A CLINICALLY PROVEN TECHNIQUE TO REDUCE CARDIOVASCULAR DISEASE AND ITS RISK FACTORS

Scientific evidence of the clinical efficacy and cost effectiveness of the Transcendental Meditation® program

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Nonpharmacologic Treatment of Cardiovascular Disease

The Transcendental Meditation technique in the treatment of hypertension and coronary heart disease

EXECUTIVE SUMMARY

Recent clinical trials, other controlled studies, and meta-analyses (of all relevant studies) have identified a new non-drug treatment that leads to improved medical outcomes for patients with cardiovascular disease including hypertension and coronary heart disease.

This treatment, the Transcendental Meditation program, is widely acceptable, cost effective, and free of harmful side effects. We propose that the Transcendental Meditation program be actively utilized (1.) as a first-line or adjunctive non-drug therapy in high blood pressure—hypertension (HTN) and (2.) in the adjunctive treatment of coronary heart disease (CHD).

We recommend that insurance companies and other third-party payers provide reimbursement for Transcendental Meditation instruction for:

1. treatment of hypertension—either as sole therapy or adjunctive to other conventional therapies
2. treatment of coronary heart disease—as part of a multifaceted program including other forms of lifestyle modification and drug therapy as indicated.

The scientific rationale for the effectiveness of the Transcendental Meditation program for these conditions is based on two premises: (i) the well-established principle that stress causes, contributes to and/or exacerbates cardiovascular diseases such as hypertension and coronary heart disease, and (ii) a large body of evidence showing that the Transcendental Meditation technique is the most effective stress-reduction technique available for cardiovascular disease patients. Extensive scientific research has shown reductions in high blood pressure, hardening of the arteries, enlarged heart size, insulin resistance, anxiety, smoking, alcohol use and mortality.

Reducing stress, which means reducing abnormalities in the body that are the result of overload, naturally reduces the physiological and pathological consequences of chronic stress.

There are yet other reasons for insurance companies to cover this intervention. Several cost-benefit analyses indicate lower hospitalization rates, lower outpatient utilization rates and longitudinal reductions in health care costs for those who regularly practice this particular meditation technique.

Further, there are simultaneous improvements in health and quality of life in patients across a wide range of stress-related disorders.
BACKGROUND

Prevalence and burden of hypertension and coronary heart disease

Health care costs continue to spiral upward, in large part due to the increasing prevalence of chronic diseases, notably cardiovascular disease. About 30% of the adult population in developed nations has hypertension. In the US, about 15 million adults have been diagnosed with CHD, and nearly 50% will die as a result of cardiovascular disease (CHD or stroke). Thus, cardiovascular disease is the number one cause of premature death and serious disability in the US and other developed nations, as well as worldwide.

Conventional therapies

More than $300 billion is spent each year in the US on the diagnosis and treatment of cardiovascular disease. Conventional therapies encompass a wide variety of drugs including diuretics, beta blockers, ACE inhibitors, angiotensin II receptor blockers, calcium channel blockers, alpha receptor blockers, vasodilators, statins, nitrates, resins, fibrates, niacin, thrombolytics, aspirin and hormone replacement therapy. Surgical procedures include angioplasty and coronary artery bypass graft surgery.

Inadequacies of conventional therapy

Conventional drug therapies do not address the causes of cardiovascular disease, which are often rooted in unhealthy lifestyle behaviors. Furthermore, conventional pharmacological and surgical therapies for cardiovascular disease often lead to serious adverse effects, including adverse drug effects, impairments in quality of life, and increased mortality.

For these reasons, national practice guidelines of the American Heart Association, the American College of Cardiology, the National Institutes of Health (NIH) and other professional associations recommend non-drug lifestyle modifications (i) as the first line of therapy for individuals with hypertension and (ii) as part of a comprehensive package of lifestyle modifications and drug therapy for individuals with diagnoses of CHD.

This latter group includes patients who have had a myocardial infarction, coronary artery procedures to open clogged arteries (revascularization), chronic angina or stroke.

