J Behav Med
https://doi.org/10.1007/s10865-020-00153-2

Implementation, feasibility, and acceptability of quality of life therapy to improve positive emotions among patients with implantable cardioverter defibrillators

Allison J. Carroll[1,2] · Lillian M. Christon[1] · James R. Rodrigue[3] · Joseph L. Fava[4] · Michael B. Frisch[5] · Eva R. Serber[1]

Received: 19 September 2019 / Accepted: 1 April 2020

Abstract Implantable cardioverter defibrillators (ICDs) save lives, but often induce significant psychological distress among patients. Positive psychological constructs are associated with improved outcomes among cardiac patients. In this NHLBI-funded randomized controlled trial, one aim was to evaluate the feasibility and acceptability of a positive psychology intervention (Quality of Life Therapy; QOLT, n = 11), compared to a Heart Healthy Education (HHE) control (n = 10), among ICD patients. A majority of participants across groups attended all 12 sessions (71%) and completed homework assignments (80%). Agreement on participant engagement and interventionist protocol adherence were high, with no differences between groups ($ps > 0.20$). A greater proportion of QOLT participants rated their sessions was "very" helpful compared to HHE participants (63% vs. 10%, $p = 0.19$). These initial data support the feasibility and acceptability of QOLT. A larger-scale trial using positive psychology interventions among ICD patients is indicated to determine potential mechanisms underlying the relationship between positive psychological constructs and cardiovascular health.

Keywords Quality of life · Quality of life therapy · Positive psychology · Implantable cardioverter defibrillator (ICD) · Cardiovascular disease · Treatment fidelity

Introduction

Ongoing advancements and improvements in medical technologies, such as implantable cardioverter defibrillators (ICDs), have significantly improved both primary and secondary prevention of sudden cardiac death (Moss et al., 1996, 2002) and are being implanted with increasing frequency (Bradshaw, Stobie, Knuiman, Briffa, & Hobbs, 2014). As with many cardiac populations, ICD patients have high rates of anxiety, depression, and poor quality of life (QOL) (de Ornelas Maia, Soares-Filho, Pereira, Nardi, & Silva, 2013; Miller et al., 2019; Versteeg et al., 2017). Moreover, psychological distress predicts arrhythmias, ICD shocks, and sudden cardiac death (Lampert, 2016; Peacock & Whang, 2013; Whang et al., 2005), indicating a need to address psychological distress in this vulnerable population.

Small trials of cognitive-behavioral therapy (CBT) interventions have demonstrated efficacy for reducing psychological distress among ICD patients (Maia et al., 2014). Unfortunately, even the most effective of these interventions has not been found to significantly reduce the frequency of arrhythmias, shocks, or sudden cardiac death. Among CVD patients more generally, neither psychological nor pharmacological interventions for depression significantly improve cardiac-related outcomes or all-cause mortality (Baumeister, Hutter, & Bengel, 2011; Richards et al., 2017). Therefore, rather than focusing on decreasing psychological distress, it may be more beneficial to focus on increasing positive emotion and QOL. In fact, improving QOL has been identified an important

✉ Eva R. Serber
serbere@musc.edu

1 Division of Bio-Behavioral Medicine, Medical University of South Carolina, 67 President Street, MSC 861, Charleston, SC 29425, USA

2 Northwestern University Feinberg School of Medicine, Chicago, IL, USA

3 Beth Israel Deaconess Medical Center and Harvard Medical School, Boston, MA, USA

4 Centers for Behavioral and Preventive Medicine, The Miriam Hospital, Providence, RI, USA

5 Baylor University, Waco, TX, USA

Published online: 14 April 2020

remedial strategy to improve outcomes among patients with CVD (Labarthe et al., 2016). Among adults with ICDs, higher self-reported QOL protects against mortality (Berg, Thygesen, Svendsen, Christensen, & Zwisler, 2014) and optimism is protective of mental health and associated with improved cardiac outcomes (Flemme, Johansson, & Stromberg, 2012; Habibovic et al., 2018).

Myriad potential mechanisms underlying the relationship between positive emotions and heart disease are hypothesized (Dubois et al., 2012). For example, biological processes such as inflammation, oxidative stress, and endothelial dysfunction are often implicated as potential pathways through which psychological distress increases risk for poor cardiovascular outcomes. Correspondingly, positive psychological traits, including happiness, optimism, and general well-being, are associated with lower levels of biological dysfunction, such as fewer circulating inflammatory biomarkers (Roy et al., 2010; Steptoe, Wardle, & Marmot, 2005). Preliminary evidence indicates that ICD patients in a distress-management intervention, compared to those in a treatment-as-usual condition, had suppressed inflammatory response following the intervention (Sears et al., 2007). Another potential pathway is via autonomic system disruption. For example, positive emotional functioning has been associated with higher heart rate variability (HRV) (Oveis et al., 2009), indicating better autonomic functioning. Redwine et al., (2016) found an association between gratitude journaling and increased HRV among patients with heart failure, though they did not report correlations between HRV and gratitude levels or other positive psychological characteristics. Finally, positive psychological traits are associated with a greater prevalence of healthy behaviors related to cardiac functioning (Boehm et al., 2018). For example, a positive psychology and motivational interviewing intervention among patients who had suffered an acute coronary event was associated with significant improvements in physical activity (daily step count, time spent in moderate-vigorous activity) (Huffman et al., 2019).

Few interventions focused on QOL improvement or positive emotion enhancement have yet been developed and implemented among ICD patients. Similar but distinct approaches have included a stress-reduction intervention to improve patients' acceptance of their ICD (Sears et al., 2007); a yoga intervention to increase ICD patients' self-compassion and mindfulness (Toise et al., 2014); and a CBT intervention to improve QOL among ICD patients in a secondary analysis (Dunbar et al., 2012). To contribute to this growing area of research, the Positive Therapy for Autonomic Function & Mood in ICD Patients (PAM-ICD) NHLBI-funded randomized controlled trial was designed to investigate the protective effect of positive emotions on arrhythmias among ICD patients, given their susceptibility to emotion-triggered cardiovascular events (Serber et al., 2016). The intervention implemented in this trial was Quality of Life Therapy (QOLT; Frisch, 2006).

