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Short Report

Integrative Medicine Research at an Academic Medical Center: Patient Characteristics and Health-Related Quality-of-Life Outcomes

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Abstract

Objective: To characterize patients seeking care at a university-based integrative medicine practice, and to assess short-term changes in health-related quality of life (HRQoL) associated with integrative medical treatment.
Design: Prospective, observational study.
Setting: This study was conducted at a large U.S. academic medical center affiliated with the Consortium of Academic Health Centers for Integrative Medicine.
Participants: Seven hundred and sixty-three (763) new patients with diverse medical conditions participated in the study. Mean age was 49 years (standard deviation = 16, range = 14–93). Two thirds of patients were women and three quarters were white. The most common International Classification of Diseases 9th Revision medical diagnoses were malaise and fatigue, myalgia and myositis, allergy, anxiety or depression, hypertension, malignant neoplasm of the breast, lumbago, and irritable bowel disease. Over half the sample had two or more comorbid medical conditions.
Outcome measure: The Medical Outcomes Study 36-item Short-Form (SF-36) health survey was used to measure HRQoL at initial assessment and 3-months following integrative medicine consultation.
Results: Baseline SF-36 scores fell below the 25th percentile, indicating substantially compromised HRQoL. Physician-prescribed treatment modalities included anthroposophical medicine, nutritional medicine, Western herbs, homeopathy, nutritional counseling, and acupuncture. Three (3) month follow-up assessment revealed statistically significant improvements on all eight SF-36 subscales among survey respondents. HRQoL effect sizes ranged from 0.17 (Physical Functioning) to 0.41 (Social Functioning), with a mean of 0.30. HRQoL effects were consistent among demographic subgroups.
Conclusions: Integrative medical treatment at a university-based center is associated with significant increases in HRQoL for a medically diverse population with substantial comorbidity and functional limitations. Controlled studies that measure HRQoL and additional outcomes related to whole person health—physical, mental, social, and spiritual—are needed to determine the full therapeutic potential of integrative medicine, and to determine efficacy and cost-effectiveness relative to conventional medical care.

Introduction

Integrative medicine has been defined as "the practice of medicine that reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and makes use of all appropriate therapeutic approaches, health care professionals and disciplines to support optimal health and healing."[1] Integrative Medicine is an increasingly popular paradigm of whole-person health care; however, few empirical data are

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currently available to guide evidence-based practice.[2,3] To better understand the therapeutic effects of integrating conventional allopathic medicine and complementary and alternative medicine (CAM), scientific research institutions including the National Institutes of Health Clinical Center and university-based academic medical centers have initiated efforts to study the efficacy, safety, and cost-effectiveness of integrative medical treatment.[4–6]

Observational treatment outcome studies in real-world health care settings can provide useful information on the clinical implications of integrating philosophically different approaches to human health and healing, including (1) what types of patients present for integrative medical treatment, (2) whether individualized, integrative approaches to patient care are associated improved health-related quality of life (HRQoL), and (3) whether integrative medicine treatment outcomes generalize across patient demographics and medical conditions.[7] Such information can generate hypotheses for randomized clinical trials (RCTs) designed to definitively test the efficacy and cost-effectiveness of integrative medicine relative to conventional models of patient care, prevention, and health promotion.

The current study was conducted at a member institution of the Consortium of Academic Health Centers for Integra-

tive Medicine (CAHCIM) and aimed to (1) medically characterize the presenting patient population, (2) evaluate short-term changes in HRQoL associated with individualized integrative medical treatment, and (3) assess differences in patient-reported outcomes as a function of demographic characteristics.

Method

A prospective, observational cohort study was conducted at the Jefferson Center for Integrative Medicine (CIM) of Thomas Jefferson University and Hospital between September 1998 and June 2001. During this time, all new CIM patients were invited to participate in an open enrollment treatment outcome study. Patients were not excluded based on age, gender, ethnicity, socioeconomic status, or medical condition. The clinical research protocol was approved by the Thomas Jefferson University institutional review board and all study participants provided informed consent. Patients less than 18 years of age were enrolled if both parental consent and child assent were obtained.

