Emotional Self-Regulation Program Enhances Psychological Health and Quality of Life in Patients with Diabetes

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SUMMARY

AIMS: This pilot study was designed to assess changes in psychological status, quality of life and hematologic measures predictive of long-term health and well-being in patients with diabetes following a stress reduction and emotional self-regulation program. METHODS: Twenty-two patients with Type 1 or Type 2 diabetes mellitus participated in a 2-day HeartMath workshop, a research-based program developed to reduce stress and negative affect, increase positive affect and reduce inappropriate autonomic nervous system activation. Self-report measures of stress, psychological status and quality of life were administered before and six months following the intervention. Hemoglobin A1c, cholesterol and triglycerides, and blood pressure were also assessed. RESULTS: Participants experienced significant reductions in psychological symptomatology and negative emotions, including anxiety, depression, anger and distress, following the intervention. Significant increases in peacefulness, social support and vitality were also measured, as well as reductions in somatization, sleeplessness and fatigue. Participants showed reduced sensitivity to daily life stressors after the intervention, and quality of life significantly improved. Regression analysis revealed a significant relationship between self-reported practice of the techniques learned in the program and the change in HbA1c levels in patients with Type 2 diabetes. Increased practice was associated with reductions in HbA1c. CONCLUSIONS: Results suggest that the HeartMath emotional self-regulation intervention reduces stress, improves psychological health, enhances quality of life and may help improve glycemic control in individuals with diabetes. Replication of this study with a non-treatment control group is necessary to confirm these findings.

McCraty R, Atkinson M, Conforti K. Heart rate variability, hemoglobin A1c, and psychological health in Type 1 and 2 diabetes following an emotional self-management program. *Proceedings of the Society of Behavioral Medicine 20th Annual Scientific Sessions*, San Diego, California, 1999 [abst].

Key words: diabetes mellitus, emotion, HbA1c, stress, quality of life

Abbreviations: ANS, autonomic nervous system; BP, blood pressure; BSI, Brief Symptom Inventory; DM, diabetes mellitus; DSI, Daily Stress Inventory; HbA1c, hemoglobin A1c; IHM, Institute of HeartMath; POQA, Personal and Organizational Quality Assessment; QOLI, Quality of Life Inventory.

INTRODUCTION

There is considerable scientific rationale to support the integration of an effective stress reduction and emotional self-regulation intervention program as a fundamental component in any diabetes management regimen. Although there is evidence that appropriate interventions can significantly benefit patients with diabetes by improving quality of life, reducing symptomatology and potentially decreasing health care utilization, few studies have been performed to investigate this specifically. This study was undertaken to determine the effectiveness of the HeartMath "Heart of Wellness" stress reduction and emotional self-regulation program in improving hematologic measures, psychological health and quality of life in individuals with Type 1 and Type 2 diabetes mellitus (DM).

The importance of emotional stress in the disease process has become increasingly clear in recent years. Anger, anxiety, worry, depression and emotional reactivity have all been linked to negative health outcomes [1-5]. Such chronic emotional stress can lead to autonomic nervous system imbalances that are involved in diabetes, chronic fatigue and many forms of heart disease [6-9]. Although many physicians recognize that their patients are suffering high levels of personal, disease-related or job-related stress, they often feel powerless to help them manage and reduce this stress due to lack of training, time or financial pressures and the limited availability of effective programs.

HeartMath Research Center, Institute of HeartMath, Publication No. 00-006. Boulder Creek, CA, 2000.

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Individuals with diabetes commonly must undergo extensive lifestyle changes in order to effectively manage their disease, and frequently suffer substantial emotional stress and negative affect, including recurrent feelings of helplessness, hopelessness, anxiety and depression [10, 11]. Studies confirm that emotional disorders exhibit a significant comorbidity with the disease: diabetic patients are reported to have almost three times the rate of current and lifetime anxiety and at least three to four times the rate of current depression found in the general population [10].

A recent report of the World Health Organization/International Diabetes Federation has underscored the need for "whole-person approaches to patient care" and drawn attention to the importance of encouraging psychological well-being in diabetic patients. The establishment and maintenance of psychological well-being is recognized as an important goal of diabetes management, which is expected to reduce the occurrence of metabolic problems and complications [11]. Education in emotional self-regulation may indeed have particular clinical relevance in diabetes, as emotional disturbances have been associated with significantly poorer glycemic control, the increased report of clinical symptoms, decreased compliance and increased risk of complications [12-15]. Emotional stress can contribute to the exacerbation of diabetes by way of direct physiological effects on glucose regulation, as well as by reducing adherence to self-care behaviors [6, 16, 17].