QOLT, as one of several validated positive psychology approaches, was chosen because of its empirical and clinical support for enhancing positive emotion. QOLT treatment has three foci, now recognized as the three elements of happiness: (1) increased life satisfaction, (2) increased positive emotion, and (3) reduced negative emotional experience (Diener, Ng, Harter, & Arora, 2010). QOLT is a CBT approach that incorporates mindfulness, acceptance, and resiliency in the context of enhancing well-being and QOL. QOLT differs from traditional CBT approaches in that it is focused on building positive emotions rather than reducing negative emotions. As such, QOLT provides specific intervention strategies developed from empirical research on well-being and happiness, and it teaches that happiness is a choice and optimism can be learned (Seligman, 2006). QOLT has the flexibility to be tailored to specific patient populations, and has been validated among adults with mental health concerns (Grant, Salcedo, Hynan, Frisch, & Puster, 1995) and with medical comorbidities (e.g., solid-organ transplant candidates; Rodrigue, Baz, Widows, & Ehlers, 2005). For example, Rodrigue et al., (2005) demonstrated that, among patients who were waiting for lung transplant, QOLT predicted higher QOL and lower mood disturbance compared to supportive therapy, and these differences persisted for 3 months post-treatment. Compared to previous intervention studies addressing psychological distress among ICD patients, this study used (1) a positive-emotion focused CBT approach; (2) a more time-intensive and focused intervention than the previous CBT trials.

Main outcomes of the clinical trial (NCT02088619; R34 HL107733) focus on autonomic functioning, arrhythmias, and both positive and negative psychological constructs, and are detailed elsewhere (Serber et al., Under review). The purpose of this paper was to describe the implementation and adaptation of QOLT for ICD patients, focused on examining feasibility and acceptability of the intervention.

Methods

Participants and recruitment

Detailed procedures and rationale are available elsewhere (Serber et al., 2016). Briefly, participants were recruited through general cardiology and electrophysiology specialty clinics at a large academic health center by referral from their health care provider based on brief screening of appropriateness for the study. Eligible participants were English-speaking adults ≥ 18 years old with an ICD, who had systolic left ventricular dysfunction due to coronary disease or nonischemic cardiomyopathy, and were stable on cardiac

and/or psychotropic medications for at least 3 months prior to study enrollment.

Participants were screened for scores ≥ 5 on the Hospital Anxiety and Depression Scale (HADS) anxiety or depression scales (Zigmond & Snaith, 1983). As explained in Serber et al., (2016), this threshold on either subscale represents a level of symptoms that likely impairs some area of functioning (Aben, Verhey, Lousberg, Lodder, & Honig, 2002; Haworth, Moniz-Cook, Clark, Wang, & Cleland, 2007). Requiring some degree of distress or impairment thus allowed for improvement in mood and, importantly for the primary outcomes, autonomic function (Tolentino & Schmidt, 2016; Ziegelstein, 2007).

Participants were excluded for: (1) > 5% atrial or ventricular pacing; (2) sinus node dysfunction; (3) persistent atrial fibrillation; (4) long QT syndrome; (5) hypertrophic cardiomyopathy; (6) documented neurocognitive or cognitive impairments; (7) severe psychopathology; (8) current participation in another research trial; or (9) currently in psychological treatment. Exclusion criteria were intentionally strict to ensure homogeneity and to be able to determine the impact of the intervention on autonomic functioning and arrhythmias for the primary outcomes among patients whose cardiac rhythms and HRV are controlled by their device, medications, and/or disease.

Measures

Sociodemographics and medical information

Sociodemographic variables, including sex, race, ethnicity, and age, were collected during the screening process and confirmed at baseline. Medical details regarding the participant's ICD were collected via self-report and confirmed by the medical record, including primary or secondary prevention, year of implantation, and treatment indication.

Quality of Life Inventory

As part of the baseline assessment materials, all participants were administered the Quality of Life Inventory (QOLI; Frisch, 1994). The QOLI was designed for both clinical and nonclinical uses and has been validated in large samples beyond those enrolled in QOLT (e.g., Frisch et al., 2005; McAlinden & Oei, 2006). The QOLI assesses 16 areas of life, including: Health, Self-Esteem, Goals, Money, Work, Play, Learning, Creativity, Helping, Love, Friends, Children, Relatives, Home, Neighborhood, and Community. Participants are asked to assess the importance of each area (Not Important, Important, Extremely Important) and their satisfaction with the area on a 6-point Likert scale (Very Dissatisfied to Very Satisfied).

Treatment structure and content

Detailed data about attendance, session duration (in minutes), and delivery modality (in-person or by telephone) were documented by interventionists. Specific to the intervention group, information was recorded regarding homework completion and the 16 QOLI-derived topic areas (described in further detail below) discussed in each session. For the Heart Healthy Education (HHE) control group, educational topics were assigned and recorded for each session. No homework was assigned and behavior change was not expected. Some examples of session content for QOLT versus HHE are presented in Table 1 and more details are provided in the text below.

Treatment engagement and fidelity

The following treatment engagement and fidelity measures, collected for each completed session, were rated on a Likert scale from 1 (not at all) to 5 (completely). At the end of each session, participants were asked to rate their level of engagement at the end of each session. The interventionist rated her perception of participant engagement and her own adherence to the treatment protocol. For 20% of sessions, the principal investigator (ERS) performed treatment fidelity audits of the sessions (for both QOLT and HHE). Audited sessions were selected at random across participants and session number. The principal investigator listened to the audio recording of the entire session, reviewed the session note, and rated the interventionist's adherence to the treatment protocol.

Treatment acceptability

At the end of treatment, participants completed a Program Evaluation Survey, which was a study-specific questionnaire developed to assess participants' experiences with and acceptability of the intervention. Specifically, participants were queried as to how helpful they found the intervention on a Likert scale from 1 (not at all) to 5 (completely), whether the intervention helped them in various domains of functioning, their primary reason for participating, and barriers to participating.