Demographic data, including age, gender, ethnicity, medical history, and current symptomatic complaints, were collected using an intake evaluation form administered during

TABLE 1. DEMOGRAPHIC CHARACTERISTICS ($N = 763$)

Mean (SD)	N	%
Age	49.41 yrs (15.50 yrs)	Range 14–93 yrs
14–17 yrs	14	1.8%
18–29 yrs	62	8.2%
30–39 yrs	116	15.2%
40–49 yrs	206	27.0%
50–65 yrs	243	31.8%
66+ yrs	122	16.0%
Gender		
Women	506	66.3%
Men	223	29.2%
Not reported	34	4.5%
Ethnicity		
White	574	75.2%
African-American	55	7.2%
Asian	7	0.9%
Hispanic	5	0.7%
Native American	3	0.4%
Other	5	0.7%
Unknown/not reported	114	14.9%
ICD-9 medical diagnoses		
Malaise & fatigue	90	11.8%
Myalgia & myositis	74	9.7%
Allergy	67	8.8%
Anxiety or depression	61	8.0%
Hypertension	46	6.0%
Malignant neoplasm, breast	45	5.9%
Lumbago	39	5.1%
Irritable bowel disease	37	4.8%
Prevalence of comorbidity		
No medical diagnosis	34	4.5%
1 medical diagnosis	255	33.4%
2 medical diagnoses	281	36.8%
3 or more medical diagnoses	193	25.3%

ICD-9, International Classification of Diseases, 9th Revision; SD, standard deviation.

the initial office visit. The Medical Outcomes Study 36-item Short-Form (SF-36), a standardized general health survey that measures eight scales of HRQoL including physical, mental, and social functioning,[8–10] was completed by all new consenting patients. Medical diagnoses and physician-recommended treatments were tracked by an electronic billing system.

Patients who completed a baseline SF-36 health survey were mailed a 3-month follow-up form to assess short-term HRQoL outcomes. If a follow-up survey response was not received within 2 weeks, a second mailing was sent. Descriptive statistics were generated using all available demographic, medical, and HRQoL data. Baseline and 3-month follow-up SF-36 data were analyzed using paired samples t-tests, 95% confidence intervals and the Standardized Response Mean to estimate effect sizes.[11] Differences in demographic characteristics and baseline SF-36 data between follow-up survey respondents and nonrespondents were tested using χ^2 and independent samples t-tests. To determine whether changes in HRQoL differed as a function of age, gender, ethnicity, or medical comorbidity status, demographic variables were used to facilitate subgroup analyses of SF-36 change scores. All data are reported as mean ± standard deviation unless otherwise indicated.

Results

Demographic characteristics of the study sample

Table 1 provides a demographic summary of the study population ($n = 763$; mean age = 49 ± 16 years, range = 14–93 years; 66% female; 75% white). Of nearly 250 different primary medical diagnoses made by CIM physicians, the most common were: malaise and fatigue, myalgia and myositis, allergy, anxiety or depression, hypertension, malignant neoplasm of the breast, lumbago, and irritable bowel disease. CAM modalities prescribed by CIM physicians included anthroposophical medicine, nutritional medicine, Western herbs, homeopathy, nutritional counseling, and acupuncture.

Outcome measures and statistical analyses

Mean baseline SF-36 scores fell below the 25th percentile relative to general U.S. population norms, indicating rela-

tively poor HRQoL at the time of consultation. Nearly half of new consenting patients ($n = 370$; 48.5%) responded to the 3-month follow-up survey by mail. Median response time was 19.5 ± 33.9 days. Follow-up survey nonrespondents did not differ significantly from respondents on SF-36 subscales at baseline, indicating comparable physical and mental health status (all p values >0.05). In addition, nonrespondents to the follow-up survey did not differ significantly from respondents in terms of mean age ($t_{761} = 0.39$, $p = 0.70$), gender ($\chi^2_1 = 0.12$, $p = .73$), ethnicity ($\chi^2_1 = 2.84$, $p = 0.09$), or medical comorbidity ($\chi^2_3 = 6.05$, $p = 0.11$), indicating comparable demographic characteristics and illness severity.