Evidence suggests that patients' perceptions, attitudes and stress coping styles may substantially influence clinical status. For example, helplessness and hopelessness have been linked with the onset and exacerbation of the disorder [18]. Ineffective coping styles characterized by anger, high emotional arousal, avoidance, detachment or denial may also adversely affect glycemic control as well as compliance with treatment regimens [19-21]. Conversely, studies have shown that significant relationships exist between self-efficacy, self-care and HbAlc levels [22, 23]. The above discussion highlights the need for practical, time-efficient and cost-effective interventions to help patients more effectively manage stress and regulate the self-defeating emotions that aggravate their illness and reduce quality of life.

The Heart of Wellness program, developed by the Institute of HeartMath (IHM), is intended to provide patients with straightforward, easy-to-learn techniques that enable them to reduce or prevent psychological stress while increasing positive affect and emotional well-being. These tools give patients a step-by-step process to transform their in-the-moment stress responses and empower themselves to make more efficient choices in the activities and behaviors in which they choose to engage [24]. This, in turn, aids them in adhering to other components of their diabetes management program (dietary and exercise regimens, smoking cessation etc.), which is likely to improve clinical status as well as encourage long-term behavioral improvements.

Physiologically, the interventions are intended to decrease stress-induced autonomic and neuroendocrine arousal and enhance the body's natural regenerative processes. Previous research in both healthy populations and in individuals with diverse clinical conditions has demonstrated an association between the practice of these techniques and a wide range of beneficial health-related outcomes [25]. These include: reduced psychological stress and negative affect [26-32]; increased positive affect [26-28, 30-32]; improved psychosocial functioning [26, 30-32]; enhanced cognitive performance [33]; reduced inappropriate autonomic nervous system activation and increased parasympathetic activity [34, 35]; reduced cortisol and increased DHEA [27]; increased humoral immunity [36, 37]; and increased heart rhythm coherence, synchronization and entrainment of physiological oscillatory systems [34, 38]. The techniques have been shown to reduce trait anxiety and symptomatology in individuals with HIV [39], and to reduce perceived stress and depression while improving functional capacity in elderly patients with congestive heart failure [29, 40]. In addition, a growing number of case histories demonstrate that practice of the techniques taught in the program can reduce symptomatology and improve clinical status in patients with several types of cardiovascular disease, which is a major high-risk, high-cost complication of diabetes [40]. Notably, practice of the interventions has been shown to reduce blood pressure to normal levels in individuals with hypertension, a prominent cardiovascular risk factor in diabetic populations, without the aid of other treatments or medications [26]. Given the range of health benefits previously associated with the use of HeartMath techniques, it was hypothesized that the intervention would similarly improve key indicators of psychological and physical health in a diabetic patient population.

PATIENTS AND METHODS

Patients

Thirty-five patients with either Type 1 or Type 2 DM were recruited from the local community (Milpitas, California) through e-mail announcements and notices placed at local diabetic counselors' offices. All participants were recruited throughout the same four-week time period. Of these 35 individuals, 29 attended the intervention program. Twenty-two individuals (8 male and 14 females, mean age 49, age range 31-67) completed the study. Fourteen of the participants had Type 2 DM and 8 had Type 1. Written informed consent for participation in the study was obtained from each participant. Inclusion criteria required participants to be between the ages of 18 and 70, speak English, be able to arrive at the training and test site and sign a consent form. Subjects were excluded if they had had a major diabetes complication requiring hospitalization or a major life change (*e.g.* death in family, divorce, etc.) in the previous 6 months.

Of the 7 participants who did not finish the study, one moved from the area, one had a hearing problem, four reported that they did not have the time and one had to leave town on an unexpected long-term business trip and thus could not complete the training. An analysis of the dropouts revealed that the only significant differences at baseline between these individuals and those that completed the study were in the Health ($p < .05$) and Neighborhood ($p < .05$) scales on the QOLI survey and in Anxiety ($p < .05$) on the POQA survey (see below for a description of these measures). In all cases the dropouts had lower scores.