Pilot trial design and procedures

During recruitment, a researcher explained the study, assessed interest, and completed the initial eligibility screening. If eligible and interested, the participant would sign the informed consent and be scheduled for the baseline assessment. At this assessment, participants completed psychosocial measures and a 24-h Holter monitor recording. After the baseline assessment, eligible participants were randomized to QOLT or HHE, an education-based control

Table 1 Examples of session content for Quality of Life Therapy and Heart Healthy Education groups

Session	QOLT content	HHE didactic content
1	Introduction and psychoeducation; review of QOLI; Introduction to CASIO model; Happiness pie	Learning about your heart—Family history and heart disease
2	Three pillars of QOLT and Tenets of contentment; Introduction to Happiness Habits; Diaphragmatic breathing	Benefits and barriers to heart healthy living
3	Health and ICD-specific coping; Progressive muscle relaxation	Adherence for health
4	Play, recreation, and behavioral activation; Pleasurable and meaningful acts	Diet and healthy eating 1—Dietary guidelines
5	Goals and Values/Spiritual Life; Mindfulness and cultivating sacred moments	Diet and healthy eating 2—Cholesterol, fats, and food labels
6	Self-esteem; Loving kindness meditation	Heart risk behaviors—alcohol caffeine, smoking
7	Relationships; Counting blessings	Wet your whistle—Heat exhaustion and water intake
8	Work/Retirement; Benefit finding	Take a break—Vacation and sleep
9	Relatives, Children, and Love; Best possible future self, best possible future social relationships	Relationships and your heart
10	Helping; Three acts of kindness	Metabolism and physical activity
11	Creativity; Using strengths—Street signs to success	Communication—Talking to the doctor
12	Relapse prevention and goal setting	Healthy feet and exercise apparel

QOLT Quality of Life Therapy, *HHE* Heart Healthy Education, *QOLI* Quality of Life Inventory, *CASIO* Circumstances, Attitudes, Standards and goals, prioritizing and changing what is Important, and boosting Overall satisfaction, *ICD* implantable cardioverter defibrillator

condition without therapeutic intervention, and stratified by ICD indication (primary vs. secondary prevention) and age ($<$ or $\geq$ 65 years) using a permuted-block randomization procedure within each stratum. Within 7 days of randomization, participants began weekly sessions over the following 12 weeks. Follow-up assessments were conducted at end-of-treatment (3 months) and at 6 months post-treatment (9 months); data from the 9-month assessment were not included here as treatment engagement and fidelity assessments were not completed. Further details about the study design and implementation are described elsewhere (Serber et al., 2016).

Intervention: Quality of Life Therapy (QOLT)

Materials

QOLT participants' baseline responses on the QOLI were used to guide the intervention targets. A priori, Health, Play, Relationships, and Self-esteem were determined to be important areas to address for ICD patients and thus were included as standard treatment for all participants. The remaining time focused on the QOL areas identified as most important to each participant, targeting areas of dissatisfaction and highlighting participant strengths in the areas of high satisfaction, with discussion tailored to ICD-specific concerns. For example, Relatives, Children, and Love were frequently discussed because a patient's loved ones and caregivers are also impacted by the patient's chronic illness. In addition, the interventionist asked participants to rate their "happiness thermometer" at each session on a scale from 0 (no happiness) to 10 (most happiness), created for this study by employing the inverse of a distress thermometer (e.g., Holland et al., 2013) to focus on positive emotions and life satisfaction.

Delivery

All sessions were delivered as individual therapy sessions, either in-person or by telephone (per participant preference). Each session comprised: (1) review of the previous week's content and homework, (2) didactic content of new material and/or techniques, (3) a relaxation exercise, and (4) discussion of new content, homework assignment, and, as needed, barriers to treatment adherence. Participants also received a workbook containing the treatment content, homework assignments, and additional worksheets.

Throughout the intervention, a five-step model of problem-solving (i.e., CASIO) was utilized: (1) Circumstances, (2) Attitudes, (3) Standards and goals, (4) prioritizing and changing what is Important, and (5) boosting Overall satisfaction in a variety of areas of life. A focus on cognitive and behavioral techniques for boosting participant satisfaction and happiness was employed. Specific therapeutic techniques included implementing happiness habits, relaxation techniques, self-monitoring and cognitive restructuring, pleasant activity scheduling, and problem-solving and goal setting. Participants were taught skills for improving self-esteem, as well as other positive emotions (e.g., optimism), to encourage adaptation to and acceptance of disease and

ICD. In addition, as in other interventions among medical populations (Witkiewitz & Marlatt, 2004), QOLT includes health behavior promotion and relapse prevention training (i.e., maintenance of progress made in QOLT and improvements in level of quality of life, satisfaction, and happiness).

Training and supervision

All QOLT sessions were conducted by one interventionist (LMC), a post-doctoral fellow in clinical psychology with specialty training in behavioral medicine. Interventionist training and supervision was provided by the principal investigator (ERS), a licensed clinical psychologist with advanced training in QOLT. Advanced training and supervision was also provided by the study consultant (MBF), as needed. Training consisted of didactic teaching, regular supervision and review, studying the QOLT treatment manual, completing worksheets, and supplemental training materials (e.g., webinar training; Frisch, 2006, 2014). The principal investigator reviewed 20% of sessions (as described above, Treatment engagement and fidelity) and was immediately available for direct supervision during all sessions as needed.

Control: Heart Healthy Education (HHE)

The HHE control was an attention-matched control designed to provide participants with information about health and lifestyle issues related to cardiovascular disease. Contact during these sessions did not include any therapeutic techniques or instructions beyond the didactic materials. Sessions were a dissemination of health topics (e.g., hydration, choosing the right shoe, reading food labels), with no goal-setting or behavioral intervention. Providers were Bachelor's level research coordinators with interests in pursuing doctoral education. HHE participants were offered the same number of sessions (12), at the same intervals (i.e., weekly), and by the same modality (in-person or by telephone).

Data analysis

All analyses were two-tailed, with significance (where appropriate) determined by $p < 0.05$, and were conducted in SPSS version 24 (IBM Corp, Released 2016). For the treatment structure and content variables proportions, means, and standard deviations were calculated using descriptive statistics. Comparisons between QOLT versus HHE were examined with Chi square analyses or *t*-tests as appropriate. Paired sample *t*-tests were used to assess agreement in participant treatment engagement (participant vs. interventionist ratings) and interventionist treatment fidelity (interventionist vs. principal investigator ratings). Treatment engagement, fidelity, and acceptability were compared between QOLT and HHE groups using independent sample *t*-tests. Among the QOLT participants, trends in happiness ratings throughout treatment (Session 1 through Session 12) were evaluated. In both groups, pre-post changes (Session 1 versus Session 12) on the QOLI were assessed using Cohen's d, as this pilot study was not powered to detect statistically significant changes.