Comparison of baseline and 3-month follow-up SF-36 data for 370 survey completers revealed significant changes on all eight HRQoL subscales (Table 2). Mean effect size was 0.30, with a range between 0.17 (Physical Functioning) and 0.41 (Social Functioning); these values represented small to medium effects.[12] Six (6) of eight SF-36 subscales improved five points or more, indicative of clinically relevant change.[9] HRQoL outcomes did not differ significantly by age, gender, ethnic minority status, or medical comorbidity (all p-values > 0.10).

Discussion

This study is the first to describe patient characteristics and HRQoL treatment outcomes at a university-based integrative medicine clinic in the United States. Consistent with national survey data on CAM use, three quarters of the presenting patients were white and two thirds of the patients were female.[13–15] Also consistent with national data, patients presenting for integrative medical care tended to report multiple medical conditions and relatively poor HRQoL.[13–15] Clinically significant changes on 6 of 8 HRQoL measures were detected at 3-month follow-up in a medically and demographically representative sample of 370 new patients. These data indicate that individualized, integrative medical treatment was associated with meaningful short-term improvement in physical, mental, and social functioning among patients who responded to follow-up assessment. This study extends previous findings by demonstrating that patients who seek to integrate CAM with allopathic medicine at a university-based academic medical center practice

TABLE 2. CHANGES IN HEALTH-RELATED QUALITY OF LIFE ASSOCIATED WITH INTEGRATIVE MEDICAL TREATMENT ($N = 370$)

SF-36 scales (0–100)	Mean baseline (SD)	Mean 3-month follow-up (SD)	Mean difference[a] (95% CI)	t-value[b]	Effect size[c]
Physical functioning	70.02 (28.72)	73.04 (28.08)	3.02 (1.73, 5.42)	3.27	0.17
Role limitations, physical	41.24 (41.84)	56.02 (43.67)	14.78 (9.96, 19.47)	6.32	0.33
Bodily pain	53.36 (27.87)	60.70 (28.73)	7.34 (5.36, 10.07)	6.11	0.32
General health perception	57.20 (24.76)	60.78 (24.79)	3.58 (1.65, 5.16)	3.99	0.21
Vitality	42.72 (24.28)	50.90 (24.42)	8.18 (5.81, 10.35)	7.27	0.38
Social functioning	58.98 (29.35)	70.60 (28.81)	11.62 (8.74, 14.67)	7.78	0.41
Role limitations, emotional	60.66 (41.86)	72.68 (39.39)	12.02 (7.17, 16.91)	4.96	0.26
Mental health	63.99 (20.17)	70.17 (19.48)	6.18 (4.21, 8.05)	6.44	0.34
Physical component summary	40.70 (12.29)	43.03 (12.39)	2.33 (1.40, 3.15)	5.24	0.28
Mental component summary	43.56 (11.69)	47.84 (11.29)	4.28 (3.11, 5.51)	6.98	0.38

[a]Positive difference indicates improvement. Five (5) point change or greater is clinically relevant.[9]
[b]All paired samples t-tested are two-tailed and significant at $p \leq 0.001$.
[c]Standardized response mean [mean difference]/[SD of mean difference]; 0.20 = small, 0.50 = medium, 0.80 = large.[12]
SF, Short Form; SD, standard deviation; CI, confidence interval.

are not simply the "worried well"; rather they are individuals with complex health conditions who may benefit significantly from a whole-person model of care.