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**Figure 1: Decreased Blood Pressure**

This study was a meta-analysis examining the effect of all published randomized, controlled clinical trials on the effects of the Transcendental Meditation program on blood pressure, comprising nine studies with 711 subjects. The Transcendental Meditation program was found to have a statistically significant impact of reducing both systolic and diastolic blood pressure. Reference: *American Journal of Hypertension* 21: 310–316, 2008.

**Figure 2: Decreased Blood Pressure Compared to Other Techniques**

This meta-analysis of 107 published studies on stress reduction and blood pressure found that only the Transcendental Meditation program had a statistically significant impact of reducing high blood pressure among hypertensive subjects. Reference: *Current Hypertension Reports* 9: 520–528, 2007.

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In contrast, the Transcendental Meditation program, introduced to the world 50 years ago by Maharishi Mahesh Yogi, targets a basic, contributing cause of cardiovascular disease, the lifestyle factor we call ‘stress’. Many research studies document the stress-reducing and health-promoting effects of the Transcendental Meditation program, and there have been no documented adverse effects associated with the use of the program to reduce stress, treat cardiovascular disease, or with its use by the general population for disease prevention and health promotion.

Data supporting the effectiveness of the Transcendental Meditation program in treating cardiovascular disease

a. Hypertension: Randomized clinical trials and other controlled studies show that the Transcendental Meditation program reduces blood pressure in persons with hypertension [1-4]. End organ damage associated with hypertensive heart disease is also reduced.

Dr. J. Anderson and colleagues of the University of Kentucky Medical Center [5] conducted a systematic review and meta-analysis to assess the effects of the Transcendental Meditation program on BP, incorporating objective quality assessments of the research literature. They reviewed the published literature through December 2006. The meta-study evaluated all randomized controlled trials that compared BP responses between a group practicing the Transcendental Meditation technique and a control group.

Primary outcome measures were changes in systolic and diastolic BP. A specific rating system (0–20 points) was used to evaluate the quality of studies and appropriate statistical procedures (random effects models) were used for the meta-analysis. The meta-analysis indicated that the Transcendental Meditation program, compared to control, was associated with the following statistically significant changes: −4.7 mm Hg in systolic BP and −3.2 mm Hg in diastolic BP (FIGURE 1). When the analyses were limited just to hypertensive groups or just to the highest-quality studies, similar reductions in BP were found.

The authors concluded that: (a) the Transcendental Meditation program significantly reduces high blood pressure; (b) it reduces SBP by ~5 mm Hg and DBP by ~3 mm Hg; and, (c) sustained BP reductions of this magnitude are likely to signifi-

Through Transcendental Meditation

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<th>Reduction of High Blood Pressure</th>
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<td><strong>Figure 3: Reduction of High Blood Pressure</strong></td>
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<td>Patients with high blood pressure who learned the Transcendental Meditation program showed a significant reduction of systolic and diastolic blood pressure after three months, in contrast to those randomly assigned to a control technique or to those who received education on how to reduce blood pressure through diet and exercise. Reference: Hypertension 26: 820–827, 1995.</td>
<td>Patients with coronary artery disease who learned the Transcendental Meditation program showed significantly reduced carotid artery wall thickness after 9 months, a surrogate measure of reduced atherosclerotic plaque, compared to health education controls who learned how to reduce their risk of heart disease through proper diet and exercise. Reference: Stroke, 2000 Mar., 31(3):568-73.</td>
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Significantly reduce risk for serious cardiovascular disease, that is heart attacks and strokes.

Nearly simultaneously, a systematic review and meta-analysis of all the published literature on stress reduction and relaxation methods for high blood pressure was conducted by Rainforth et al. [6] (FIGURE 2). These authors critiqued previous meta-analyses of stress reduction, other relaxation methods and high blood pressure and concluded that most were outdated and/or methodologically limited.

They, therefore, conducted an updated systematic review of the published literature and identified 107 studies on stress reduction and BP. Seventeen trials (with 23 treatment comparisons and 960 participants with elevated BP) met criteria for a well-designed, randomized controlled trial.

Meta-analysis was used to calculate BP changes (SBP/DBP) for biofeedback, -0.8/-2.0 mm Hg (P = not significant [NS]); relaxation-assisted biofeedback, +4.3/+2.4 mm Hg (P = NS); progressive muscle relaxation, -1.9/-1.4 mm Hg (P = NS); stress management training, -2.3/-1.3 mm (P = NS); and the Transcendental Meditation program, -5.0 / -2.8 mm Hg (P = 0.002/0.02).