Results

Sample characteristics

Details of the sample are provided elsewhere (Serber et al., Under review). Briefly, 23 participants were consented to the trial. Two participants (1 QOLT participant, 1 HHE participant) did not attend any sessions and thus were excluded from the present analyses given the focus on treatment fidelity. Of the remaining 21 participants, 11 were randomized to the QOLT intervention and 10 were randomized to HHE. The sample was 62 years old on average (SD = 9 years), 38% female, and 38% white. Participants had completed an average of 14 years of education (SD = 3 years), with 33% of participants having achieved their high school diploma/GED or less, and 33% were currently working. Nineteen participants (90%) had an ICD for primary prevention of sudden cardiac death while two participants had an ICD for secondary prevention; on average, participants had their ICD for 2 years (SD = 3 years). At baseline, participants had experienced 6.0 ventricular arrhythmia episodes (SD = 14.4) and 2.3 ventricular shocks (SD = 4.9) in the previous 3 months.

Treatment structure and content

The majority of participants attended all 12 sessions (15/21; 71%), with similar rates of complete attendance between QOLT (73%) and HEE attendance (70%), $p > 0.05$. In the end, 18 participants (8 QOLT, 10 HHE) completed the end-of-treatment assessment. Thirty-six percent of sessions were conducted by telephone (78/215), with a greater proportion of sessions completed by telephone among HHE participants (48%) than QOLT participants (23%), $p = 0.046$. On average, sessions lasted for 44 min (SD = 14), with longer QOLT sessions (M = 56 min, SD = 6) than HHE sessions (M = 31 min, SD = 6), $p < 0.001$.

Among QOLT participants, adherence to homework assignments was high, with 9/11 participants completing at least one homework assignment and 6/11 participants completing > 80% of the assigned homework. Between 1 and 9 (out of 16) QOLI topics were discussed in a given session, with the average number of topics discussed ranging from 2.4 (SD = 1.2) to 5.9 (SD = 2.0). All of the topic areas were discussed at least once by at least one participant (see Fig. 1 for the proportion of treatment spent discussing each topic).

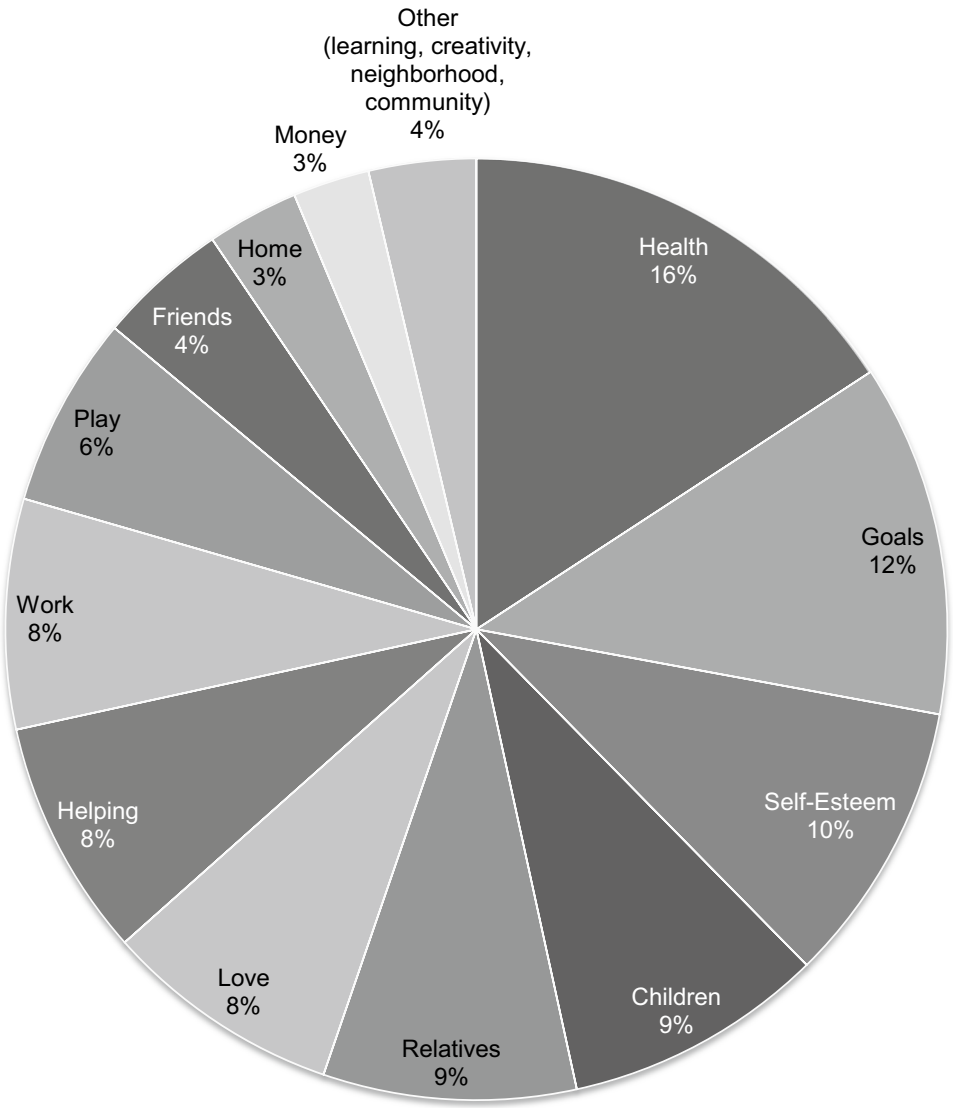

Fig. 1 Proportion of 16 Quality of Life Therapy topics discussed throughout treatment in the PAM-ICD Study

Of the 16 topic areas, Health was the most commonly discussed (M = 5.5 sessions, SD = 3.1), and along with Goals and Values (M = 4.2 sessions, SD = 2.6) was the only topic that was discussed at least once by each participant. The five topics that were least discussed were Money, Creativity, Community, Neighborhood, and Learning.

Treatment engagement and fidelity

Participant engagement in the sessions was rated as high by both the participants (M = 4.7, SD = 0.4) and the interventionists (M = 4.7, SD = 0.3), indicating that participants in both groups felt "very" or "completely" comfortable with their interventionist; there was no difference between participant and interventionist ratings of participant engagement, $t(19) = 0.98$, $p > 0.05$. Interventionists' adherence to the study protocol was rated as "very" or "completely" adherent to the protocol by the interventionists (M = 4.7, SD = 0.5) and the principal investigator (M = 4.7, SD = 0.4), $t(19) = 0.09$, $p > 0.05$. There were no differences between QOLT and HHE groups on participant engagement or treatment fidelity (all $ps > 0.20$).

