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# A Randomized Controlled Trial of the Effects of Transcendental Meditation on Quality of Life in Older Breast Cancer Patients

Sanford I. Nidich, Jeremy Z. Fields, Maxwell V. Rainforth, Rhoda Pomerantz, David Cella, Jean Kristeller, John W. Salerno, and Robert H. Schneider<sup>1</sup>

## Abstract

This single-blind, randomized controlled trial evaluated the impact of the Transcendental Meditation program plus standard care as compared with standard care alone on the quality of life (QOL) of older women ( $\geq 55$  years) with stage II to IV breast cancer. One hundred and thirty women (mean age = 63.8) were randomly assigned to either experimental ( $n = 64$ ) or control ( $n = 66$ ) groups. Functional Assessment of Cancer Therapy–Breast (FACT-B), Functional Assessment of Chronic Illness Therapy–Spiritual Well-Being (FACIT-SP), and Short-Form (SF)-36 mental health and vitality scales were administered every 6 months over an average 18-month intervention period. Significant improvements were found in the Transcendental Meditation group compared with controls in overall QOL, measured by the FACT-B total score ( $P = .037$ ), emotional well-being ( $P = .046$ ), and social well-being ( $P = .003$ ) subscales, and SF-36 mental health ( $P = .017$ ). Results indicate that the Transcendental Meditation technique improves the QOL of older breast cancer patients. It is recommended that this stress reduction program, with its ease of implementation and home practice, be adopted in public health programs.

## Keywords

Transcendental Meditation, breast cancer, survival, oncology

## Background

Breast cancer is the most prevalent form of cancer in women, with women above the age of 50 having nearly 4 times the incidence compared with women below this age.<sup>1,2</sup> Quality of life (QOL) in breast cancer patients has been well documented, indicating that both newly diagnosed and long-term survivors have impairments in emotional, physical, functional, social, and spiritual well-being.<sup>3–5</sup>

The causes of breast cancer are multifactorial<sup>6</sup>; however, psychosocial stress is implicating as contributing to cancer onset, progression, and mortality.<sup>7–23</sup> Increased psychosocial stress is observed in women diagnosed with breast cancer,<sup>14</sup> with sustained distress occurring during cancer treatment<sup>24,25</sup> and continuing for 2 years or more postsurgery.<sup>15–22</sup>

Previous studies on stress reduction and other psycho-educational interventions have indicated beneficial changes in the QOL of breast cancer patients.<sup>26–33</sup> Preliminary research on the Transcendental Meditation program, one of the most widely researched modalities for reducing psychosocial

stress,<sup>34–36</sup> suggests reduced cancer mortality, reduced hospitalization for benign and cancerous tumors, and reduced hospital admission rates for all cancers.<sup>37–40</sup>

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However, there is a lack of research focused specifically on stress reduction in older women with breast cancer. We therefore undertook a randomized controlled trial to evaluate the effects of the Transcendental Meditation program on QOL in older women. This was the first randomized controlled trial to evaluate the impact of this intervention on breast cancer patients. It was hypothesized that there would be a significant improvement in overall QOL, as measured by the Functional Assessment of Cancer Therapy–Breast (FACT-B) total score, for those in the program with Transcendental Meditation plus standard care compared with those with standard care alone.

## Methods

### Design

This was a single-blind, randomized controlled trial with 130 women, 55 years and older, with stages II to IV breast cancer. The study began on November 1, 1999, with the first randomization taking place on December 1, 1999, and the conclusion of the intervention and testing taking place on July 31, 2002. All patients had the consent of their treating physician or oncologist to participate in this study approved by the local institutional review board, had a life expectancy of at least 3 months, and gave written informed consent. Study participants were recruited primarily from St Joseph's Hospital in Chicago and surrounding areas through networking with oncologists, cancer clinics, and cancer support groups as well as through advertising. Patients were randomized by stratification on age (<65 vs ≥65), cancer stage (stage IV vs II or III), membership in a social support group, and timing of metastases for stage IV patients, and they were assigned to either the Transcendental Meditation program or the control group.

