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BRIEF REPORT

Phone-Delivered Mindfulness Training for Patients with Implantable Cardioverter Defibrillators: Results of a Pilot Randomized Controlled Trial

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Abstract
Background The reduction in adrenergic activity and anxiety associated with meditation may be beneficial for patients with implantable cardioverter defibrillators.
Purpose This study aims to determine the feasibility of a phone-delivered mindfulness intervention in patients with defibrillators and to obtain preliminary indications of efficacy on mindfulness and anxiety.
Methods Clinically stable outpatients were randomized to a mindfulness intervention (eight weekly individual phone sessions) or to a scripted follow-up phone call. We used the Hospital Anxiety and Depression Scale and the Five Facets of Mindfulness to measure anxiety and mindfulness, and multivariate linear regression to estimate the intervention effect on pre-post-intervention changes in these variables.
Results We enrolled 45 patients (23 mindfulness and 22 control; age, 43–83; 30 % women). Retention was 93 %; attendance was 94 %. Mindfulness (beta=3.31; p=0.04) and anxiety (beta=−1.15; p=0.059) improved in the mindfulness group.
Conclusions Mindfulness training can be effectively phone-delivered and may improve mindfulness and anxiety in cardiac defibrillator outpatients.

Keywords Mindfulness · Anxiety · Implantable cardioverter defibrillators · Phone-delivery

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Introduction

Based on the results of primary and secondary prevention trials [1–5], implantable cardioverter defibrillators are currently first line therapy for patients at risk of sudden cardiac death. Despite their proven efficacy, concerns have been raised about the impact of defibrillators on quality of life [6–8] and psychological wellbeing [9, 10] as up to 40 % of patients may experience symptoms compatible with a diagnosis of anxiety disorder [11, 12].

Anxiety may have a significant negative impact on cardiovascular morbidity and mortality, likely by increasing the activity of the sympathetic nervous system and the incidence of severe arrhythmias [3, 13, 14]. Consequently, several behavioral interventions have been developed to improve the psychological wellbeing of patients with defibrillators [15–17]. Despite employing meditation or relaxation training as an adjunct to cognitive behavioral therapy or educational programs, these studies have not evaluated the effect of meditation alone on psychological distress [18]. Meditation practices reduce the activity of the sympathetic nervous system [19] and arrhythmias in patients with coronary heart disease [20]. Mindfulness meditation [21] has been shown to improve anxiety in patients with various chronic medical conditions [22], including heart failure [23]. Mindfulness meditation may thus produce a reduction

in anxiety levels and in the activity of the sympathetic nervous system that may be extremely beneficial in patients living with a defibrillator and suffering from psychological distress. To date, however, the study of the effect of mindfulness training in these patients has received limited attention, possibly because most programs typically require driving to the intervention site and intensive training. This may prevent attendance by patients with cardiac defibrillators who often have driving limitations and severe underlying cardiac conditions [24]. For these reasons, our group designed a phone-delivered mindfulness intervention that adapted the basic elements of traditional mindfulness training to the needs of these patients.

The primary aim of this study was to evaluate the feasibility, acceptability, and safety of a phone-delivered mindfulness intervention in a group of outpatients with cardiac defibrillators. Secondary exploratory outcomes were to obtain preliminary indications of the intervention's efficacy on mindfulness, anxiety, and on the number of shock therapies and hospital readmissions during the study period.

Methods

Design and methods for this study have been described in detail elsewhere [25]. Briefly, this pilot, randomized, controlled, parallel-group trial (ClinicalTrials.gov NCT 01035294) was conducted at the UMass Memorial Medical Center in Worcester, MA. Inclusion criteria included age 21 or older, ability to understand and speak English, and access to a telephone. Exclusion criteria were inability or unwillingness to give informed consent, cognitive impairment (Blessed Orientation Memory and Concentration test scores, ≥10) [26], New York Heart Association functional class >III or clinical instability, pending coronary bypass or heart transplantation, life-threatening comorbidities, and current depression or psychosis. A diagnosis of ongoing depression or psychosis was based on the physician's report as documented in the medical record.