Interpretation of results is limited by a nonrandomized study design, which precludes causal inferences. Although a direct comparison group was not available in this study, patient-reported outcomes on the SF-36 were consistent with those published by three other integrative medicine practices: one in California, one in Canada, and one in Germany.[16–18] A novel finding of this study was that short-term improvements in HRQoL did not differ significantly as a function of age group, gender, ethnic minority status, or medical comorbidity, suggesting that integrative medical treatment effects were consistent across demographic subgroups and different levels of illness severity. Whereas data were not collected on duration of illness for this study, results indicated that responders and nonresponders to the follow-up SF-36 survey did not differ significantly on measures of illness severity, including physical and mental functioning and the number of medical conditions diagnosed at baseline. These findings suggest that individuals who responded to the follow-up survey were neither healthier nor sicker compared to patients who did not respond. Collectively, this investigation and others demonstrate that integrative, whole-person models of care are associated with clinical benefits among a variety of patients who present with diminished quality of life.

Future research on Integrative Medicine can build upon early HRQoL findings. First, observational estimates of treatment effects can be used to statistically power RCTs, which are needed to compare the relative efficacy, safety, and cost-effectiveness of Integrative Medicine versus conventional care for specific medical conditions. Second, given the relationship-centered focus of Integrative Medicine,[19] investigation of the role patient–provider relationships play in determining treatment outcomes is essential. Previous research on family medicine and general internal medicine clinics found that patients treated by physicians who spent more time counseling on psychosocial aspects of care, including interpersonal relationships and emotional well-being, reported significantly greater improvement in HRQoL, even though mean HRQoL did not improve significantly following 1 year of treatment in either specialty.[20] Those findings suggest that mean HRQoL improvements observed at a university-based Integrative Medicine clinic compare favorably to conventional primary care practices. Although the relative cost-effectiveness of Integrative Medicine remains unknown, a recent systematic review found that several CAM therapies appear to be of good health economic value.[21]

Future clinical studies on Integrative Medicine will benefit from taking an integrative "systems" approach to outcome assessment.[22,23] For instance, concurrent measurement of biologic, psychologic, social, spiritual, and contextual dimensions of whole-person health can help elucidate patterns of change in medical conditions, risk factors, and/or health behaviors that occur during integrative medical treatment. Advanced data analytic methods, such as structural equation modeling, can be applied to test complex systems of variables that may involve multiple predictors, mediators, and outcomes.[24] Similarly, mixed-effects models can be applied to understand sources of variability in Integrative Medicine treatment outcome(s) attributable to group-level (e.g.,

gender or ethnicity) and individual-level factors (e.g., symptom severity or patient–provider relationship quality) in a single model.[25]

In conclusion, integrative medical treatment at a university-based practice is associated with notable improvement in HRQoL for a variety of patients. Moreover, the degree of improvement in HRQoL does not appear to differ significantly as a function of demographic characteristics, including illness severity at the time of initial treatment. Controlled studies that measure HRQoL and additional outcomes related to whole-person health—physical, mental, social, and spiritual—are needed to determine the full therapeutic potential of Integrative Medicine, including efficacy and cost-effectiveness relative to conventional medical care.

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References

1. Consortium of Academic Health Centers for Integrative Medicine (CAHCIM). Definition of integrative medicine. Online document at: http://imconsortium.org/cahcim/about/home.html Accessed December 16, 2007.

2. Snyderman R, Weil AT. Integrative medicine: Bringing medicine back to its roots. Arch Intern Med 2002;162:395–397.

3. Mann D, Gaylord S, Norton S. Moving toward integrative care: Rationales, models, and steps for conventional-care providers. Complement Health Prac Rev 2004;9:155–172.

4. National Center for Complementary and Alternative Medicine, National Institutes of Health. Integrative medicine consult service established at the NIH clinical center. Online document at: http://nccam.nih.gov/news/2007/051407.htm Accessed May 31, 2007.