They concluded that simple biofeedback, relaxation-assisted biofeedback, progressive muscle relaxation and stress management training did not elicit statistically significant reductions in elevated BP while the Transcendental Meditation technique did.

They also concluded that the Transcendental Meditation program should be recommended to patients with elevated BP for preventing or treating hypertension and other forms of cardiovascular disease.

Available evidence thus indicates that: (i) among stress reduction approaches, only the Transcendental Meditation program is associated with statistically significant reductions in BP and (ii) Transcendental Meditation causes reductions in other risk factors for cardiovascular disease and improvements in clinical cardiovascular disease-related outcomes.

b. Coronary Heart Disease: A series of NIH-sponsored clinical trials found that high-risk patients who were randomly assigned to the Trans-

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**Figure 5: Prevention of Left Ventricular Hypertrophy**

Patients with hypertensive heart disease who learned the Transcendental Meditation program did not show significantly elevated left ventricular mass after 7 months compared to health education controls who learned how to reduce their risk of hypertensive heart disease through proper diet and exercise. Reference: *Ethnicity and Disease*, 2004. 14: S2-54.

**Figure 6: Decreased Insulin Resistance of Metabolic Syndrome in Heart Disease Patients**

This randomized controlled clinical trial among individuals with stable cardiac heart disease found that 16 weeks of practice of the Transcendental Meditation program, in contrast to participation in a health education program, led to a significant reduction in insulin resistance, which is considered the basis of metabolic syndrome that often leads to diabetes and heart disease. Reference: *Archives of Internal Medicine* 166: 1218–1224, 2006.
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**Figure 7: Long-Term Effects of Transcendental Meditation on All-Cause Mortality**

Elderly patients (average age 72 years) with high blood pressure who learned the Transcendental Meditation program showed significantly lower all-cause mortality rates including cardiovascular over a 10 year period compared to combined controls (health education, mindfulness, generic relaxation and usual care). Reference: *American Journal of Cardiology*, 2005. 95(9): 1060-1064.

**Figure 8: Reduction of Cardiovascular Mortality**

This study followed the mortality pattern an average of 8 years after elderly individuals with high blood pressure learned the Transcendental Meditation technique or participated in control interventions. The results showed a 30% decrease in the rate of cardiovascular mortality among those who learned the Transcendental Meditation technique. Reference: *American Journal of Cardiology* 95:1060–1064, 2005

**Figure 9: Effectiveness in Reducing Trait Anxiety**

A meta-analysis of 146 studies comparing the effectiveness of different mental and physical relaxation techniques including biofeedback on reducing trait anxiety showed that the Transcendental Meditation technique was most effective by a statistically significant margin. Reference: *Journal of Clinical Psychology*, 1989. 45(6): 957–974.

**Figure 10: Decreased Cigarette Smoking**

A meta-analysis of all research studies on the Transcendental Meditation program related to cigarette smoking, in comparison to meta-analyses of standard treatment and prevention programmes for smoking, found a significantly greater reduction of cigarette use among those who learn the Transcendental Meditation program, even though this programme does not involve any guidance about change in lifestyle or habits. Reference: *Alcoholism Treatment Quarterly* 11: 13–87, 1994.
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The Transcendental Meditation program showed reductions in risk factors for CHD including hypertension [1,2] (FIGURE 3), clogging of the arteries (atherosclerosis) [7,8] (FIGURE 4), the size of the heart’s left ventricle [9] (FIGURE 5) and resistance to the effects of insulin [10] (FIGURE 6). Another trial showed that the Transcendental Meditation program increases exercise tolerance in coronary heart disease patients [11].

The long-term effects of the Transcendental Meditation program were also assessed by evaluating its effects on all-cause mortality and cardiovascular mortality (FIGURES 7-8). This analysis was done for older subjects who had high blood pressure and who had participated in randomized controlled trials that included the Transcendental Meditation program and other behavioral interventions [12]. The Transcendental Meditation program increased survival (that is, decreased mortality). A statistical analysis showed 23% reduction in the mortality rate from all causes.