All consecutive patients scheduled for a defibrillator-related procedure or who received a shock therapy from the defibrillator were screened for preliminary eligibility (from the medical record) within a month of the procedure or shock. All potentially eligible patients received a letter inviting them to participate and asking them to call a dedicated phone number to communicate their possible interest. If no contact was made, the research coordinator followed up by phone within 2 weeks.

Randomization

Once informed consent was obtained and baseline data were collected, participants were randomized to the mindfulness intervention or to the control group (1:1 allocation ratio). The random allocation sequence was generated using STATA [27] "ralloc" command, which produced a sequence of group assignments randomly permuted in blocks of sizes of 4 and 6. The table containing the random sequence was uploaded to an Access database. The research coordinator automatically assigned each participant to a group by clicking the "randomize" button.

Mindfulness-Based Intervention

The intervention (described previously) [25] consisted of eight weekly phone-delivered, 30-min individual training sessions. Patients also received an audio-CD containing instructions consistent with the training session techniques, and were encouraged to listen at least once daily. The intervention included two main components: (1) the body scan, in which attention is brought to notice bodily sensations and cognitions that would normally go unnoticed and (2) sitting meditation in which participants were trained in bringing awareness to the sensation of breathing as an arousal-neutral object of attention and to recognize when the attention wandered from it. In addition, participants were gradually encouraged to bring their awareness to the activities of daily life that normally go unnoticed such as eating and drinking, sounds, visual objects, thoughts, and emotions. Mindfulness instructors were graduates of the Center for Mindfulness professional training program at the University of Massachusetts with at least 5 years' experience. Although not blinded to group assignment, instructors were blinded to the study outcomes.

Control Group

To help equalize the amount of study contact between study arms, patients in the control group received a 10-min, scripted, weekly phone call addressing possible concerns regarding the defibrillator. If such concerns presented, the patient was advised to contact his/her physician or nurse at the electrophysiology clinic. Participants in either arm were not expected to stop any of their usual support services (e.g., professional counseling or any anti-anxiety or antidepressant treatment) during the study period.

Assessments

The research coordinator administered all study questionnaires via in person interview at baseline and via phone interview between 9 and 10 weeks after enrollment and abstracted information about medical history, medications, shock therapy delivery, and hospital readmissions from the electronic version of the patients' follow-up visits.

Primary Outcomes

Feasibility assessments included recruitment and retention rates, adherence, and treatment fidelity. Recruitment metrics included number of screened and eligible patients, number of patients who refused to participate, and reasons for refusal. Retention measures were the number of patients who dropped out or were lost to follow-up and reason(s) for dropping out. Adherence metrics included attendance rate and time spent in mindfulness practice. Attendance was recorded by the mindfulness instructor after each session; mindfulness practice was recorded in a daily diary that patients mailed back weekly using prepaid envelopes. Treatment fidelity procedures were developed following the Treatment Fidelity Workgroup guidelines [28]. At the end of each session, the instructors completed a checklist recording the duration of the intervention and the number of script-specified objectives achieved. In addition, each session was digitally recorded. A random sample (10 %) of all recorded sessions was audited by the research coordinator. Treatment fidelity was defined as the percentage of planned objectives achieved, calculated from the checklist form.

Acceptability was evaluated through a semi-structured qualitative phone interview conducted by the research coordinator at the end of the study. Participants were asked to rate their overall experience with the intervention (impact on wellbeing and helpfulness in coping with the defibrillator's implantation) and with the most important components of the intervention (instructor, body scan, and sitting meditation) using a pre-designed questionnaire described later.

To assess safety, the mindfulness instructor actively inquired at each session whether the participant experienced psychological discomfort during or between sessions; also, participants were encouraged to contact the instructor if any discomfort arose during individual mindfulness practice. Since the intervention was phone-delivered, and the instructor was not able to assess nonverbal expression of discomfort, we needed to ascertain that the intervention did not cause psychological discomfort in these severely ill patients.