### Interventions

**Transcendental Meditation program.** The Transcendental Meditation technique\* is the principal mind–body modality of the Maharishi Vedic Approach to Health,<sup>41–43</sup> a comprehensive traditional system of natural medicine derived from the ancient Vedic tradition (*Veda* means pertaining to knowledge) that enlivens the body's "inner intelligence." The Transcendental Meditation technique is described as a simple, natural, and easy-to-learn procedure that allows the ordinary thinking process to become more quiescent and a unique psychophysiological state of "restful alertness" to be gained.<sup>44</sup> This distinctive state of restful alertness<sup>44,45</sup> is characterized by decreased respiration rates, blood lactate, and basal skin conductance levels<sup>46</sup>; regulation of cortisol and other hormones related to chronic stress<sup>47,48</sup>; and high EEG coherence.<sup>49</sup> The

program is practiced individually at home twice a day for 20 minutes while sitting comfortably with eyes closed.<sup>43</sup> Those who learned the Transcendental Meditation technique were taught by a qualified instructor at the Chicago Transcendental Meditation Center or surrounding centers, according to the standardized format offered in the United States by Maharishi Vedic Education Development Corporation. Instruction involved a 7-step course that lasted approximately 1 to 1.5 hours per session. These sessions included 2 introductory lectures covering previous scientific research and principles of correct practice, a brief personal interview, individual personal instruction, and 3 follow-up group meetings. Optional follow-up sessions were offered through monthly meetings to encourage participants to continue to practice the Transcendental Meditation technique regularly at home.

**Control group.** Patients randomized to this group were recruited through the recruitment methods described above. Following assignment, patients received basic literature on breast cancer recommended by the National Cancer Institute and the American Cancer Society.

**Standard care.** All participants in both the experimental and control groups continued their medical care prescribed by their physicians or oncologists.

### Measures

The primary outcome of the study was overall QOL, as measured by the FACT-B total score. QOL data were collected using the following standardized assessment instruments at baseline and every 6 months over a 2-year period.

**The Functional Assessment of Cancer Therapy–Breast.** This instrument provides a total QOL score and subscales for functional well-being, emotional well-being, physical well-being, and social/family well-being.<sup>50–52</sup> The FACT-B also provides an additional scale related to breast cancer concerns, which was analyzed separately.

**The Functional Assessment of Chronic Illness Therapy–Spiritual Well-Being (FACIT-SP).** This instrument was used to assess patients' sense of meaning, peace, and purposefulness in life and their faith or optimism in the future.<sup>53</sup>

**Short-Form Health Survey (SF-36) mental health and vitality subscales.** These 2 subscales of the SF-36 were administered to obtain additional information on mental health and vitality status.<sup>54</sup>

### Data Collection, Statistical Analyses, and Missing Data

Data forms were administered individually at St Joseph's Hospital by the research assistant at scheduled testing visits at baseline (prior to randomization) and every 6 months thereafter for the duration of the study. Those patients who lived too far away to personally come in for testing were mailed the testing battery to fill out at home and mail back to the research assistant in a sealed envelope.

\*Transcendental Meditation, TM, and Maharishi Vedic Approach to Health are service marks registered in the US patent and trademark office, licensed to Maharishi Vedic Development Corporation and used under sublicense.

Patients were randomized to treatment group, using random number assignment generated by the SAS statistical software program by the study statistician at Maharishi University of Management Research Institute. The schedule of treatment group allocations was concealed by the study statistician, with individual treatment group assignments revealed to the project manager by e-mail only when study participants completed baseline testing and met all eligibility criteria.

All investigators, data collection and data entry staff, and treating physicians were masked to treatment assignment, except for the project manager. Therefore, this was a single-blinded randomized clinical trial. Two-sided *P* values were used for all analyses.

Changes in each QOL outcome variable were analyzed by repeated measures analysis of covariance, covarying for the baseline outcome measure and baseline differences between groups. The SAS PROC MIXED routine, which estimates a repeated measures model over all available observations with at least 1 posttest,<sup>55</sup> was used for all QOL analyses. The analysis using the SAS PROC MIXED routine estimated the statistical model given all the observed values of the dependent variable.<sup>55</sup> Missing values of the covariates in the ANCOVA model for QOL were handled using single imputation.<sup>55</sup> Hence, all available cases were included in the QOL analyses.