Intervention

The Heart of Wellness program was delivered in two consecutive days at a local hotel meeting room after baseline measurements were taken. In the program, patients learned to recognize and identify the specific issues, attitudes and experiences that contribute to their stress, and to make perceptual and attitudinal shifts to transform inefficient reactions to potential stressors. Participants were also provided with home study materials to facilitate practice and application of the techniques learned in the training in their day-to-day lives. Several of the core techniques of the intervention program are described briefly in the following paragraphs. More detailed descriptions of the techniques, their conceptual basis and applications can be found elsewhere [24, 25, 41-43].

Freeze-Frame [42] is a positive emotion-refocusing technique designed to aid people in shifting their perception so they may effectively deal with stressors in the moment an inefficient stress response is recognized, or, with practice, prevent the stress response altogether. In essence, the technique instructs people to consciously disengage from inefficient, negative mental and emotional reactions as they occur by shifting their attention from the mind to the area of the heart and self-generating a sincere positive feeling state, such as appreciation or care. This prevents or reverses the body's normal destructive stress response, and changes the bodily feedback sent to the brain [33, 34], thus arresting physiological and psychological wear and tear. As a result of using Freeze-Frame, one can think more clearly and often transform an inefficient, emotionally draining response into a proactive, creative one. With practice, this tool can be used effectively in less than one minute.

The Heart Lock-In emotional restructuring technique enables people to establish and sustain positive affective and physiologically coherent states associated with increased parasympathetic activity, improved cardiovascular function and hormonal balance, reduced fatigue, and heightened inner calm, emotional stability and mental clarity [27, 38]. With practice of the technique, individuals can effectively retrain their physiological systems to sustain longer periods of balanced, coherent function. The technique involves focusing one's attention on the physical area around the heart and experiencing a sincere positive feeling state such as appreciation, while listening to music specifically designed to facilitate stress reduction and promote mental clarity and emotional balance [41, 44]. Regular practice of the Heart Lock-in as part of an emotional management program has been demonstrated to decrease cortisol levels [27], which should help improve metabolic control in diabetic patients.

Additional tools and techniques covered in the Heart of Wellness program help participants improve communication effectiveness [43] and facilitate self-directed attitude/ behavior modifications that enable the actualization of greater self-care, a critical factor in the management of diabetes. Exercises also facilitate the successful integration of key concepts and interventions into patients' disease management regimens, work and personal lives.

Also incorporated in the program was a heart rhythm education component. Using the Freeze-Framer® interactive heart rhythm monitoring and coherence-building system (HeartMath LLC, Boulder Creek, CA), participants' heart rate variability patterns (heart rhythms) were fed back in real-time as they practiced the Freeze-Frame and Heart Lock-In techniques. This enabled participants to see and feel for themselves how stress and emotions affect their autonomic nervous system, and visualize the positive shifts in autonomic function and balance they could achieve through use of the techniques. The process also facilitated the experience of the inner emotional shift necessary to increase physiological coherence, a state in which heart rhythm patterns become more ordered and there is increased synchronization and entrainment between diverse physiological oscillatory systems [34, 38].

In addition to the initial two-day training program, three two-hour follow-up meetings were held once per month for the first three months to help reinforce the use of the interventions. During the last three months of the study, the participants were contacted by telephone by an IHM certified health coach who inquired about their use of the techniques and answered any questions.

Measures

Psychological Measures

Patients' stress, psychological health and quality of life were assessed three weeks before and six months after the Heart of Wellness Program using several self-report psychological surveys, described briefly below:

- **Personal and Organizational Quality Assessment (POQA)** [45]: provides a broad overview of an individual's emotional stresses, social attitudes, vitality and physical symptoms of stress. Although the survey measures both personal and job-related constructs, only the personal items were used in this study.
- **Brief Symptom Inventory (BSI)** [46]: used to assess psychological symptom patterns of medical patients. The BSI measures nine primary symptom dimensions and provides three global indices of distress. The Global Severity Index quantifies a patient's severity of illness and reflects the overall outcome of a treatment program based on reducing symptom severity. The Positive Symptom Distress Index measures the intensity of symptoms, while the Positive Symptom Total indicates the number of patient-reported symptoms.
- **Daily Stress Inventory (DSI)** [47]: measures the number and relative impact of common minor stresses frequently experienced in everyday life.
- **Quality of Life Inventory (QOLI)** [48]: assesses overall quality of life and reveals areas of satisfaction and dissatisfaction in 16 major areas of life.