Secondary Outcomes

Mindfulness was measured using the 15-item Five Facets of Mindfulness [29], an instrument derived from a factor analysis of questionnaires measuring mindfulness in daily life. Each item is rated on a Likert scale ranging from 1 (never or very rarely true) to 5 (very often or always true) with total scores ranging from zero to 75.

Anxiety was measured using the Hospital Anxiety and Depression Scale [30], a 14-item self-administered questionnaire with two subscales measuring anxiety and depression. Higher scores indicate greater psychological morbidity. A cutoff point of 8 for each subscale is usually recommended to screen patients for clinically significant depression and anxiety [31].

Covariates

Medical history, medications, time since the defibrillator procedure or shock, New York Heart Association functional class, and ejection fraction (end diastolic volume—end systolic volume/end diastolic volume) from the most recent echocardiogram were gathered from the medical record. A functional class III or IV and a low ejection fraction (normal value, ≥ 0.50) indicate a severe impairment of the function of the left ventricle. Functional status was measured using the physical limitation subscale of the Seattle Angina Questionnaire [32]. All study procedures and materials were approved by the Committee for the Protection of Human Subjects at the University of Massachusetts Medical School.

Sample Size

The final sample size of 42 patients (21 for each arm) was calculated using hypothetical estimates of effect size on anxiety based on other behavioral studies that used the Hospital Anxiety and Depression Scale [25].

Statistical Analysis

Descriptive statistics were used to analyze indicators of feasibility (i.e., retention and adherence). The effect of the intervention on change from baseline mindfulness and anxiety scores was estimated using multivariate linear regression models. Covariates that were associated with the outcome with $p \leq 0.1$ (regardless of their association with group assignment) were included in the model [33, 34], as well as baseline mindfulness and anxiety scores to account for possible regression to the mean [35]. All data were analyzed using STATA version 10.

Results

Feasibility

Recruitment

Recruitment for this study started in May 2009 and ended in November 2011 when the target sample size was reached. The flow of patients through the study and reasons for ineligibility and refusals are shown in Fig. 1. Among 529 consecutive patients scheduled for a defibrillator-related procedure or who received a shock therapy from the defibrillator during the study period, 354 were eligible and 46