### Sample Size Calculation for Primary Outcome: FACT-B Total

The sample size was determined based on FACT-B total scores as the primary outcome. We assumed the following: (1) repeated measures ANCOVA on change every 6 months over an average 1-year period, with baseline FACT-B score as the covariate; (2) 2-sided tests at the .05  $\alpha$  level; and (3) 20% attrition. A treatment effect size of .25 was assumed based on data reported by Brady et al.<sup>51</sup> Also based on Brady et al,<sup>51</sup> the standard deviation of the FACT-B scores was assumed to be 13.7 and the test-retest correlation was set at .85. Based on these assumptions, and using PASS 2000 statistical software for power and sample size calculation, it was determined that 65 participants in each group would provide 80% statistical power to detect a treatment effect of .25 standard deviation units or greater. Hence a total sample size of 130 would provide adequate power to detect a significant difference in the primary outcome.

## Results

### Baseline and Demographic Characteristics

In all, 130 participants (mean age = 63.84) were randomized into the study, 64 to the Transcendental Meditation group and 66 to the control group. The majority of the patients (72.3%) had stage II breast cancer (see Table 1).

**Table 1.** Demographic and Baseline Characteristics by Treatment Group

Variable	TM (n = 64)		Usual Care (n = 66)		P Value
	Mean	SD	Mean	SD	
Age	64.4	7.6	63.3	6.1	.38
Married (%)	62.7		66.7		.65
Education (some college)	72.4		58.7		.11
Support group member (%)	23.4		22.7		.92
Breast cancer stage, % (n)					.34
II	68.8% (44)		75.8% (50)		
III	4.7% (3)		7.6% <sup>56</sup>		
IV	26.6% (17)		16.7% (11)		
Tumor size (mm)	29.2	16.5	29.6	15.0	.90
No. of nodes	3.3	6.5	2.5	3.9	.44
Estrogen- receptor status					.01
Positive	71.9% (46)		60.1% (40)		
Negative	4.7% (3)		25.8% (17)		
Unknown	23.4% <sup>56</sup>		13.6% (9)		
Progesterone- receptor status					.21
Positive	48.4% (31)		47.0% (31)		
Negative	20.3% (13)		36.3% (24)		
Unknown	31.3% (20)		16.7% (11)		
Type of surgery					.07
Mastectomy	54.7% (35)		33.3% (22)		
Lumpectomy	26.6% (17)		47.0% (31)		
Other	4.7% (3)		6.1% (4)		
None	14.1% (9)		13.6% (9)		
Tamoxifen	50.0% (32)		43.9% (29)		.49
Radiation (%)	61.0% (39)		60.6% (40)		.99
Chemotherapy (%)	67.2% (43)		80.3% (53)		.71
Years since initial diagnosis	5.9	4.9	5.3	4.2	.42
Smoking (%)	3.2		1.5		.54
Drinking (number of alcoholic drinks/week)	2.4	3.9	1.7	2.6	.24
FACT-B total score (0-104)	80.8	15.8	83.9	12.3	.23
Physical well-being (0-28)	22.6	5.5	23.1	4.6	.56
Social well-being (0-24)	19.8	4.6	20.5	4.0	.33
Emotional well-being (0-24)	17.8	4.8	18.3	3.4	.49
Functional well-being (0-28)	20.7	5.7	21.9	4.4	.16
Additional concerns (0-36)	11.9	5.0	10.8	5.1	.22
FACIT-SP (0-48)	37.7	7.5	36.5	8.3	.36
Meaning/Peace	25.2	4.8	24.4	5.9	.43
Faith	12.3	4.2	12.0	4.0	.70
SF-36 mental health (0-100)	72.0	18.1	75.2	14.7	.28
SF-36 vitality (0-100)	50.2	22.5	53.6	23.0	.40
Duke Social Support (0-36)	32.9	6.7	33.1	6.7	.86

Abbreviations: TM, Transcendental Meditation; FACT-B, Functional Assessment of Cancer Therapy–Breast; FACIT-SP, Functional Assessment of Chronic Illness Therapy–Spiritual Well-Being.

