Short-Term Impact of a Stress Management and Health Promotion Program on Perceived Stress, Parental Stress, Health Locus of Control, and Cortisol Levels in Parents of Children and Adolescents With Diabetes Type 1: A Pilot Randomized Controlled Trial

Eleni Tsiouli, MSc,[1] Vassilis Pavlopoulos, PhD,[2] Evangelos C. Alexopoulos, MD, DSc, MSc, PhD,[1] George Chrousos, MD, DSc,[1,3,*] and Christina Darviri, Pr[1#,*]

Background: Parents of children and adolescents with diabetes type 1 (DT1) usually experience high stress levels, as they have to cope with multiple demands in their everyday life. Different complex interventions have been implemented, which sometimes have led to opposite results.

Objective: The purpose of this study was to assess stress levels in parents of children and adolescents with DT1 and to evaluate the effectiveness of a stress management program (progressive muscle relaxation combined with diaphragmatic breathing) in reducing perceived and parenting stress, increasing internal locus of control, promoting healthy lifestyle, and normalizing cortisol levels.

Study Design: Randomized controlled trial.

Methods: A total of 44 parents were randomly assigned to the intervention group (performing relaxation for eight weeks, n 19) and control group (n 25). Pre–post measurements included cortisol levels, lifestyle characteristics, perceived stress, perception of health, and parenting stress.

Results: A statistically significant decrease in perceived stress (from 27.21 to 19.00, P .001), as well as in parenting stress (from 85.79 to 73.68, P .003), was observed in the intervention group. A statistically significant difference was found in perceived stress between the two groups after the intervention (D_{mean} 6.64, P .010). No significant difference was revealed between or within the groups in cortisol levels. Significant improvement was reported by the subjects of the intervention group in various lifestyle parameters.

Conclusions: Relaxation techniques seem to have a positive impact on stress and on various lifestyle factors in parents of children and adolescents with DT1. Future research on long-term benefits of an intervention program comprising of various relaxation schemes is warranted.

Key words: Diabetes type 1, cortisol, parenting stress, perceived stress, stress management

BACKGROUND

Diabetes type 1 (DT1) is a chronic and progressive disease that has been on the increase during the last decades.[1] It requires dramatic lifestyle changes for both patients and their parents. DT1 is associated with several short- and long-term complications. Given the aforementioned, in the case of impaired glucose control, DT1 sets the perfect ground for increased stress levels within family members, causing disruptions in diabetes management and leading to early onset of several complications.[2]

Such lifestyle imposes restrictions on activities; causes discomfort and fear of the future; and may result in a continuous stimulation due to economic problems associated with the therapy. Parents usually feel guilt as they seek the causes of the disease and hold high expectations for scientific progress that may lead to more effective medical treatment.[3–7] In addition, parental caregiving quality increases as children grow and face different challenges.

1 Postgraduate Course Stress Management and Health Promotion, School of Medicine, University of Athens, Athens, Greece
2 Department of Psychology, School of Philosophy, University of Athens, Athens, Greece
3 First Department of Pediatrics, Children's Hospital Aghia Sofia, School of Medicine, University of Athens, Athens, Greece
* These authors contributed equally and share last authorship.
The authors declare that no financial support was received, there was a submission for approval to the Ethics Committee Department of the Pediatric Hospital, "Agia Sofia," and there are no conflicts of interest.
Registration number: UoAMedPR 4716 180211 25.
Corresponding author
e mail: cdarviri@yahoo.com

ISSN 1550 8307/$36.00

http://dx.doi.org/10.1016/j.explore.2013.12.004

Childhood is considered to be a happy stage of life, when everything is simple and life problems are minor. DT1 complicates this fragile developmental stage both physically and mentally. The quality of life for parents with diabetic children deteriorates very rapidly[11] as they are constantly concerned with feeding issues,[8] hospitalizations,[9,10] ongoing caring responsibilities, and their children's resistance to insulin therapy. Adolescence is another strenuous stage[12] during which patients are faced with a complex set of developmental changes and changing disease demands. Their diabetes-coping style varies considerably and is influenced by family's stress levels.[13]

In summary, DT1 patients and their families are under chronic stress.[14,15] Rearing a diabetic child also places considerable stress on marriages. One parent may blame the other about genetics, distribution of diabetes management responsibilities, and how that might impact the glycemic control of the child.[16]