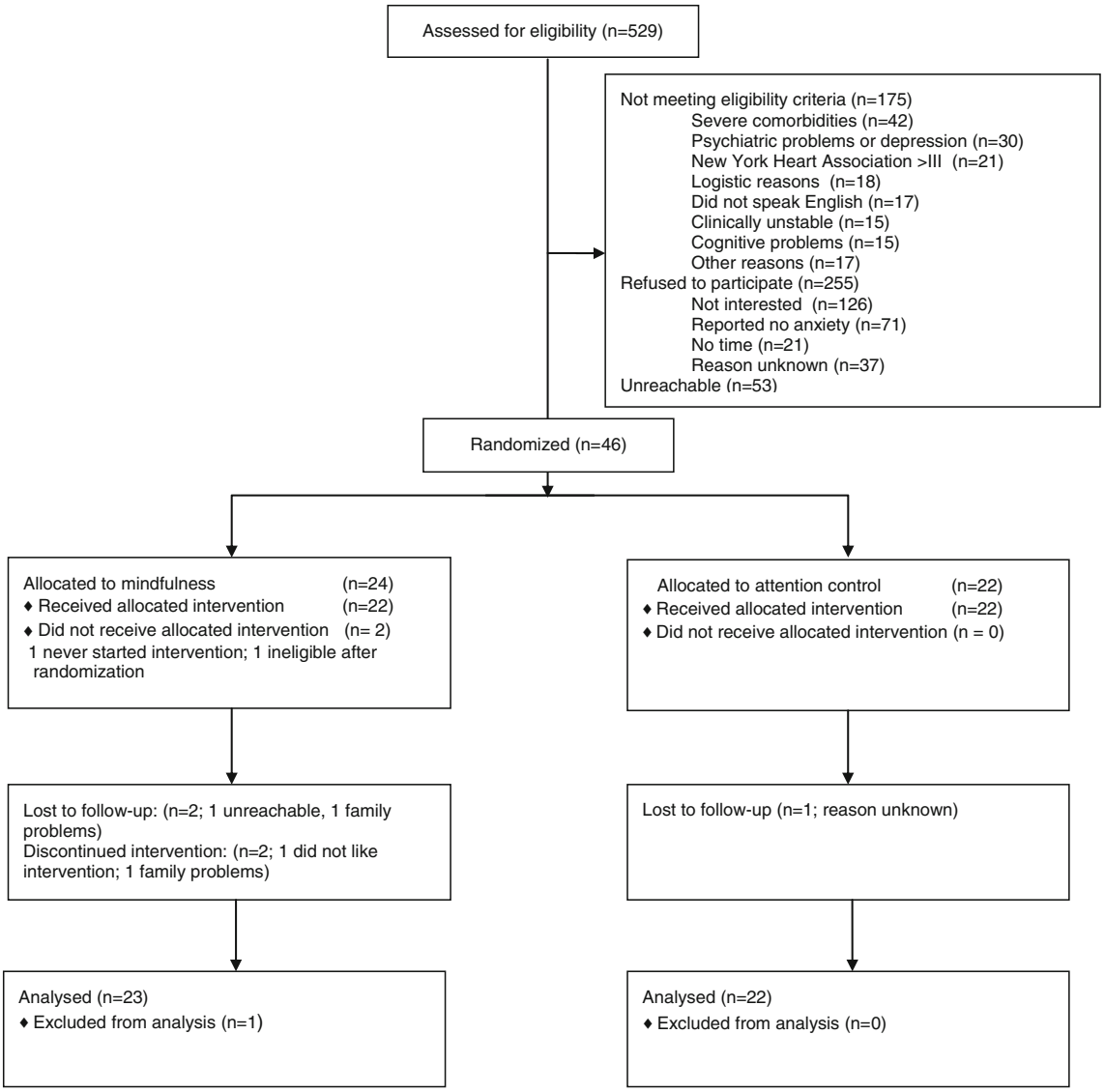

Fig. 1 CONSORT flow diagram

(32 males, 14 females; age range, 43–83; 13 % of all eligible patients) consented to be enrolled in the study; one patient was found to be ineligible after randomization and was excluded from the analysis, thus resulting in a final sample size of 45 participants (23 mindfulness and 22 control). Table 1 shows the baseline characteristics of the study sample by treatment group.

Retention

The overall retention rate was 93 %. Two patients assigned to the mindfulness intervention dropped out: one never received the intervention and one withdrew after three sessions for family reasons; both patients were lost to follow-up. In the control group, one patient withdrew 8 weeks since enrollment and was lost to follow-up.

Adherence

Patients attended a mean of seven (SD 2.4) of eight sessions. Attendance was 94 % with 90 % of patients attending all planned mindfulness sessions. Patients spent a median of 15 h (interquartile range (IQR), 12.5) practicing study techniques. Awareness of breath was practiced most frequently (median, 7.6 h; IQR, 8.5), followed by the body scan (median, 4.3 h; IQR, 4.7), and by informal practice (median, 3.4 h; IQR, 7.6).

Treatment Fidelity

Results from the review of a random sample of 10 % of all recordings indicate that the instructors delivered the content of the intervention with fidelity to the protocol 96 % of the time.