Treatment acceptability

On the Program Evaluation Survey, a greater proportion of QOLT participants (62.5%) rated their sessions as "very" helpful compared to HHE participants (10%; $p = 0.019$), though all participants across groups rated their sessions as helpful. Participants were interested in the intervention because they viewed it as a useful resource to them, and because it would allow them to make the changes they wanted to make, while none of the participants primarily joined the study because of their medical team or the financial incentives of participation. Only one participant (QOLT arm) who completed the Program Evaluation Survey

at end-of-treatment missed several sessions; that participant indicated that Illness was the primary barrier to their attending more sessions. See Table 2 for detailed results of the survey.

Quality of Life Therapy outcomes

Consistent with the intervention content and as confirmation of the difference in intervention techniques, in a forced choice item, nearly all QOLT participants (87.5%) reported improved mental health whereas nearly all HHE participants (90.0%) reported improved physical health ($p = 0.001$). Over the 12 weeks of the intervention, QOLT participants' happiness levels increased modestly with average scores of 5.6 (SD = 1.6) at Session 1 to 6.1 (SD = 1.8) at Session 12 (d = 0.31), with a peak happiness level at Session 7 (M = 7.8, SD = 0.8; Fig. 2). QOLT participants' self-reported life satisfaction across various domains of functioning also increased, with QOLI standard scores that placed them in the low average range at baseline (T = 44, SD = 12) and improved to average at end-of-treatment (T = 50, SD = 10; d = 1.02). HHE participants also evidenced a smaller but moderate increase in QOLI scores from baseline (T = 49, SD = 12) through end-of-treatment (T = 55, SD = 12; d = 0.84).

Discussion

QOLT is an empirically supported positive psychotherapeutic approach that has been adapted for various medical populations, and the PAM-ICD study was the first to employ QOLT, compared to the HHE control, to address the specific needs of ICD patients who reported symptoms of anxiety and depression. This study found that a positive psychology intervention (QOLT) delivered to ICD patients was feasible and acceptable. Though the sample size was small, we found that participants were readily engaged in QOLT sessions and homework, had low attrition, and they reported that it helped them significantly. Overall, QOLT participants were more likely to endorse improvements in mental health where as HHE control participants were much more likely to endorse improvements in physical health. During treatment, QOLT participants participated in discussions about a variety of QOL topics. The most common topics were Health

Table 2 Participant program evaluation at end-of-treatment

	M (SD) or N (%)			
	QOLT (n = 8)		HHE (n = 10)	
What was your main reason for participating (choose one)?				
It provided a resource to me	4	(50%)	4	(40%)
Allowed me to make changes	3	(38%)	4	(40%)
Support from family/friends	1	(13%)	1	(10%)
Encouragement from medical team	0	(0%)	1	(10%)
Financial Incentive	0	(0%)	0	(0%)
In general, how helpful did you find the sessions (rate 1–5)?	4.4	(0.5)	4.9	(0.3)
Which best describes what you learned (choose one)?				
How to improve how I feel	4	(50%)	1	(10%)
How to improve how I take care of myself	1	(13%)	4	(40%)
How to improve satisfaction in life	3	(38%)	0	(0%)
How to live more healthfully	0	(0%)	5	(50%)
This program helped me with my (choose one):				
Mental Health	7	(88%)	1	(10%)
Physical Health	1	(13%)	9	(90%)
In which areas has your image of yourself changed (all that apply)?				
Fitness	4	(50%)	5	(50%)
Health	6	(75%)	9	(90%)
Home/environment	6	(75%)	2	(20%)
Independence	2	(25%)	3	(30%)
Knowledge	6	(75%)	8	(80%)
Personal Pursuits	2	(25%)	3	(30%)
Relationships	8	(100%)	2	(20%)
Wellbeing	5	(63%)	5	(50%)
Average number of areas (out of 8) with noted changes	4.9	(2.2)	3.7	(1.9)

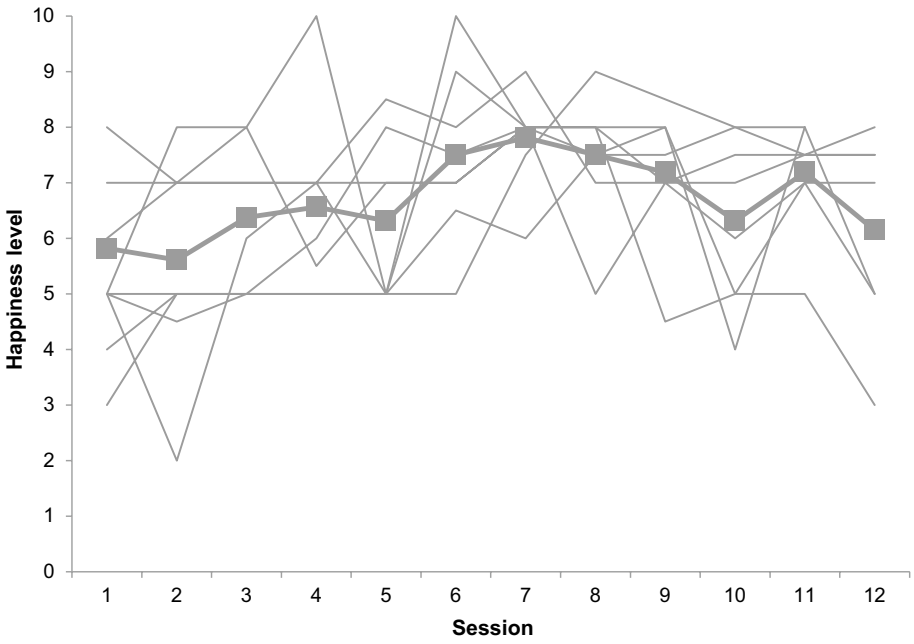

Fig. 2 Happiness ratings at weekly sessions over 12 weeks of treatment in the PAM-ICD Study. Thin gray lines: individual participant ratings. Thick gray line with squares: mean happiness rating at each session

and Goals and Values, followed closely by those addressing personal relationships.

Based on these feasibility and acceptability results, we are prepared to introduce certain changes when preparing for and designing a fully powered randomized controlled trial. First, we will conduct a multi-site study to recruit an appropriate sample size to be adequately powered for analyses. Second, given that we expect to maintain similar aims of examining autonomic functioning and arrhythmia variables as the primary outcome, the inclusion/exclusion criteria will remain similar to ensure robust between-group differences and be able to draw accurate conclusions from the analyses.