Chronic stress has been associated with anxiety disorders, mood disorders,[17] addiction disorders,[18] and premature aging.[19] Chronic stress affects the whole family and, consequently, the aforementioned effects can be demonstrated in family members. Moreover, chronic stress is associated with chronic hypercortisolemia, which worsens glycemic control in diabetic patients.[20]

In the light of the evidence presented so far, there is a pressing need to assess the developmental, behavioral, and psychosocial history of children with diabetes and their families. Assessments should be performed at the time of diagnosis and periodically thereafter. If problems are identified, early interventions, such as stress management programs, should be implemented.[21]

Stress management programs have been used by parents of children with DT1, including (a) relaxation[22,23]; (b) behavioral family counseling[24]; and (c) specific behavioral and cognitive strategies, such as empowerment, goal setting, or cognitive restructuring.[23,24] Several studies have shown that relaxation techniques and meditation practices have a positive impact on biomarkers of stress regulation, such as cortisol secretion.[25] In addition, cognitive–behavioral stress management intervention may be effective in regulating stress biological markers.[26] Common relaxation techniques, like progressive muscle relaxation and diaphragmatic breathing, have a positive effect on stress reduction.[27–30,32] However, the combined implementation of these techniques in parents of children and adolescents with DT1 has not been extensively studied. Progressive muscle relaxation assists one to relax various body muscle groups and learn how to release accumulated tension. It is considered to be an effective therapeutic option for reducing state anxiety and psychological distress and improving psychological health and quality of life of psychiatric patients and patients with physical illness.[27–30] Diaphragmatic breathing is a practice that can be useful in educating people about a more effective way of breathing in comparison to thoracic breathing—irregular and fast breathing is regulated, and blood pressure and cardiovascular function are positively affected. Clinical data have shown a reduction in systolic blood pressure in healthy populations.[31] In addition, studies report both short- and long-term effects of diaphragmatic breathing exercise on asthma quality of life.[32]

The goal of this study was to assess the perceived stress levels of parents of children and adolescents with DT1 and to evaluate the effectiveness of a stress management program. In particular, we aimed to estimate: (a) stress levels of parents of children and adolescents with DT1, (b) effects of intervention on stress levels (as assessed by psychometric tools and biomarkers), and (c) effects of intervention on health-related lifestyle factors.

METHODS

Study Design

The present study was a randomized controlled trial designed to evaluate the effectiveness of a stress management program, including relaxation techniques (progressive muscle relaxation and diaphragmatic breathing). The study protocol was submitted to the Ethics Committee Department of the Pediatric Hospital, "Agia Sofia," for approval before the implementation of the study.

Flow and Participants

Upon admission to the Diabetes Center, parents (i.e., the dominant parental figure who accompanied the child during their visit to the hospital and had the main responsibility for their care) were interviewed by the first author for the purpose of checking for eligibility (see below). Information on psychiatric medication, diagnosis of major or minor psychiatric illness (e.g., neurosis, psychosis, personality disorders, and mood disorders), participation in psychological or psychiatric sessions, and previous implementation of relaxation techniques was based on self-reports in the course of a face-to-face interview. This did not include complete medical history information as it was not meant to be a typical psychiatric interview.

Of the 360 subjects assessed for eligibility, 280 were excluded. Overall, 157 refused to participate and 123 did not meet the inclusion criteria. The 80 participants who met the criteria and signed the informed consent document were first randomized (by using the web random number generator www.random.org) and then assigned to intervention and control groups by a fellow researcher (Figure 1). The final sample of the study consisted of 44 individuals of both the sexes. Table 1 shows baseline characteristics of participants. A total of 42 parents were recruited from the Diabetes Center of the Pediatric Hospital, "P. & A. Kyriakou," and two parents from the Diabetes Center of the Pediatric Hospital, "Agia Sofia." The following inclusion criteria were used:

(a) Patient age being less than 18 years.
(b) Children should meet all criteria for diagnosis of DT1; yet, they should not have been diagnosed in the last six months (in order to avoid confounding stress-control connections due to the "honeymoon period," i.e., insulin secretion by the remaining healthy beta-cells).
(c) Parents should have never been diagnosed as psychiatric patients. Consequently, they should not be on any psychiatric medication.

(d) Parents should not perform any relaxation techniques or other stress reduction strategies.