Table 1 Baseline characteristics of the study population

	Mindfulness (n=23)	Control (n=22)
Age (mean, SD)	66.3 (10.4)	62.9 (10.2)
Females	10 (43.4)	4 (18.2)
White non-Hispanic	22 (95.6)	21 (95.4)
High School	3 (13.1)	9 (40.9)
Some college	9 (39.1)	5 (22.7)
College graduate	7 (30.4)	3 (13.6)
Post graduate	4 (17.4)	5 (22.8)
Married or in committed relationship	18 (78.3)	16 (72.7)
How hard to pay for basics[a]		
Not at all hard	11 (47.8)	15 (68.2)
Somewhat hard	9 (39.1)	4 (18.2)
Very hard	3 (13.1)	3 (13.6)
Coronary heart disease	16 (69.6)	12 (54.5)
Primary prevention implantation	17 (69.6)	19 (86.4)
Secondary prevention implantation	7 (30.4)	3 (13.6)
Days since ICD procedure or shock (median, interquartile range)	28.5 (47)	25 (49)
Current smoker	2 (8.7)	1 (4.6)
Beta-blockers	23 (95.8)	17 (77.3)
Anti-arrhythmics	3 (12.5)	5 (22.7)
Anxiolytics	4 (16.6)	6 (27.3)
Anti-depressants	4 (16.7)	7 (31.8)
Ejection fraction (mean, SD)	0.31 (0.13)	0.28 (0.12)
New York Heart Association class III	5 (21.7)	8 (36.4)
Modified Seattle Angina Questionnaire (mean, SD)	58.2 (25.9)	60.4 (23.1)
Prior diagnosis of depression	4 (17.4)	7 (31.8)
Prior diagnosis of anxiety	4 (17.4)	4 (18.2)
Hospital Anxiety and Depression Scale (mean, SD)	5.5 (4.1)	6.4 (4.1)
Five Facets of Mindfulness (mean, SD)	57.4 (8.4)	54.5 (7.0)

Values are n (in percent) unless otherwise indicated

[a] Food, housing, medical care, and heating

Acceptability

Interview data were available for 21 of the 23 patients assigned to the mindfulness intervention (Table 2). Overall, 86 % of participants reported that the study intervention was "somewhat" to "extremely" helpful in coping with the defibrillator procedure or event and 90 % reported that the intervention had moderate to great impact on their overall wellbeing.

Safety

No side effects such as increasing anxiety, restlessness or other psychological discomfort [36] were reported during sessions or individual practice.

Secondary Outcomes

Differences in favor of the mindfulness group were seen for mindfulness scores: all patients: mindfulness vs. control, beta=3.31 (95 % confidence interval (CI), 6.482, 0.137; p=0.04) and patients attending all sessions (21 out of 23): beta=4.53 (95 % CI, 7.876, 1.189; p=0.01). More modest changes were seen for anxiety scores: all patients, mindfulness vs. control: beta=−1.15 (95 % CI, 0.046, −2.344; p=0.059) and patients attending all sessions (21 out of 23): beta=−1.33 (95 % CI, − 0.163, −2.487; p=0.027). Nearly 30 % of patients reported events during the 2-month study period. Seven patients (three mindfulness and four control) were hospitalized. Reasons for readmission were worsening of heart failure (two), shocks (two), pre-syncope (one), pneumonia (one), and unstable angina (one). Three patients in the control group received shock therapy from the defibrillator, none in the intervention group.

Discussion

Overall, this pilot study indicates that phone-delivered mindfulness-based interventions are feasible, safe, and acceptable to outpatients with defibrillators. Furthermore, preliminary evidence was found for an effect of the intervention on mindfulness levels and possibly on anxiety symptoms in these patients.

The 93 % retention rate compares favorably with those (69 % [37] and 95 % [38], respectively) reported in two studies of psychosocial interventions of similar duration in outpatients with defibrillators. The fact that the attrition rate (7 %) was similar to that (7.6 %) reported in a meta-analysis [39] of studies evaluating the effect of telephone-administered psychotherapy on symptoms of depression indicates that the phone delivery had an important impact on retention. Patients' adherence was satisfactory, especially when considering the participants' age and the severity of their underlying cardiac condition.

Recruitment rates were not optimal, as only about 13 % of eligible patients were ultimately enrolled. The majority of patients stated "lack of interest" as the reason for not participating. Although specific reasons for the stated lack of interest were not inquired, it is possible that some patients might have been concerned by terms such as "mindfulness" that are unfamiliar to an older age group. Interestingly, similar recruitment rates have been reported in a well-designed study of a Tai Chi intervention in patients with chronic heart failure [40]. Future studies will need to carefully tailor the presentation of the study to the characteristics of these patients. Finally, due to the study's limited budget, no financial incentives were offered to participants, and this might have also contributed to the low recruitment rates.