Third, we will consider making portions of the intervention entirely by telephone to increase participation and retention, as interventions have been shown to be as effective when delivered by telephone compared to in-person delivery (Mohr et al., 2012). In the present study, approximately 36% of sessions were conducted via telephone. This delivery modality has been used among cardiac patients and found to have positive, sustained effects on patient's mental health after ICD implantation (Dougherty, Thompson, & Lewis, 2005), high retention and attendance for a mindfulness intervention among ICD patients (Salmoirago-Blotcher et al., 2013), and high acceptability for a positive psychology intervention among acute coronary syndrome patients (Huffman, Millstein, et al., 2016). It is imperative to consider novel modes of delivery that may reach a greater population of ICD patients, particularly given common barriers to medical populations participating in psychological interventions (e.g., disease severity, frequent hospitalization, limited resources, low health literacy). Future studies should continue to utilize treatment modalities that will extend reach and uptake among patients and providers and ultimately barriers to care by harnessing available technology. This approach will also require buy-in and support from insurance companies in supporting and reimbursing clinicians for telephone- and telehealth-based interventions (Christon et al., 2019).

Finally, regarding the QOLT implementation, a considerable strength of the present study was the ability to tailor the intervention to each participant's specific QOL deficit(s). However, some of the 16 topics introduced in the treatment were not often discussed, and certain topic content areas could be consolidated—for example, children, relatives, and friends may be combined into a single category of "interpersonal relationships." Some may benefit from focusing more specifically on personal characteristics. For example, adults who are more optimistic following a heart attack are more likely to eat healthier, exercise more regularly, and quit smoking (Huffman, DuBois, et al., 2016; Ronaldson et al., 2015), which in turn improves cardiac outcomes. Identifying those areas that are most associated with psychological and physical improvements remains an area for future study.

Of course, the results of this study should be taken within the context of its limitations. First, approximately 25% of the QOLT sessions and 50% of the HHE sessions were conducted via telephone, and this modality was employed at the participant's discretion. Telephone sessions may have negatively affected therapeutic alliance, but it is arguably more likely that it increased participant engagement (e.g., due to disease severity, as indicated by one participant who missed the greatest number of sessions). Second, the length of HHE sessions was considerably shorter than QOLT sessions due to the intervention content, which may have impacted the

treatment acceptability outcomes between the two groups. Third, the observed changes in the participants' self-reported happiness level throughout treatment were significant but small (< 1 point difference pre-post) and with significant variability between participants; these results should be interpreted with caution. Finally, these results have limited generalizability for ICD patients given the exclusion of participants with more severe cardiovascular conditions.

Positive psychological traits, including happiness, life satisfaction, vitality, and optimism, are associated with reduced mortality and greater longevity in healthy, medical, and cardiac populations (Chida & Steptoe, 2008; DuBois et al., 2015). As such, increasing ICD patients' positive psychological traits may lead to improved cardiac outcomes (DuBois et al., 2015). Few trials focused on improving these positive psychological constructs have been conducted among cardiac patients. Among a small sample of ICD patients, we found that QOLT was an acceptable and feasible treatment to address psychological distress and improve mental health. Continued efforts are needed to incorporate positive psychology in the maintenance and promotion of cardiovascular health among cardiac patients.

Funding This study was funded by the National Heart, Lung, and Blood Institute (R34 HL107733, PI: Serber).

Compliance with ethical standards

Conflict of interest Allison J. Carroll, Lillian M. Christon, James R. Rodrigue, Joseph L Fava, Michael B. Frisch, Eva R. Serber declare that they have no conflict of interest.

Human and animal rights and Informed consent All procedures involving human participants were performed in line with ethical standards of the responsible committee on human experimentation (institutional and national) and with the ethical principles of the 1964 Helsinki Declaration and its later amendments. Informed consent was obtained from all patients for being included in the study.

References

Aben, I., Verhey, F., Lousberg, R., Lodder, J., & Honig, A. (2002). Validity of the beck depression inventory, hospital anxiety and depression scale, SCL-90, and hamilton depression rating scale as screening instruments for depression in stroke patients. *Psychosomatics, 43,* 386–393.

Baumeister, H., Hutter, N., & Bengel, J. (2011). Psychological and pharmacological interventions for depression in patients with coronary artery disease. *Cochrane Database of Systematic Reviews*. https://doi.org/10.1002/14651858.CD008012.pub3.

Berg, S. K., Thygesen, L. A. U. C., Svendsen, J. H., Christensen, A. V., & Zwisler, A.-D. (2014). Anxiety predicts mortality in ICD patients: Results from the cross-sectional national copenHeartICD survey with register follow-up. *Pacing and Clinical Electrophysiology, 37,* 1641–1650. https://doi.org/10.1111/pace.12490

Boehm, J. K., Chen, Y., Koga, H., Mathur, M. B., Vie, L. L., & Kubzansky, L. D. (2018). Is optimism associated with healthier cardiovascular-related behavior? *Circulation Research, 122,* 1119–1134. https://doi.org/10.1161/CIRCRESAHA.117.310828

Bradshaw, P. J., Stobie, P., Knuiman, M. W., Briffa, T. G., & Hobbs, M. S. T. (2014). Trends in the incidence and prevalence of cardiac pacemaker insertions in an ageing population. *Open Heart*. https://doi.org/10.1136/openhrt-2014-000177

Chida, Y., & Steptoe, A. (2008). Positive psychological well-being and mortality: A quantitative review of prospective observational studies. *Psychosomatic Medicine, 70,* 741–756. https://doi.org/10.1097/PSY.0b013e31818105ba

Christon, L. M., Correll, J., Balliet, W., Serber, E. R., Wedin, S., Kilpatrick, R., et al. (2019). Bringing specialty telebehavioral medicine home: Feasibility of a quality improvement pilot for medically complex patients. *Telehealth and Medicine Today, 4,* 1–15. https://doi.org/10.30953/tmt.v4.152

de Ornelas Maia, A. C., Soares-Filho, G., Pereira, V., Nardi, A. E., & Silva, A. C. (2013). Psychiatric disorders and quality of life in patients with implantable cardioverter defibrillators: a systematic review. *Prim Care Companion CNS Disord*. https://doi.org/10.4088/pcc.12r01456

Diener, E., Ng, W., Harter, J., & Arora, R. (2010). Wealth and happiness across the world: material prosperity predicts life evaluation, whereas psychosocial prosperity predicts positive feeling. *Journal of Personality and Social Psychology, 99,* 52–61. https://doi.org/10.1037/a0018066