Intervention

The participants of the intervention group were trained by the first author in progressive muscle relaxation and diaphragmatic breathing with the additional help of an educational audio CD that was prepared by stress management experts in the postgraduate "Stress Management and Health Promotion" program of the University of Athens. The relaxation instructions followed a script proposed by the last author. Training took place in a dedicated, quiet place in the Diabetes Center and was performed during individual sessions. This included combined relaxation techniques of diaphragmatic breathing and progressive muscle relaxation, with a total duration of 37 min. Then, the subjects were given material containing instructions on exercising relaxation techniques and were asked to perform these techniques twice each day for eight weeks. Their compliance was evaluated by the completion of a daily diary and by a weekly telephone call. At the same meeting, participants were instructed to adapt a healthy lifestyle (e.g., diet and exercise). They were also asked to apply positive health behaviors for the next two months. The distributed instructions for a healthy lifestyle consisted of guidelines from the Hellenic Cardiological Society and the Hellenic Dietetic Association. Additional information was given on the connection between stress and lifestyle. Participants were informed that all measurements (i.e., cortisol sample and completion of psychometric tools measuring stress and lifestyle) would be repeated after a two-month period. Participants of the control group were instructed in establishing a healthy lifestyle (including recommendations on how to adapt healthy nutritional habits and increase physical activity). They were also given educational pamphlets consisting of written instructions on healthy lifestyle practices. The education of the control group (distributed instructions for a healthy lifestyle including information about diet and exercise) followed the healthy lifestyle provided protocol similarly to the intervention group. Their compliance during the two-month period was not examined by a weekly telephone call as they were not obliged to complete a daily diary. However, they had the option to call—and some of them actually did—the researcher on their own initiative.

Data Collection

Data were collected as follows. The researcher visited the two Diabetes Centers from October 2010 to March 2011. Motivation for participation was simple gratitude for the subjects of the intervention group. Participants of the control group were promised to receive educational information on the connection between stress and lifestyle, as well as an educational audio CD containing relaxation techniques at the end of the study period. Subjects were given written instructions on collection and measurement of salivary cortisol at the first meeting.[33] Each participant was provided with five special collectors—salivettes—and was asked to collect a sample at home or at work at five different time points (08:00, 12:00, 15:00, 18:00, 21:00, and at bedtime).[33] In addition, the researcher explained to the subjects the entire process of collecting the biological material. Participants were asked to return the samples to the Diabetes Center within a week. They were notified that the collection of salivary cortisol should take place one day before the meeting at the Diabetes Center in order to avoid deterioration of the biological material. Then, they were asked to complete the lifestyle questionnaire and the psychometric tools measuring stress, i.e., the Perceived Stress Scale,[34,35] the Parenting Stress Index-Short Form (PSI-SF),[36] and the Health Locus of Control scale (HLC).[37] Participants returned to the Diabetes Center within the next week in order to deliver the cortisol samples. They were all informed that in two months time they would be invited to repeat measurements of stress and lifestyle (i.e., collection of salivary cortisol and completion of the psychometric tools measuring stress and lifestyle). All samples were returned to the researcher in eight weeks.

Measurements

Salivary Cortisol. Five cortisol samples were collected in order to assess physiological stress.[33] Salivary cortisol measurements were used for observing the diurnal rhythm of cortisol secretion in response to real-life stress. All samples were analyzed in the Endocrinology Department of "Choremeio" Laboratory at the Pediatric Hospital, "Agia Sofia," by using an automatic immunological chemiluminescence analyzer (electrochemiluminescence).

Lifestyle Parameters. A questionnaire (constructed by the last author) measuring daily routine, lifestyle, and health was administered by the researcher to the dominant parental figure who accompanied the diabetic child in the Diabetes Department of the Hospital. The questionnaire contained questions on demographic characteristics, medical history (hypertension), somatometric characteristics, quality of sleep, eating habits, smoking habits, drug use, family history, general health status, oral hygiene, personal cleanliness, physical exercise, and the use of health services. Information on stress levels was collected by recording a list of non-specific stress-related symptoms.

Perceived Stress. The Perceived Stress Scale (PSS) was used as a primary measure of self-perceived stress.[34,35] PSS is a 14-item inventory developed by Sheldon Cohen for the purpose of evaluating the feelings and thoughts of a parent during the last month of his/her life. Responses are generated using a 5-point Likert scale (0 never, 1 almost never, 2 sometimes, 3 often, and 4 very often). In the present study, PSS proved to be very reliable both at baseline and at reassessment (Cronbach α 0.86).