There were no significant differences between the Transcendental Meditation and control groups at baseline in terms of age, breast cancer stage, time from initial diagnosis, surgery, number of positive nodes involved, average tumor size, positive estrogen-receptor (ER) and progesterone-receptor status, psychosocial and QOL variables, marital status, college education, membership in a social support group, alcohol, and smoking. The only statistically significant difference between groups at baseline was in terms of ER negative status (25.8% of the control group were ER negative, compared with 4.7% in the experimental group).

### Quality-of-Life Changes

For the primary outcome—namely, FACT-B total score—repeated-measures ANCOVA (covarying for baseline FACT-B total and ER status) indicated a significant improvement over the intervention period in the Transcendental Meditation group compared with controls ( $P = .037$ ).

In terms of the FACT-B subscales the Transcendental Meditation group showed significant increases in emotional well-being ( $P = .046$ ) and social well-being ( $P = .003$ ) compared with the usual care control group. Also, on the SF-36 mental health scale, the Transcendental Meditation group exhibited significant improvement compared with the control group ( $P = .017$ ). Functional well-being and spiritual well-being change were in the predicted direction but were not found to be statistically significant ( $P = .103$  and  $P = .175$ , respectively). Table 2 shows the adjusted change scores from pretest to posttest for all variables, with a median testing time of 18 months (range = 6-24 months).

Effect sizes for the QOL variables that showed significant changes between groups, ranged from 0.25 to 0.43 over the intervention period. The overall number of dropouts in the study not completing at least 1 posttest was 27 (21%): 12 (19%) in the Transcendental Meditation group and 15 (23%) in the control group.

### Mortality

Survival was tracked from randomization until the end of the intervention period or mortality event (median = 18 months; range = 0-32 months). There were 3 deaths in the Transcendental Meditation group (2 stage 4 and 1 nonstage 4) and 6 in the usual care group (3 stage 4 and 3 nonstage 4). Causes of death, according to the National Death Index, were all cancer related. Exploratory survival analysis, using multivariate Cox regression, covarying for baseline differences and predictors of survival (negative ER status, FACIT meaningfulness, and SF-36 vitality) showed a hazard ratio of 0.58 for the Transcendental Meditation group compared with the usual care group, although it was not statistically significant ( $P = .57$ ; 95% confidence interval = 0.09, 3.74).

**Table 2.** Pre-Post Change Scores for All Variables<sup>a</sup>

Variable	TM	Usual Care	P Value <sup>b</sup>
FACT-B total	2.19 ± 1.19	-1.43 ± 1.19	.037
Physical well-being	-0.33 ± 0.46	0.36 ± 0.46	.294
Social well-being	0.62 ± 0.41	-1.20 ± 0.41	.003
Emotional well-being	1.46 ± 0.36	0.41 ± 0.36	.046
Functional well-being	0.21 ± 0.51	-0.98 ± 0.51	.103
Additional concerns	-1.55 ± 0.52	-1.91 ± 0.48	.607
FACIT-SP total	1.04 ± 0.76	0.18 ± 0.76	.175
Meaning/Peace	1.05 ± 0.54	0.02 ± 0.54	.190
Faith	0.34 ± 0.36	0.28 ± 0.36	.907
SF-36 mental health	2.08 ± 1.62	-3.57 ± 1.62	.017
SF-36 vitality	2.53 ± 2.05	3.45 ± 2.05	.755

Abbreviations: TM, Transcendental Meditation; FACT-B, Functional Assessment of Cancer Therapy–Breast; FACIT-SP, Functional Assessment of Chronic Illness Therapy–Spiritual Well-Being.

<sup>a</sup> Data are reported as adjusted mean change ± SEM.

<sup>b</sup> Two-tailed.

### Practice Regularity of the Transcendental Meditation Program

Among the 64 participants randomized to the Transcendental Meditation group, 58 (91%) were instructed in the Transcendental Meditation program. For those who completed instruction, 72% meditated at home at least once a day over the course of the study, as determined by self-report.