Physiological Measures

Each patient's weight, blood pressure (BP), glycosylated hemoglobin (HbA1c) and cholesterol and triglyceride levels were assessed three weeks before and six months following the Heart of Wellness training.

For BP measurements, three resting, left arm readings were obtained for each participant. The first measurement was taken after a 5-minute resting period, with 2 minutes between each successive measurement. The average of the last two readings was used for analysis.

The HbAlc level is considered a key indicator of average glycemic control for the 2 to 3 months prior to the time a blood sample is taken. HbA1c, which composes 3 to 6% of the total hemoglobin in healthy individuals, is increased in people with diabetes. Increased HbA1c synthesis in diabetic individuals correlates with poorer glycemic control, with each 1% increase in HbA1c reflecting an increase in mean blood glucose of approximately 30 mg/dl. As a treatment for diabetes becomes more effective and brings the disease under control, HbAlc levels decrease and approach normal values [49-51]. HbA1c measurements were performed by SmithKline Beecham Laboratories (San Francisco, CA) using an immunoturbidimetric assay.

Intervention Practice

All participants were asked to keep a record of their practice of the Heart Lock-In intervention over the course of the study by making an entry in a logbook each time they used the technique. The Heart Lock-In was selected as the measure of intervention practice as, (i) it is generally performed during an allotted period of time and is thus easier to track than most of the other techniques, which are intended for use in the midst of potentially stressful situations; and (ii) it involves a longer time period of focused practice than the other interventions, and is thus particularly important in the process of repatterning inefficient physiological and emotional responses [27, 52].

RESULTS

Psychological Changes

The Wilcoxon signed ranks test was used to analyze mean differences in the psychological measures from time one (three weeks before the Heart of Wellness intervention) to time two (six months after the intervention). All statistical tests for outcomes were performed at the $p < 0.05$ significance level.

Brief Symptom Inventory

There was a significant decrease on the BSI Global Severity Index, Positive Symptom Distress Index, and Positive Symptom Total from time one to time two ($p < .01$), reflecting a reduction in the severity, intensity and number of patient-reported psychological symptoms. On the individual scales there were significant reductions in Depression, Anxiety, Phobic Anxiety, Somatization, Interpersonal Sensitivity (feelings of personal inadequacy, inferiority, self-consciousness), Paranoid Ideation (suspiciousness, mistrust) and Psychoticism (interpersonal alienation) ($p < .05$) (Table 1 and Figure 1).

Table 1. Brief Symptom Inventory Means and Standard Deviations

	Pre ± SD	Post ± SD	$p <$
Somatization	0.63 ± .50	0.40 ± .31	.05
Obsessive-Compulsive	0.98 ± .38	0.80 ± .49	ns
Interpersonal Sensitivity	0.62 ± .64	0.32 ± .48	.05
Depression	0.67 ± .71	0.32 ± .51	.05
Anxiety	0.64 ± .49	0.37 ± .30	.05
Hostility	0.49 ± .64	0.27 ± .26	ns
Phobic Anxiety	0.24 ± .40	0.07 ± .16	.05
Paranoid Ideation	0.53 ± .59	0.27 ± .31	.05
Psychoticism	0.40 ± .56	0.24 ± .40	.05
Global Severity Index	0.59 ± .37	0.36 ± .25	.01
Positive Symptom Distress Index	1.39 ± .37	1.22 ± .36	.01
Positive Symptom Total	21.52 ± 9.72	15.38 ± 8.85	.01

N=22

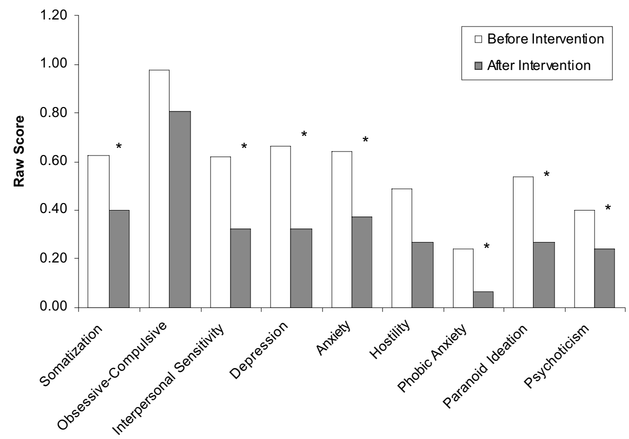

Figure 1. Reductions in psychological symptomatology. Diabetic patients (n = 22) demonstrated significant reductions in numerous psychological symptoms (Brief Symptom Inventory) after practicing the HeartMath techniques for six months. Assessments were conducted three weeks before the intervention program (white bars) and six months afterwards (shaded bars). *$p < .05$.