Parental Stress. Parental stress was assessed by using the Parenting Stress Index-Short Form (PSI-SF) self-report questionnaire.[36] PSI-SF consists of 36 items, which encompass three categories: Parental Distress, Parent–Child Dysfunctional Interaction, and Difficult Child. Responses used a 5-point Likert scale (1 strongly disagree to 5 strongly agree). The total score was also calculated to serve as an indicator for the overall parental stress experienced by a person. This does not include

stress associated with other roles or life events. Our study replicated the excellent reliability of this instrument. Its internal consistency (Cronbach α) was 0.91 at baseline; it was even slightly higher at the second measurement (0.94).

Perception of Health. The Health Locus of Control scale is an 18-item self-report questionnaire designed to measure perceptions and locus of control on issues concerning health.[37] Respondents report on a 6-point scale the extent to which each statement is representative of them (1 strongly disagree to 6 strongly agree). Scores are generated for three categories. The first measures the extent to which the individual feels that he/she has control over his/her health (HLC1). The second measures the extent to which the individual believes that his/her health is controlled by others (HLC2). The third measures the extent to which the individual believes that health is a matter of luck (HLC3). In this study the reliability of HLC was satisfactory at both measurement points, i.e., baseline and reassessment (Cronbach α 0.76).

Statistical Analysis

Statistical analyses were performed using the SPSS 18.0 statistical software. Results on scale variables are presented in terms of means and standard deviations, whereas absolute and relative frequencies are reported for nominal variables. The probability level for statistical significance was set at α 0.05 because of the exploratory nature of the study and in order to balance type II error (i.e., the small sample size of n 44