Dougherty, C. M., Thompson, E. A., & Lewis, F. M. (2005). Long-term outcomes of a telephone intervention after an ICD. *Pacing and Clinical Electrophysiology, 28,* 1157–1167. https://doi.org/10.1111/j.1540-8159.2005.09500.x

Dubois, C. M., Beach, S. R., Kashdan, T. B., Nyer, M. B., Park, E. R., Celano, C. M., et al. (2012). Positive psychological attributes and cardiac outcomes: Associations, mechanisms, and interventions. *Psychosomatics, 53,* 303–318. https://doi.org/10.1016/j.psym.2012.04.004

DuBois, C. M., Lopez, O. V., Beale, E. E., Healy, B. C., Boehm, J. K., & Huffman, J. C. (2015). Relationships between positive psychological constructs and health outcomes in patients with cardiovascular disease: A systematic review. *International Journal of Cardiology, 195,* 265–280. https://doi.org/10.1016/j.ijcard.2015.05.121

Dunbar, S. B., Dougherty, C. M., Sears, S. F., Carroll, D. L., Goldstein, N. E., Mark, D. B., et al. (2012). Educational and psychological interventions to improve outcomes for recipients of implantable cardioverter defibrillators and their families. *A Scientific Statement From the American Heart Association, 126,* 2146–2172. https://doi.org/10.1161/CIR.0b013e31825d59fd

Flemme, I., Johansson, I., & Stromberg, A. (2012). Living with life-saving technology—Coping strategies in implantable cardioverter defibrillators recipients. *Journal of Clinical Nursing, 21,* 311–321. https://doi.org/10.1111/j.1365-2702.2011.03847.x

Frisch, M. (1994). *Manual and treatment guide for the quality of life inventory or QOLI®*. Minneapolis: Pearson Assessments (formerly, National Computer Systems).

Frisch, M. (2006). *Quality of life therapy: Applying a life satistation approach to positive psychology and cognitve therapy*. Hobokon: Wiley.

Frisch, M. (2014). *Adding positive psychology (PP) to your practice*. http://images.pearsonclinical.com/images/pdf/webinar/QOLI-Presentation-3.18.2014.pdf

Frisch, M., Clark, M. P., Rouse, S. V., Rudd, M. D., Paweleck, J. K., Greenstone, A., et al. (2005). Predictive and treatment validity of life satisfaction and the quality of life inventory. *Assessment, 12,* 66–78. https://doi.org/10.1177/1073191104268006

Grant, G. M., Salcedo, V., Hynan, L. S., Frisch, M., & Puster, K. (1995). Effectiveness of quality of life therapy for depression. *Psychological Reports, 76,* 1203–1208.

Habibovic, M., Broers, E., Heumen, D., Widdershoven, J., Pedersen, S. S., & Denollet, J. (2018). Optimism as predictor of patient-reported outcomes in patients with an implantable cardioverter defibrillator (data from the WEBCARE study). *General Hospital Psychiatry, 50,* 90–95. https://doi.org/10.1016/j.genhosppsych.2017.10.005

Haworth, J. E., Moniz-Cook, E., Clark, A. L., Wang, M., & Cleland, J. G. (2007). An evaluation of two self-report screening measures for mood in an out-patient chronic heart failure population. *International Journal of Geriatric Psychiatry, 22,* 1147–1153.

Holland, J. C., Andersen, B., Breitbart, W. S., Buchmann, L. O., Compas, B., Deshields, T. L., et al. (2013). Distress management. *Journal of the National Comprehensive Cancer Network, 11,* 190–209.

Huffman, J. C., DuBois, C. M., Mastromauro, C. A., Moore, S. V., Suarez, L., & Park, E. R. (2016a). Positive psychological states and health behaviors in acute coronary syndrome patients: A qualitative study. *J Health Psychol, 21,* 1026–1036. https://doi.org/10.1177/1359105314544135

Huffman, J. C., Feig, E. H., Millstein, R. A., Freedman, M., Healy, B. C., Chung, W.-J., et al. (2019). Usefulness of a positive psychology-motivational interviewing intervention to promote positive affect and physical activity after an acute coronary syndrome. *American Journal of Cardiology, 123,* 1906–1914. https://doi.org/10.1016/j.amjcard.2019.03.023

Huffman, J. C., Millstein, R. A., Mastromauro, C. A., Moore, S. V., Celano, C. M., Bedoya, C. A., et al. (2016b). A positive psychology intervention for patients with an acute coronary syndrome: Treatment development and proof-of-concept trial. *Journal of Happiness Studies, 17,* 1985–2006. https://doi.org/10.1007/s10902-015-9681-1

IBM Corp. (2016). *IBM SPSS statistics for windows, version 24*. Armonk: IBM Corp.

Labarthe, D. R., Kubzansky, L. D., Boehm, J. K., Lloyd-Jones, D. M., Berry, J. D., & Seligman, M. E. (2016). Positive cardiovascular health: A timely convergence. *Journal of the American College of Cardiology, 68,* 860–867. https://doi.org/10.1016/j.jacc.2016.03.608

Lampert, R. (2016). Mental stress and ventricular arrhythmias. *Current Cardiology Reports, 18,* 118. https://doi.org/10.1007/s11886-016-0798-6

Maia, A. C., Braga, A. A., Soares-Filho, G., Pereira, V., Nardi, A. E., & Silva, A. C. (2014). Efficacy of cognitive behavioral therapy in reducing psychiatric symptoms in patients with implantable cardioverter defibrillator: An integrative review. *Brazilian Journal of Medical and Biological Research, 47,* 265–272. https://doi.org/10.1590/1414-431x20133418

McAlinden, N. M., & Oei, T. P. (2006). Validation of the quality of life inventory for patients with anxiety and depression. *Comprehensive Psychiatry, 47,* 307–314. https://doi.org/10.1016/j.comppsych.2005.09.003

Miller, J. L., Thylen, I., Elayi, S. C., Etaee, F., Fleming, S., Czarapata, M. M., et al. (2019). Multi-morbidity burden, psychological distress, and quality of life in implantable cardioverter defibrillator recipients: Results from a nationwide study. *Journal of Psychosomatic Research, 120,* 39–45. https://doi.org/10.1016/j.jpsychores.2019.03.006

Mohr, D. C., Ho, J., Duffecy, J., Reifler, D., Sokol, L., Burns, M. N., et al. (2012). Effect of telephone-administered vs face-to-face cognitive behavioral therapy on adherence to therapy and depression outcomes among primary care patients: a randomized trial. *JAMA, 307,* 2278–2285. https://doi.org/10.1001/jama.2012.5588

Moss, A. J., Hall, W. J., Cannom, D. S., Daubert, J. P., Higgins, S. L., Klein, H., et al. (1996). Improved survival with an implanted defibrillator in patients with coronary disease at high risk for ventricular arrhythmia multicenter automatic defibrillator implantation trial investigators. *N Engl J Med, 335,* 1933–1940.