Quality of Life Inventory

Overall patient quality of life significantly improved ($p < .01$) from time one to time two (Table 2 and Figure 2). Figure 2 plots the mean overall quality of life percentile score for study participants as compared to the normative data. At time one the participants' mean score was near the bottom of the average range, whereas at time two it had moved into the high range. There were significant improvements in the individual scales of Health ($p < .01$), Self-Esteem ($p < .01$), Love ($p < .01$) and Home ($p < .05$).

Table 2. Quality Of Life Inventory Means and Standard Deviations

	Pre SD	Post SD	*p* <
Health	1.43 ± 3.46	3.19 ± 2.36	.01
Self-Esteem	1.57 ± 3.41	3.76 ± 1.70	.01
Goals & Values	3.52 ± 2.46	3.29 ± 2.72	ns
Money	1.05 ± 2.58	1.24 ± 2.32	ns
Work	2.25 ± 3.01	2.62 ± 2.33	ns
Play	0.71 ± 3.32	1.71 ± 2.83	ns
Learning	1.81 ± 2.56	2.19 ± 2.38	ns
Creativity	2.10 ± 2.43	2.52 ± 2.27	ns
Helping	2.48 ± 2.46	2.24 ± 2.70	ns
Love	0.14 ± 4.11	2.38 ± 3.12	.01
Friends	2.10 ± 2.57	2.29 ± 2.61	ns
Children	2.90 ± 3.08	3.19 ± 3.25	ns
Relatives	2.76 ± 2.61	3.29 ± 1.74	ns
Home	2.05 ± 3.46	3.81 ± 2.09	.05
Neighborhood	3.43 ± 2.38	3.14 ± 1.68	ns
Community	2.38 ± 2.04	2.71 ± 2.03	ns
Overall Quality of Life (raw score)	2.20 ± 1.85	2.91 ± 1.44	.01
Overall Quality of Life (T score)	47.24 ± 14.57	53.00 ± 11.10	-
Overall Quality of Life (percentile)	45.24 ± 35.14	60.38 ± 30.95	-

N=22

Personal and Organizational Quality Assessment

Table 3 shows the results of the POQA survey. There were significant improvements from time one to time two in Global Negative Emotion ($p < .001$), Anger ($p < .01$), Distress ($p < .001$), Anxiety ($p < .01$), Depression ($p < .001$), Sadness ($p < .001$), Fatigue ($p < .001$), Sleeplessness ($p < .05$), Social Support ($p < .01$) Peacefulness ($p < .01$) and Vitality ($p < .05$).

Daily Stress Inventory

Table 4 illustrates the results of the DSI assessment. There was no significant change from time one to time two in the number of stressful events patients experienced. However, there was a significant reduction in the impact of events (perceived stressfulness) ($p < .05$) and the Impact/Events ratio (sensitivity to the events) ($p < .05$).

Table 3. Personal and Organizational Quality Assessment Means and Standard Deviations

	Pre SD	Post SD	*p* <
Global Negative Emotion	2.51 ± .62	1.84 ± .53	.001
Anger	2.60 ± .79	2.06 ± .67	.01
Distress	2.97 ± .85	2.21 ± .78	.001
Depression	1.97 ± .76	1.35 ± .49	.001
Sadness	2.51 ± .87	1.75 ± .74	.001
Fatigue	3.24 ± .88	2.60 ± .85	.001
Positive Emotion	4.14 ± .64	4.31 ± .50	ns
Peacefulness	3.44 ± .92	3.90 ± .83	.01
Vitality	3.65 ± .70	3.95 ± .67	.05
Social Support	3.81 ± .80	4.25 ± .65	.01
Sleeplessness	2.71 ± 1.31	2.29 ± 1.27	.05
Anxiety	3.14 ± .91	2.33 ± .97	.01
Body Aches	2.67 ± 1.15	2.43 ± .75	ns
Indigestion	2.14 ± 1.15	1.86 ± .85	ns
Rapid Heartbeats	2.05 ± 1.02	1.67 ± .80	ns

N=22

Table 4. Daily Stress Inventory Means and Standard Deviations

	Mean SD	Mean SD	*p* <
Number of Events	21.76 ± 10.21	19.86 ± 9.51	ns
Impact	65.48 ± 35.75	51.48 ± 31.67	.05
I/E Ratio	3.01 ± 1.05	2.52 ± .86	.05

N=22

Physiological Changes

Hematologic, Weight and Intervention Practice Measures

Tables 5 and 6 show participants' hematologic measures (HbA1c, triglycerides and cholesterol), weight and amount of practice of the HeartMath techniques (as measured by the total number of Heart Lock-Ins participants performed during the study period).