5. National Center for Complementary and Alternative Medicine (NCCAM). Expanding Horizons of Health Care. Strategic Plan 2005–2009. Bethesda, MD: U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health. December 2004. NIH Publication No. 04-5568.

6. Nahin RL, Straus SE. Research into complementary and alternative medicine: Problems and potential. BMJ 2001;322:161–164.

7. Walach H, Jonas WB, Lewith GT. The role of outcomes research in evaluating complementary and alternative medicine. Altern Ther Health Med 2002;8:88–95.

8. Ware JE, Sherbourne CD. The MOS 36-Item Short-Form Health Survey (SF-36). I. Conceptual framework and item selection. Med Care 1992;30:473–483.

9. Ware JE. SF-36 Health Survey Manual and Interpretation Guide. Boston, MA: The Health Institute, 1993.

10. Ware JE, Kosinski M, Keller SD. SF-36 Physical and Mental Health Summary Scales: A User's Manual. Boston, MA: Health Assessment Lab, 1994.

11. Liang MH, Fossel AH, Larson MG. Comparisons of five health status instruments for orthopedic evaluation. Med Care 1990;28:632–642.

12. Cohen J. Statistical Power Analysis for the Behavioral Sciences. 2nd ed. Hillsdale, NJ: Lawrence Erlbaum, 1988.

13. Barnes PM, Powell-Griner E, McFann K, et al. Complementary and alternative medicine use among adults: United States, 2002. Advance Data from Vital and Health Statistics; no. 343. Hyattsville, Maryland: National Center for Health Statistics, 2004.

14. Bausell RB, Lee W-L, Berman BM. Demographic and health-related correlates of visits to complementary and alternative medical providers. Med Care 2001;2:190–196.

15. Tindle HA, Davis RB, Phillips RS, et al. Trends in use of complementary and alternative medicine by US adults: 1997–2002. Altern Ther Health Med 2005;11:42–49.

16. Scherwitz LW, Cantwell M, McHenry P, et al. A descriptive analysis of an integrative medicine clinic. J Altern Complement Med 2004;10:651–659.

17. Mulkins A, Verhoef M, Eng J, et al. Evaluation of the Tzu Chi Institute for Complementary and Alternative Medicine's Integrative Care Program. J Altern Complement Med 2003;9:585–592.

18. Michalsen A, Hoffmann B, Moebus S, et al. Incorporation of fasting therapy in an integrative medicine ward: Evaluation of outcome, safety, and effects on lifestyle adherence in a large prospective cohort study. J Altern Complement Med 2005;11:601–607.

19. Gaudet TW. Integrative medicine: The evolution of a new approach to medicine and medical education. Integrative Med 1998;1:67–73.

20. Bertakis KD, Callahan, EJ, Helms JL, et al. Physician practice styles and patient outcomes: Differences between family practice and general internal medicine. Med Care 1998;36:879–891.

21. Herman PM, Craig BM, Caspi O. Is complementary and alternative medicine (CAM) cost-effective? A systematic review. BMC Complement Altern Med 2005;5:11. doi:10.1186/1472-6882-5-11

22. Bell IR, Caspi O, Schwartz GER, et al. Integrative medicine and systemic outcomes research: Issues in the emergence of a new model for primary health care. Arch Intern Med 2002;162:133–140.

23. Verhoef MJ, Vanderheyden LC, Dryden T, et al. Evaluating complementary and alternative medicine interventions: In search of appropriate patient-centered outcome measures. BMC Complement Altern Med 2006;6:38. doi:10.1186/1472-6882-6-38.

24. Schuck JR, Chappell LT, Kindness G. Causal modeling and alternative medicine. Altern Ther Health Med 1997;3:40–47.

25. Gueorguieva R, Krystal JH. Move over ANOVA: Progress in analyzing repeated-measures data and its reflection in papers published in the Archives of General Psychiatry. Arch Gen Psychiatry 2004;61:310–317.

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