### Discussion

The results of this randomized controlled trial indicate that the practice of the Transcendental Meditation program can improve QOL in older women with breast cancer. Breast cancer patients practicing the Transcendental Meditation program showed a beneficial change in overall QOL—the primary outcome of the study—as well as in mental health and emotional and social well-being.

Research has shown that QOL and psychosocial stress factors can affect physiological processes related to the onset and progression of cancer,<sup>6,57-61</sup> including breast cancer.<sup>60,61</sup> In recent years, research on neurophysiological, endocrine, and immune pathways has identified biological processes that may mediate the effects of stress on breast cancer and may explain the mechanism of action of an effective stress reduction approach in modifying the progression of neoplastic disease.<sup>7</sup> Psychosocial stress factors may initiate a cascade of changes in the information processing pathways of the central nervous system that regulate the activity of the hypothalamic–pituitary–adrenal axis and the autonomic nervous system. This in turn results in increased circulating levels of cortisol, epinephrine, and norepinephrine.<sup>62-65</sup> Cellular and molecular studies have demonstrated that these and other stress-related hormones can modulate multiple components of the tumor microenvironment.<sup>62,66-69</sup> Chronic

stress, through neuroendocrine mediators, may alter tumorigenesis, oxidative metabolism, DNA repair, oncogene expression, growth factors, and other regulators of cell growth as well as dysregulate the activity of proteases, angiogenic factors, cytokines, and adhesion molecules involved in tumor invasion and metastasis.<sup>7</sup> Meditation may improve the individual's ability to disengage hyperreactive responses to stress triggers and may also promote natural physiological healing processes.

In the present study, the Transcendental Meditation program produced a positive effect on affect as indicated by the FACT-B emotional well-being and SF-36 mental health scales (see Table 2). Previous research on the Transcendental Meditation program in other populations has found significant reductions in anxiety,<sup>34,70</sup> anger,<sup>71</sup> and depression<sup>70</sup> as well as reduced cortisol levels during the practice<sup>72</sup> and over time.<sup>36,73</sup>

In comparing effect sizes for QOL with recent research conducted on other psychoeducational interventions, the range of QOL effect sizes in the present 2-year study ( $d = 0.25-0.43$ ) appear to be in the same general range as those of the Kissane et al<sup>14</sup> study with group psychotherapy ( $d = 0.25$ ) and the Goodwin et al<sup>74</sup> study with group psychosocial support ( $d = 0.32$ ) over 1-year periods. Previous research with a yoga intervention showed no significant effect compared with a wait-list control in the entire sample on overall QOL, although significant differences were observed in secondary subgroup analyses.<sup>3-5</sup>

There have been an increasing number of women using complementary and alternative medicine (CAM) for female-specific cancers. In terms of breast cancer, recent studies indicate that CAM use among women may be as high as 90%.<sup>75</sup> Because breast cancer is the most frequently diagnosed cancer in women<sup>2</sup> and because more women survive breast cancer than any other type of cancer,<sup>76</sup> it is important to identify CAM interventions that can maintain and even improve health-related QOL for this disease group.<sup>77</sup>

Exploratory survival analysis indicated a nonstatistically significant 42% risk reduction in cancer-related mortality. Larger sample sizes and longer-term trials are needed to confirm this level of risk reduction and to evaluate the association of survival status with change in QOL factors.

### Strengths and Limitations of the Study

The major strength of this study was the use of a single-blind randomized controlled design with stratification for cancer stage, age, and membership in a social support group. Although this design helped equate the treatment groups on a number of important factors related to QOL in breast cancer patients, there was still a significant difference in negative ER status. Therefore, baseline receptor status was adjusted for by ANCOVA to statistically equate the groups. Future studies with larger sample sizes should confirm the findings of this trial with the use of active control groups rather than usual care alone.

## Conclusions

The results of this randomized controlled trial indicate that the practice of the Transcendental Meditation program can improve the overall QOL of older women with breast cancer. In light of the pervasive problem cancer patients have of maintaining their QOL, this stress reduction program, with its ease of implementation and home practice, should be adopted in comprehensive care programs for women with breast cancer.

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## Declaration of Conflicting Interests

The authors declared no conflicts of interest with respect to the authorship and/or the publication of this article.

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