Table 2 Results of the semi-structured interview after study completion (n=21)

What has been the impact, if any, of this program on your overall wellbeing?	None	Some/moderate	Great
	10 %	47 %	43 %
Did the intervention help you to cope with the experience of living with an ICD?	Not at all/a little	Somewhat	Very much/extremely
	14 %	24 %	62 %
Have you noticed any other change in your life that you associated with your participation in the study?	No	–	Yes
	29 %		71 %
Was the interaction with the instructor helpful?	Not at all	Somewhat	Very much/extremely
	5 %	0 %	95 %
Was the body scan helpful?	Not at all/a little	Somewhat	Very much/extremely
	19 %	33 %	48 %
Was the awareness of breath exercise helpful?	Not at all/a little	Somewhat	Very much/extremely
	14 %	5 %	81 %
How often do you use the techniques learned during the study?	Never	Occasionally	Often/always
	5 %	14 %	81 %

Similarly to previous investigations of behavioral interventions in patients with cardiac defibrillators [18], this study included a majority of white males; however, in contrast with previous research, it included less educated patients (60 % with less than college degree) and a significant proportion of women (30 %). Furthermore, the patients' clinical condition was more severe, as approximately three out of four patients were in functional class II or III and had very low ejection fractions.

The finding of a significant change in mindfulness scores in the intervention group indicates that the phone-delivered mindfulness intervention increased mindfulness levels as observed in group-delivered interventions [41, 42]. The effect on anxiety symptoms was not significant (p=0.059) and reached statistical significance only in patients who attended all sessions (90 % of the patients assigned to the mindfulness intervention). It is possible that participants in the control group may have derived some benefit from the weekly phone call they received throughout the study; this would explain the smaller between-group differences in anxiety detected in our study compared with prior psychobehavioral studies, which did not employ attention control strategies [16–18]. Furthermore, the participants' positive feedback suggests that patients with defibrillators may benefit from a mindfulness intervention independently of the intervention's effect on anxiety. No patient allocated to the intervention received shock therapy during the study period; this finding, however, is likely entirely due to chance and has to be reproduced in a larger sample.

This study has several strengths. Most notably, our group was able to provide a mindfulness intervention to a population at high risk of severe clinical events (as indicated by the high number of hospital readmissions during the 2-month study period), with low socioeconomic status and transportation problems. Second, this is the first randomized clinical trial of a mindfulness intervention conducted in patients with severe cardiovascular disease; the first to include rigorous assessments of treatment fidelity; and one of the few studies in the field of mindfulness research that included an attention-control comparison group. Third, excellent retention rates were achieved; this finding is even more relevant considering that, due to funding limitations, no compensation was offered to our patients for their time.

Some limitations should be noted. Due to budgetary limitations, it was not possible to recruit an ethnically diverse population; the study findings may thus not apply to minorities. A second, and more general, limitation relates to the assessment of mindfulness; all currently available measures of mindfulness are self-reported, and moreover, there have been concerns in regard to their ability to effectively measure changes in mindfulness levels [43, 44]. Third, study assessments were performed only at baseline and soon after the conclusion of the intervention. Fourth, due to the small sample size, and to the assessment of mindfulness and anxiety at the same point in time, it was not possible to conduct mediation analyses. Finally, the additional attention received by the patients assigned to the mindfulness intervention was only partially accounted for, as the duration of the phone call received by the control group was only 10 min.

In conclusion, phone delivery is a feasible way of offering mindfulness training to patients with severe cardiovascular disease. If these findings are reproduced in a larger randomized clinical trial with adequate follow-up duration, this study will open important possibilities for the diffusion of mindfulness training to treat psychological distress in patients with cardiac defibrillators.

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Conflict of Interest Statement The authors have no conflict of interest to disclose.

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