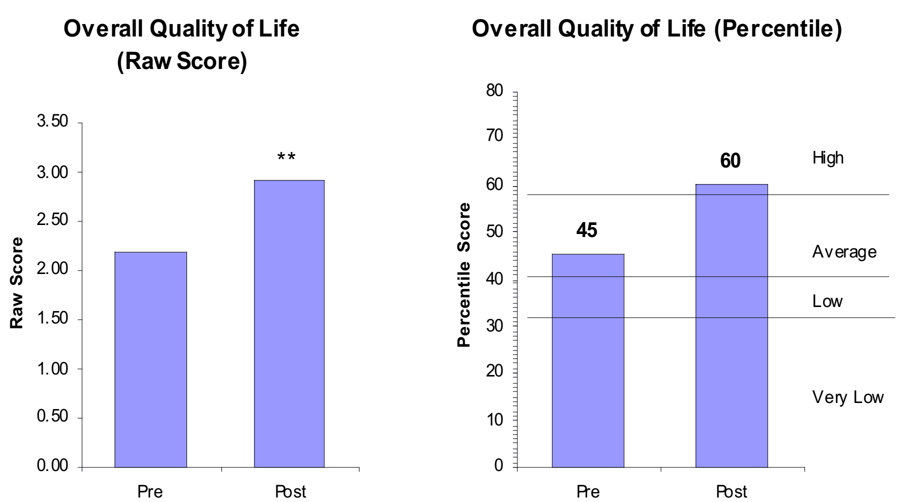

Figure 2. Quality of life improvements. The lefthand graph illustrates the significant increase in the group's (n = 22) mean overall quality of life raw score, as measured by the Quality of Life Inventory three weeks before versus six months after the HeartMath program. $**p < .01$. The righthand graph plots the mean overall quality of life percentile score for study participants as compared to normative data. Before the intervention, the group's mean percentile score plotted very near the bottom of the average range, whereas six months after the program it had moved into the high range.

Table 5. Physiological Measures and Intervention Practice in Type 2 Diabetic Patients: Means and Standard Deviations

	Pre SD	Post SD	$p <$
HbA1c (%)	7.50 ± 1.69	7.29 ± 1.25	ns
Total Cholesterol (mg/dl)	211.29 ± 38.96	211.57 ± 38.99	ns
Triglycerides (mg/dl)	231.64 ± 103.51	217.07 ± 130.46	ns
Weight (lbs.)	203.43 ± 61.71	201.93 ± 61.90	ns
Amount of Practice (Number of Heart Lock-Ins)	- -	92.21 ± 66.52	

N=14

Table 6. Physiological Measures and Intervention Practice in Type 1 Diabetic Patients: Means and Standard Deviations

	Pre SD	Post SD	$p <$
HbA1c (%)	8.58 ± 1.14	9.01 ± 1.75	ns
Total Cholesterol (mg/dl)	208.38 ± 53.40	221.13 ± 53.09	ns
Triglycerides (mg/dl)	96.13 ± 51.94	97.00 ± 36.60	ns
Weight (lbs.)	154.63 ± 29.80	154.38 ± 30.61	ns
Amount of Practice (Number of Heart Lock-Ins)	- -	45.13 ± 42.83	

N=8

Table 7. Linear Regression Analysis of Change in HbA1c vs. Intervention Practice in Type 2 Diabetic Patients

R^2	.43
Adjusted R^2	.39
Std. Error	.90
F	9.23
p of F	.01

	B	Std. Error	Beta	t	$p <$
Amount of Practice (Number of Heart Lock-Ins)	-.01	.00	-.66	-3.04	.01

There were no significant differences in mean levels of any of the physiological measures from time one to time two. However, a linear regression analysis indicated a significant relationship between the amount of self-reported practice of the interventions and the pre-post change in HbA1c in participants with Type 2 diabetes ($R^2 = .43$; $p < .01$) (Table 7). Increased intervention practice was associated with reductions in HbA1c, which reflects improved glycemic control. Type 2 patients who performed the recommended number of Heart Lock-Ins over the six-month study period (≥120, or 5 per week) showed an average HbA1c reduction of 1.1%, while patients who practiced only minimally or not at all (0-40) had an average increase in HbA1c of 0.8%. In Type 1 subjects the regression ($R^2 = .28$) was not significant; however, the trend was in the same direction.