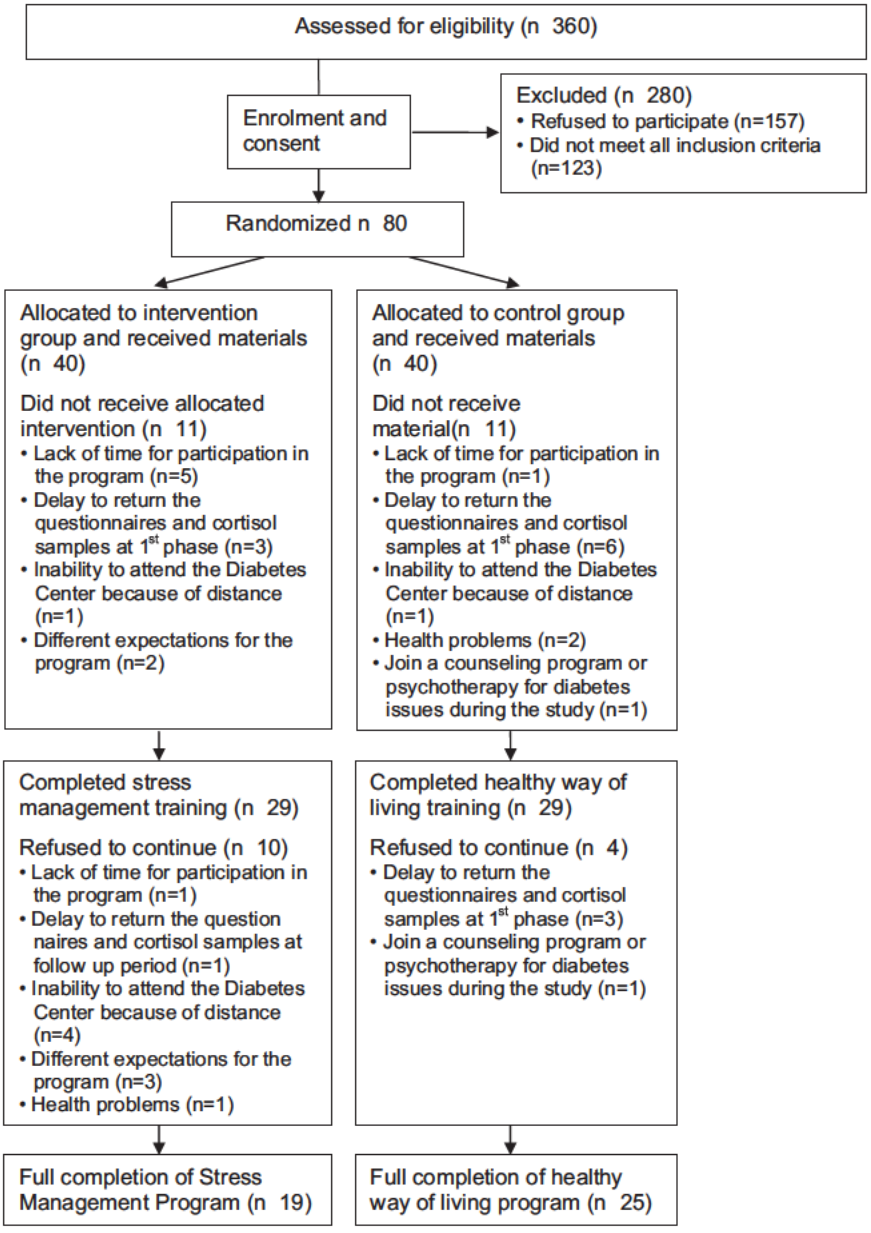

Figure 1. Participant flowchart.

would not allow for enough power to detect true associations or mean differences at a lower α level). The parametric *t*-test and χ^2 tests were conducted to examine differences between the intervention and control groups in terms of sociodemographic factors, scores of psychometric tools, and 24-h cortisol levels. Where the test of normality did not allow for parametric tests, their nonparametric equivalent (Mann–Whitney *U*) was used. Mean comparisons within groups were performed using paired-samples *t*-test or the nonparametric equivalent, Wilcoxon test, where appropriate. Cohen's *d* was used to indicate effect sizes of statistically significant differences between groups.

RESULTS

Baseline Characteristics of Participants

The compliance of parents who belonged to the intervention group (*n* 19) was satisfactory. Of them, 26.3% (*n* 5) completed the stress management program of 56 days, while 58% (*n* 11) implemented the program for at least 43 days (mean 48.72, range: 43–54). Three subjects implemented the relaxation techniques for 30, 40, and 41 days. Therefore, compliance was not considered as a factor differentiating the subjects of the intervention group into stress levels.

The two groups (intervention vs. control) were compared on various sociodemographic factors (i.e., age, gender, education level, and average monthly income). No significant differences were found for any of the above variables (Table 1).

Mean comparisons using independent samples *t*-test showed that the control group and the intervention group did not differ significantly in what concerns perceived stress, parental stress, perception of health, and cortisol levels at baseline (Table 1).

Of the tools used to measure stress, only the Parenting Stress Index (PSI-SF) estimates clinical levels of stress. Therefore, 36%

Table 1. Frequencies of Gender, Marital Status, Education Level, and Average Monthly Income; and Means and SDs of Age, Perceived Stress, and Perception of Health for the Intervention Group and Control Group at Baseline

Between Groups Comparisons (Baseline)	Intervention Group (*n* 19)	Control Group (*n* 25)	*P*[a]
Gender (F, %)			1.00[a]
Men	4 (21.1)	5 (20)	
Women	15 (78.9)	20 (80)	
Education level (F, %)			.869[a]
Master's/PhD	2 (10.5)	3 (12.0)	
University	6 (31.6)	4 (16.0)	
Technological education	2 (10.5)	6 (24.0)	
Post-secondary (professional)	1 (5.3)	2 (8.0)	
Senior high school (lyceum)	5 (26.3)	7 (28.0)	
Junior high school (gymnasium)	1 (5.3)	1 (4.0)	
Elementary school	2 (10.5)	2 (8.0)	
Monthly average income (F, %)			.166[a]
>€1000	3 (21.4)	4 (19.0)	
€1000–€1500	7 (50.0)	14 (66.7)	
€1500–€2000	0	2 (9.5)	
>€2000	4 (28.6)	1 (4.8)	
Age (mean, range)	43.95 (36–65)	42.60 (31–56)	.479[a]
PSS (mean, SD)	27.21 (7.65)	27.24 (7.70)	.990[a]
MHLC1 (mean, SD)	26.95 (4.57)	27.16 (3.35)	.617[b]
MHLC2 (mean, SD)	23.74 (5.82)	20.60 (7.72)	.147[a]
MHLC3 (mean, SD)	17.21 (6.03)	17.72 (7.34)	.807[a]
PSI-SF (mean, SD)	85.79 (18.08)	79.76 (20.21)	.311[a]
PSI-SF1 (mean, SD)	33.89 (8.54)	30.44 (9.32)	.214[a]
PSI-SF2 (mean, SD)	22.53 (7.68)	21.52 (5.87)	.625[a]
PSI-SF3 (mean, SD)	29.37 (6.64)	27.80 (8.83)	.469[b]