Additional analyses showed that after an average of 7.6 years, there was a 30% decrease, in the rate of cardiovascular disease-related mortality (relative risk = 0.70) in the Transcendental Meditation group (compared to combined controls).

c. **Psychosocial Stress:** In a meta-analysis of the effects of stress reduction and relaxation techniques on anxiety, the most commonly studied form of psychosocial stress, Dr. K. Eppley of Stanford University and his colleagues separately estimated and compared the effects of the main classes of mind-body techniques: stress reduction, relaxation, and the Transcendental Meditation program (FIGURE 9).

They reported that the Transcendental Meditation technique reduced anxiety to a significantly greater extent than other clinically devised forms of relaxation or stylized rest. These differences were found even after adjustment for experimental design, duration of treatment, expectancy of benefits, and experimenter attitude [14,16].

This meta-analysis has been critically reviewed [17,18]. Other published meta-analyses have reported that the Transcendental Meditation technique reduced other risk factors for CHD, including sympathetic nervous system arousal [13], smoking [16] (FIGURE 10), and alcohol consumption [16] (FIGURE 11).

**Figure 11: Decreased Alcohol Use**

A meta-analysis of all research studies on the Transcendental Meditation program related to alcohol use, in comparison to meta-analyses of standard alcohol treatment and prevention programmes, found a significantly greater reduction of alcohol use among those who learn the Transcendental Meditation program, even though this programme does not involve any guidance about change in lifestyle or habits. Reference: *Alcoholism Treatment Quarterly* 11: 13–87, 1994.

**Figure 12: Decreased Hospitalization Indicating Healthier Ageing**

An analysis of five years of medical insurance data found that the significant reduction in hospitalization among participants in the Transcendental Meditation program, in comparison to other insured persons, was even more dramatic among participants who were older. Reference: *Psychosomatic Medicine* 49: 493–507, 1987.
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What is the Transcendental Meditation program?

The Transcendental Meditation program has its origin in the ancient Vedic tradition [19,20]. Maharishi Mahesh Yogi restored the Vedic knowledge for the full scientific value of its theory and practice [21]. The Transcendental Meditation technique does not use concentration or contemplation; it is not a philosophy or religion. It is a simple, natural yet precise mental technique, practiced twice daily for 15 or 20 minutes each session, while sitting comfortably in a chair with eyes closed. The practice produces a unique state of restful alertness.

The Transcendental Meditation technique has been taught worldwide since 1957. Over 6 million people worldwide have learned the Transcendental Meditation technique, 2 million people in the United States. Hundreds of published scientific research studies document its benefits [22].

How does the Transcendental Meditation technique work?

Basic and clinical research indicates that practice of the Transcendental Meditation technique ameliorates hypertension and cardiovascular disease by reducing stress. This in turn reduces the chronic activation of physiological stress response systems, especially ones that affect the cardiovascular system.

One of these is the sympathetic nervous system (SNS), which causes fight or flight response to the heart and blood vessels. Another is the hypothalamic pituitary-adrenal (HPA) axis [23, 24] which allows psychosocial stress to drive up blood levels of stress hormones such as cortisol.

As the chronic effects of stress on mind and body are reduced by regular practice of the Transcendental Meditation technique, risk factors for CHD are reduced. As shown above, these include: (1) cardiovascular reactivity [25-27]; (2) anxiety [14]; (3) hypertension [1,2,6,15]; (4) insulin resistance (considered the basis of metabolic syndrome) [10]; (5) smoking [16]; (6) alcohol abuse [16]; and (7) surrogate and intermediate endpoints for CHD such as (a) myocardial ischemia [11], (b) carotid artery wall

Figure 13: Decreased Outpatient Visits Indicating Healthier Ageing

Participants in the Transcendental Meditation program, in contrast to the average of all other insured persons, showed a significant reduction in outpatient doctor visits that was even more pronounced among participants who were older, as indicated by analysis of five years of medical insurance data. Reference: Psychosomatic Medicine 49: 493–507, 1987.