Moss, A. J., Zareba, W., Hall, W. J., Klein, H., Wilber, D. J., Cannom, D. S., et al. (2002). Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *New England Journal of Medicine, 346,* 877–883.

Oveis, C., Cohen, A. B., Gruber, J., Shiota, M. N., Haidt, J., & Keltner, D. (2009). Resting respiratory sinus arrhythmia is associated with tonic positive emotionality. *Emotion, 9,* 265–270.

Peacock, J., & Whang, W. (2013). Psychological distress and arrhythmia: risk prediction and potential modifiers. *Progress in Cardiovascular Diseases, 55,* 582–589. https://doi.org/10.1016/j.pcad.2013.03.001

Redwine, L. S., Henry, B. L., Pung, M. A., Wilson, K., Chinh, K., Knight, B., et al. (2016). Pilot randomized study of a gratitude journaling intervention on heart rate variability and inflammatory biomarkers in patients with stage B heart failure. *Psychosomatic Medicine, 78,* 667–676. https://doi.org/10.1097/psy.0000000000000316

Richards, S. H., Anderson, L., Jenkinson, C. E., Whalley, B., Rees, K., Davies, P., et al. (2017). Psychological interventions for coronary heart disease. *Cochrane Database Syst Rev, 4,* Cd002902. https://doi.org/10.1002/14651858.cd002902.pub4

Rodrigue, J., Baz, M. A., Widows, M. R., & Ehlers, S. L. (2005). A randomized evaluation of quality-of-life therapy with patients awaiting lung transplantation. *American Journal of Transplantation, 5,* 2425–2432.

Ronaldson, A., Molloy, G. J., Wikman, A., Poole, L., Kaski, J. C., & Steptoe, A. (2015). Optimism and recovery after acute coronary syndrome: a clinical cohort study. *Psychosomatic Medicine, 77,* 311–318. https://doi.org/10.1097/psy.0000000000000155

Roy, B., Diez-Roux, A. V., Seeman, T., Ranjit, N., Shea, S., & Cushman, M. (2010). Association of optimism and pessimism with inflammation and hemostasis in the Multi-Ethnic Study of Atherosclerosis (MESA). *Psychosomatic Medicine, 72,* 134–140. https://doi.org/10.1097/PSY.0b013e3181cb981b

Salmoirago-Blotcher, E., Crawford, S. L., Carmody, J., Rosenthal, L., Yeh, G., Stanley, M., et al. (2013). Phone-delivered mindfulness training for patients with implantable cardioverter defibrillators: results of a pilot randomized controlled trial. *Annals of Behavioral Medicine, 46,* 243–250. https://doi.org/10.1007/s12160-013-9505-7

Sears, S. F., Sowell, L. D., Kuhl, E. A., Kovacs, A. H., Serber, E. R., Handberg, E., et al. (2007). The ICD shock and stress management program: a randomized trial of psychosocial treatment to optimize quality of life in ICD patients. *Pacing and Clinical Electrophysiology, 30,* 858–864. https://doi.org/10.1111/j.1540-8159.2007.00773.x

Seligman, M. (2006). *Learned optimism: How to change your mind and your life* (2nd ed.). New York: Random House.

Serber, E. R., Christon, L. M., Fava, J. L., Verrier, R. L., Nearing, B. D., Buxton, A. E., & Frisch, M. B. (Under review). Positive psychotherapy improves cardiac electrical stability and mood in ICD patients: PAM-ICD trial results.

Serber, E. R., Fava, J. L., Christon, L. M., Buxton, A. E., Goldberger, J. J., Gold, M. R., et al. (2016). Positive psychotherapy to improve autonomic function and mood in ICD patients (PAM-ICD): Rationale and design of an RCT currently underway. *Pacing and Clinical Electrophysiology, 39,* 458–470. https://doi.org/10.1111/pace.12820

Steptoe, A., Wardle, J., & Marmot, M. (2005). Positive affect and health-related neuroendocrine, cardiovascular, and inflammatory processes. *Proc Natl Acad Sci US A, 102,* 6508–6512. https://doi.org/10.1073/pnas.0409174102

Toise, S. C., Sears, S. F., Schoenfeld, M. H., Blitzer, M. L., Marieb, M. A., Drury, J. H., et al. (2014). Psychosocial and cardiac outcomes of yoga for ICD patients: a randomized clinical control trial. *Pacing and Clinical Electrophysiology, 37,* 48–62. https://doi.org/10.1111/pace.12252

Tolentino, J. C., & Schmidt, S. L. (2016). Association between depression severity and cardiac autonomic modulation. *Journal of Psychosomatic Research, 85,* 9–11. https://doi.org/10.1016/j.jpsychores.2016.03.125

Versteeg, H., Timmermans, I., Meine, M., Zitron, E., Mabo, P., & Denollet, J. (2017). Prevalence and risk markers of early psychological distress after ICD implantation in the European REMOTE-CIED study cohort. *International Journal of Cardiology, 240,* 208–213. https://doi.org/10.1016/j.ijcard.2017.03.124

Whang, W., Albert, C. M., Sears, S. F., Jr., Lampert, R., Conti, J. B., Wang, P. J., et al. (2005). Depression as a predictor for appropriate shocks among patients with implantable cardioverter-defibrillators: results from the triggers of ventricular arrhythmias (TOVA) study. *Journal of the American College of Cardiology, 45,* 1090–1095. https://doi.org/10.1016/j.jacc.2004.12.053

Witkiewitz, K., & Marlatt, G. A. (2004). Relapse prevention for alcohol and drug problems: that was Zen, this is Tao. *American Psychologist, 59,* 224–235. https://doi.org/10.1037/0003-066X.59.4.224

Ziegelstein, R. C. (2007). Acute emotional stress and cardiac arrhythmias. *JAMA, 298,* 324–329. https://doi.org/10.1001/jama.298.3.324

Zigmond, A. S., & Snaith, R. P. (1983). The hospital anxiety and depression scale. *Acta Psychiatrica Scand., 67,* 361–370.