Blood Pressure

Baseline measurements revealed that there were only 4 subjects with mild hypertension in the study group. There were no significant differences from time one to time two in the group mean values for either systolic or diastolic blood pressure.

DISCUSSION

The results of this pilot study suggest that the Heart of Wellness program led to reductions in emotional stress, improvements in psychological health and enhancement of quality of life in a diabetic population. Patients also experienced significantly less fatigue, increased physical vitality and improved perceived health at the post-test assessment. Furthermore, results provide evidence that individuals with diabetes can reduce HbA1c levels by utilizing the HeartMath tools and techniques. The indication that patients can lower their HbA1c levels by using straightforward and practical stress management techniques is of particular clinical relevance, as research suggests that patients who are able to maintain their levels at 7% or less reduce their risk for complications such as blindness, kidney disease and nerve damage [49, 53-55] and incur significantly lower health care costs [56].

Participants' scores on the POQA and BSI surveys revealed significant reductions in stress, negative affect and a variety of psychological symptoms from the pre- to post-training assessment. Also consistent with these outcomes were the DSI results, which indicated that stressful daily life events had significantly less psychological impact on participants six months after the program. These psychological changes may have important implications for patients' physical health status, as there is strong evidence that psychological stress and ineffective stress coping styles are related to a deterioration in glycemic control [6, 19-21, 57]. The improvements in the Home and Love QOLI scales and the Social Support POQA scale are noteworthy, as stress arising from family, friend and work sources have been found to be particularly relevant to both short-term and long-term glucose regulation in diabetic patients. Conversely, social support has been shown to substantially buffer the negative effects of life stress on metabolic control [16, 58, 59]. Also of note are the reductions in symptoms of anxiety and depression, emotional disturbances that are especially prominent in diabetic populations and associated with significant decrements in health, including poor glycemic control and increased diabetes symptoms and complications [12-15, 60]. Given the potent association between emotional stress and metabolic control in diabetes, we suggest that the significant relationship between increased practice of the techniques and reduced HbA1c levels in patients with Type 2 DM in this study is likely due to the reduction in stress and negative emotional arousal that these individuals experienced.

At the physiological level, emotional stresses stimulate the release of glucocorticoids and catecholamines into the serum, resulting in glycogenolysis, gluconeogenesis and impaired glucose tolerance in both types of diabetes [61]. This, in effect, increases serum glucose and presumably HbA1c. This energy-mobilizing effect is of adaptive importance in a healthy person. However, in diabetic patients, because of the relative lack of insulin (Type 1) or lack of insulin sensitivity (Type 2), the glucose is inadequately transported intracellularly. Thus, it is proposed that stress can contribute to chronic hyperglycemia [62]. The techniques taught in the intervention program have been previously shown to increase DHEA and reduce cortisol levels [27], changes which should reduce stress-induced hyperglycemia.

Another pathway by which stress influences glucose regulation is through inappropriate activation of the autonomic nervous system (ANS), which directly affects insulin secretion. Parasympathetic activity, via the right vagus nerve, causes an increase in insulin secretion. Sympathetic outflow to the pancreas, through activation of beta-adrenergic receptors, also stimulates insulin secretion and the conversion of fat to free fatty acids, which are ultimately used by the liver for ketone and triglyceride production. The triglycerides are then packaged into VLDL (very low density lipoprotein) and released into the serum, thus elevating serum triglyceride levels. This process also encourages the conversion of glycogen to glucose in the liver. In Type 1 diabetes, characterized by a loss of beta-islets and absolute insulin deficiency, increased autonomic activity can lead to glycogenolysis, hyperglycemia, free fatty acid mobilization and possibly ketoacidosis. Altered ANS activity can have an even more profound effect in Type 2 diabetes where insulin secretion is retained and remains under autonomic control. Inappropriate autonomic activity can lead to insufficient insulin release and unbalanced hepatic glucose output. It has been suggested that impaired insulin secretion and glucose utilization may be related to oversensitivity of alpha-adrenergic receptors [63] and that hyperglycemia is in part a consequence of an abnormality in the endogenous opiate system that may make affected individuals more susceptible to autonomic stimulation [64].