Figure 14: Decreased Medical Expenses

This study measured annual percentage change in government payments for physicians' services over 14 years among 1,418 people in Quebec, Canada, who learned the Transcendental Meditation program in comparison to randomly-selected controls. After learning the Transcendental Meditation program, individuals showed an average annual decline of 13.8 per cent in payments. Reference: American Journal of Health Promotion 14: 284–291, 2000.
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thickness [7-8], and (c) left ventricular enlargement (hypertrophy) [7,9,11,29].

This integrated series of effects leads to a reduction in clinical CHD-related events, including premature mortality [12].

It is suggested that the Transcendental Meditation program reduces cardiovascular disease and its risk factors because it enables the individual to achieve a unique state of restful alertness, which allows the body’s endogenous homeostatic and self repair mechanisms to become restored and reactivated.

When this happens, blood pressure and other key factors revert back to their original, healthier set points. In other words, the Transcendental Meditation technique may be thought of as a technique to enliven the body’s own inner intelligence [19]. These findings are completely in accord with the widely accepted biobehavioral model of cardiovascular disease [23,24].

**INSTRUCTION AND FOLLOW-UP**

The Transcendental Meditation technique is taught by certified instructors in a standardized way everywhere in the world, through a systematic program of instruction. The Transcendental Meditation course gives the individual the experience and knowledge needed to correctly practice the Transcendental Meditation technique on their own, and gain the maximum benefits.

The course consists of seven meetings with the professional instructor, with 90 minutes per meeting. These seven meetings consist of:

1. Introductory lecture (in a group) describing the benefits.
2. Preparatory lecture (in a group) describing how the technique works
3. A brief personal interview with the instructor.
4. Personal instruction in the Transcendental Meditation technique.
5-7. Group meetings based on the individuals’ experiences of practicing Transcendental Meditation.

Individuals often notice immediate benefits of their practice of the Transcendental Meditation technique during these first days of instruction. A regular follow-up program is offered to confirm the correctness of practice.

**COST/BENEFIT CONSIDERATIONS**

Using the Transcendental Meditation program is demonstrably cost-effective. The individual fee for the Transcendental Meditation course in the USA is $2,000 which includes a life time follow-up program.

This is highly cost-effective in light of the documented benefits: Studies [30-34] show that regular practice of the Transcendental Meditation technique lowers health insurance utilization rates with significantly fewer hospital inpatient days and outpatient visits, and fewer inpatient admissions for all major categories of disease (FIGURES 12-14). Across all disease categories, there was a 56% lower utilization rate. For the two key physiological systems relevant to this proposal, reductions were even greater: 87% reductions for both cardiovascular disease and for diseases of the nervous system. A Canadian study [32-33] showed a longitudinal reduction (a cumulative savings of 13% per year) in government payments to physicians.

**CONCLUSION**

A cumulative body of well designed clinical trials, other clinical studies, and meta-analyses demonstrates that a nonpharmacologic approach, the Transcendental Meditation program—for the treatment of hypertension, coronary heart disease and their risk factors is effective in the sole or adjunctive care of cardiovascular disease. Furthermore, there are no harmful side effects from this technique Additional benefits include improved quality of life and reduction or elimination of other chronic stress-related conditions.

These clinical effects are clearly cost-effective. Based on the published biomedical evidence, it is proposed that payment of the cost of Transcendental Meditation instruction by insurance companies and third-party payers is justified and timely.

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Major Cardiovascular Disease Factors Reduced by One Natural and Effective Procedure, Free From Side-Effects

- Decreased Medical Expenses
- Decreased Hospitalization
- Decreased Outpatient Visits
- Reduction of Cardiovascular Mortality
- Improved Functional Capacity in Heart Failure
- Regression of Left Ventricular Mass
- Improved Exercise Tolerance in Angina Pectoris
- Reduction of Atherosclerosis
- Reduced Sympathetic Nervous System Arousal
- Faster Recovery from Stress
- Decreased Anxiety and Depression
- Decreased Blood Pressure
- Decreased Insulin Resistance
- Reduced Cholesterol
- Decreased Cigarette Smoking
- Decreased Alcohol Use

Published research on the Transcendental Meditation program

Improved Clinical Outcome and Reduced Need for Pharmacological and Surgical Treatments

Thousands of physicians worldwide recommend the practice of the Transcendental Meditation program to their patients

