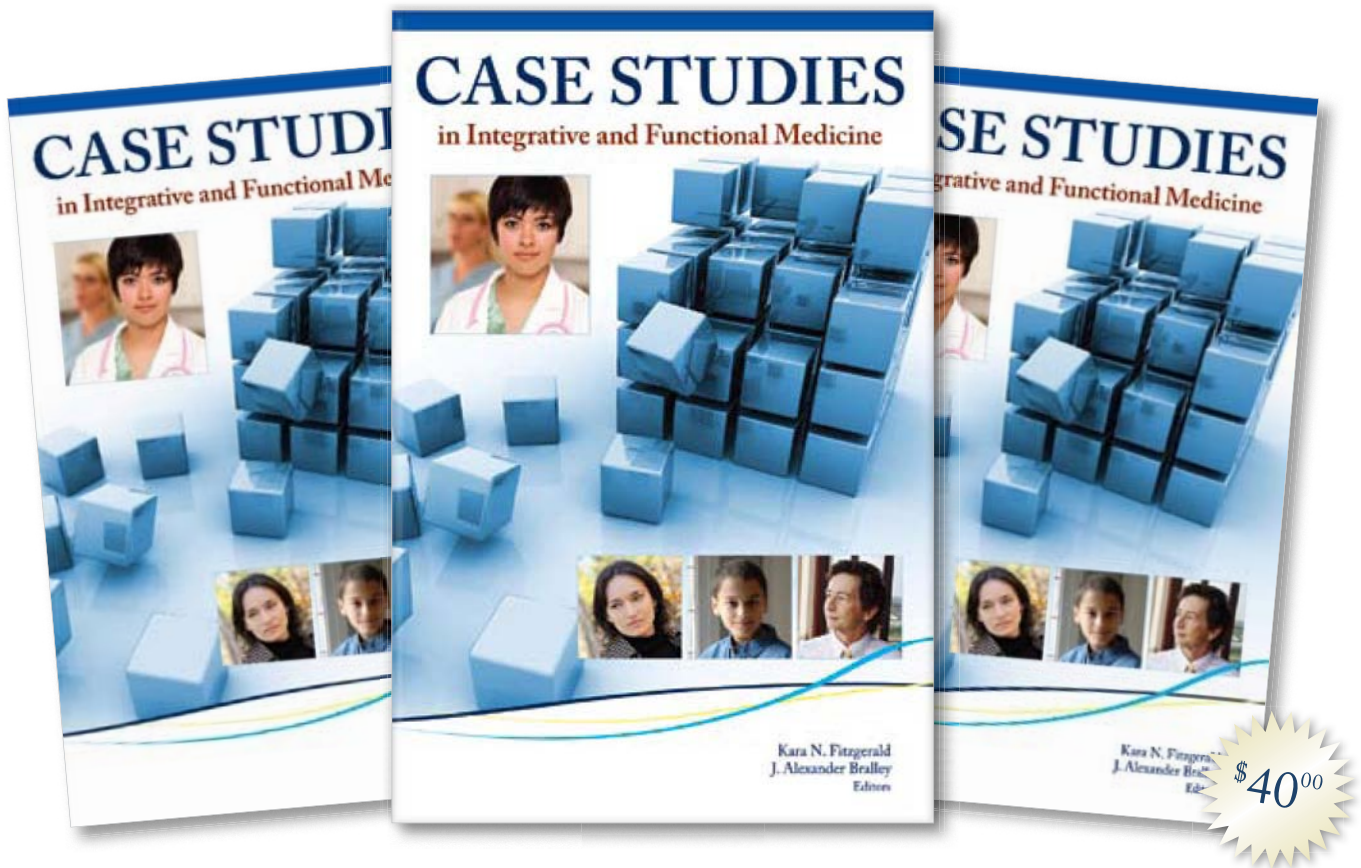
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