It is likely that the reductions in HbA1c observed in participants who practiced the techniques was mediated in part by reductions in stress-related autonomic activation, a hypothesis supported by previous data [34, 35]. Based on current knowledge, it appears that emotional self-regulation techniques that alter autonomic nervous system activity can facilitate the management of diabetes at the physiological level in two key ways: by enhancing the ability of the patient to secrete insulin, and by decreasing the production and release of glucose and triglycerides from the liver and adipose tissues. Decreased autonomic activation and improved autonomic balance should reduce excessive glucose production by the liver as well as free fatty acid mobilization and the resulting ketone and triglyceride production that occurs in patients with Type 1 diabetes.

As Type 2 patients have low insulin sensitivity, their physiological "bottleneck" occurs at the insulin/ insulin-receptor level. This "bottleneck" is underfunctional at even normal levels of glucose. It is therefore reasonable to assume that individuals with Type 2 diabetes are less able to compensate for the higher serum glucose associated with stress even with the use of exogenous insulin. Thus, it is likely that diminishing serum glucose by decreasing gluconeogenesis and glycogenolysis, via stress reduction, would substantially affect HbA1c levels. This method may in fact be equally, if not more, effective in normalizing glucose control in Type 2 diabetic patients as increasing exogenous insulin doses.

A practice trend also existed for the Type 1 participants, but did not achieve significance ($R^2 = 0.28$; $p = 0.18$). This appears to be due to an inadequate sample size ($n = 8$), although it could also reflect physiological differences between patients with Type 1 and Type 2 DM. The former possibility is supported by the fact that reanalysis of the Type 1 subjects with replication did in fact yield a significant correlation between the extent of Heart Lock-In practice and HbA1c levels. Additionally, the Type 1 participants in this study had a lower practice rate than the Type 2 subjects. It is possible that a higher practice rate would have been necessary in order for a significant practice effect to be evident in this small sample.

Given the small patient sample size utilized in this investigation, only two measurement points and the lack of a non-treatment control group, this study's results should be interpreted with caution, as it is possible that the observed positive changes in the study group derived from factors other than the intervention program. However, it is of note that HbA1c increased among participants who did not practice the techniques or practiced only minimally throughout the study period, while HbA1c reductions were associated with increased intervention practice. In addition, patients' reports in informal interviews and interactions with the trainers and experimenters provide anecdotal evidence to suggest that most did indeed benefit directly from their practice of the tools and techniques. This is further supported by comments from patients' family members, many of whom reported being impressed by the prominent positive changes they observed in participants' attitudes, behavior and overall psychological demeanor following the intervention. Notably, during the post-intervention follow-up period, a number of the participants experienced major and unforeseen stressful life events, which included the death of a spouse, injury in a car wreck, job changes and the death of a cherished pet. Participants who faced these stressors reported being able to maintain far greater peace and emotional balance in addressing them than they anticipated, thus lessening the intensity and duration of their distress considerably; all directly attributed this to their consistent practice of the techniques during the challenging periods.

Given the apparent effects of the intervention, future controlled investigations with longer time frames and larger sample sizes should be designed to confirm the outcomes reported here and to address additional parameters that are likely to improve, such as cholesterol, high blood pressure, cardiovascular-related complications and health care costs. Future investigations might further elicit functional differences in responses to self-management practices in Type 1 and Type 2 diabetic patients and their relative effects in relation to exogenous insulin utilization.

In summary, this study suggests that the HeartMath program may reduce stress, anxiety and depression, improve health status, and enhance quality of life in diabetic patients. Results provide evidence that by intervening at the emotional level, patients may be able to improve glycemic control, a key indicator of successful diabetes management. Based on previous findings, we suggest that reduced cortisol production, decreased inappropriate autonomic nervous system activation and improved autonomic balance are likely mediators of this effect. In conclusion, the intervention utilized in this investigation, which considers the patient's mental, emotional, social and physical health, holds promise as a practical approach to improve the health and well-being of individuals with diabetes.

ACKNOWLEDGMENTS

We gratefully acknowledge Lifescan for funding this investigation and the study subjects for their enthusiastic participation.

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