*The indicated sequence is a simplified version of complex and parallel physiological interactions*
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REFERENCES


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Extensive Scientific research verifies the effectiveness of the Transcendental Meditation Program

The practical benefits of the Transcendental Meditation program have been verified by more than 600 scientific research studies conducted at over 250 independent universities and research institutions in 33 countries. Scientific research on the Transcendental Meditation program has been collected in seven volumes, 6,000 pages.
**Vital Signs**

**Regimens: High Blood Pressure? Meditation May Help**

By Nicholas Bakalar

Transcendental Meditation improves blood pressure and insulin resistance in heart patients, according to a placebo-controlled study carried out at an academic medical center in California.

**Meditation Lowers Blood Pressure**

*Doc: Other Relaxation Techniques Don't Work As Well*

Transcendental Meditation helps lower blood pressure without the side effects that can come from medication, according to a new study.

**Transcendental Meditation**

Stress-reducing relaxation may improve life expectancy
Meditation benefits patients with heart disease

Blood pressure, insulin resistance improved, even without weight loss

(June 13, 2006) In a study of adults with coronary heart disease who were stable and were receiving optimal medical care, 16 weeks of transcendental meditation not only led to significant reductions in blood pressure, but also improved heart rate variability and insulin resistance, which is associated with an increase risk of diabetes.

Penn Study Shows Transcendental Meditation Can Help Combat Congestive Heart Failure

Results of NIH-Funded Study Published in the Journal Ethnicity & Disease

Science and Your Health

A guide to some of the newest research and recommendations

Meditation and Medication

Stress-reduction techniques such as meditation may help reduce high blood pressure and the need for treatment, according to a study published in the American Journal of Hypertension last week.
Meditation May Benefit Heart Patients

Study: Black Patients with Heart Failure Improve Significantly After Meditation

By Salynn Boyles, WebMD Medical News  Reviewed by Louise Chang, MD

March 7, 2007 -- Regular meditation is known to relieve stress, and now early research suggests that it can benefit patients with congestive heart failure.

The small pilot study included 23 recently hospitalized black patients. Thirteen were taught the technique of Transcendental Meditation (TM) and asked to practice it for six months. The remaining patients received educational training about their heart disease without instruction on meditation.

Changes in a six-minute walking test at three and six months were measured by the researchers, as were changes in mood, quality of life, stress, and depression.

University of Pennsylvania assistant professor Ravishankar Jayadevappa, PhD, who led the study team, tells WebMD that the patients who meditated showed significant improvements in depression and on the six-minute walking test. The six-minute walking test was used to measure functional capacity.

“This is a small study, and it needs to be replicated in a larger trial with a more diverse population,” he says. “But it is the first study to look specifically at stress reduction through meditation in African-American patients with congestive heart failure.”

What Is Heart Failure?

Each year in the U.S. roughly 500,000 people receive a diagnosis of congestive heart failure, and 300,000 people die from the disease, according to figures from the American Heart Association.

Heart failure is responsible for more than 2.5 million hospital admissions each year in the U.S.

In heart failure, the heart doesn’t pump blood as well as it should. This can lead to a backup of fluid in the body, such as in the legs and lungs. It also means that the heart isn't pumping as much oxygenated blood to different areas of the body. This can produce a decrease in tolerance of physical activity due to fatigue and shortness of breath.

Jayadevappa says the pilot study included only blacks because they are more likely than whites to develop heart failure and die from the disease.

Patients in the TM arm of the study were taught the meditation technique over seven consecutive days in daily 1.5-hour sessions. They were then asked to meditate for 15 to 20 minutes twice a day.

The remaining patients participated in nonmeditation-based educational training that paralleled the time spent teaching the meditation technique. They were then asked to listen to music or read for 20 minutes, twice each day, as a way to relieve stress.

The researchers reported significant benefits for meditation in terms of physical functioning, as measured by the six-minute walking test, and depression. And just two heart-failure related events were reported in the meditation group during the six-month study, compared with five in the patients who did not meditate.

The findings are reported in the Winter 2007 edition of the journal Ethnicity and Disease. The study was sponsored by the National Center for Complementary and Alternative Medicine, a division of the National Institutes of Health.
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