PSS, perceived stress scale; MHLC1, internal health locus of control; MHLC2, external health locus of control; MHLC3, chance health locus of control; PSI-SF, parenting stress index total score; PSI-SF1, PSI-SF parental distress subscale; PSI-SF2, PSI-SF parent–child dysfunctional interaction subscale; PSI-SF3, PSI-SF difficult child subscale.

[a]Parametric test (*t*-test, χ^2 test), significance level at .05.

[b]Nonparametric test (Mann–Whitney test, χ^2 test), significance level at .05.

(*n* 9) of subjects in the control group showed clinical levels of stress before the implementation of the stress management program (total stress >90), while the overall mean of parental stress was 79.76 (SD 20.21). In the intervention group, 31.7% (*n* 6) of participants showed clinical levels of stress at baseline (Total Stress >90), while the overall mean of parental stress was 85.79 (SD 18.08). The means of parental stress did not differ significantly between groups (Table 1).

Effects of the Intervention on Perceived Stress, Perception of Health, and Parental Stress

Paired-samples *t*-test revealed that the mean level of perceived stress for the intervention group was lower after the intervention (mean PSS 19.00, SD 6.44), compared to the respective score before the intervention (mean PSS 27.21, SD 7.65): *t*(18) 3.97, *P* .001. Cohen's *d* was 1.87, which indicates a large effect size (Table 2).

The mean of parental stress for the intervention group was lower after the intervention (mean PSI-SF 73.68, SD 17.74), compared to the respective value before the intervention (mean PSI-SF 85.79, SD 18.08): *t*(18) 3.48, *P* .003. The effect size of this difference was large (Cohen's *d* 1.64) (Table 2). Subsequent analyses of the parental stress categories revealed a significant difference for the intervention group before and after the intervention in the first category of Parental Stress Index measuring Parental Distress (Mean PSI-SF1 28.00, SD 7.26): *t*(18) 4.40, *P* < .001. Cohen's *d* was 2.07, which is indicative of a large difference (Table 2).

For the control group, paired-samples *t*-test showed that the mean of the third category of the Health Locus of Control questionnaire measuring chance (HLC3) was higher after the intervention (mean HLC3 19.52, SD 7.76), as compared to the respective value before the intervention (mean HLC3 17.72, SD 7.34): *t*(24) 2.16, *P* .041, Cohen's *d* 0.88 (Table 2). Independent samples *t*-test showed that perceived stress after the intervention differed significantly between the intervention and the control group. As shown in Table 2, the

Table 2. Means and SD (Within and Between Groups) of Perceived Stress, Perception of Health, and Parental Stress Before and After Intervention

	Within Groups Comparisons					
	Intervention Group (*n* 19)			Control Group (*n* 25)		
	Before, Mean (SD)	After, Mean (SD)	*P*	Before, Mean (SD)	After, Mean (SD)	*P*
PSS	**27.21 (7.65)**	**19.00 (6.44)**	**.001**[a]	27.24 (7.70)	25.64 (9.93)	.262[a]
MHLC1	26.95 (4.57)	28.05 (3.01)	.337[b]	27.16 (3.35)	26.48 (4.35)	.522[a]
MHLC2	23.74 (5.82)	22.84 (5.20)	.477[a]	20.60 (7.72)	22.56 (6.04)	.051[a]
MHLC3	17.21 (6.03)	17.32 (10.11)	.954[a]	**17.72 (7.34)**	**19.52 (7.76)**	**.041**[a]
PSI-SF	**85.79 (18.08)**	**73.68 (17.74)**	**.003**[a]	79.76 (20.21)	75.24 (22.88)	.194[a]
PSI-SF1	**33.89 (8.54)**	**28.00 (7.26)**	**.000**[a]	30.44 (9.32)	28.32 (10.17)	.134[a]
PSI-SF2	22.53 (7.68)	19.32 (5.30)	.077[b]	21.52 (5.87)	20.44 (6.64)	.383[a]
PSI-SF3	29.37 (6.64)	26.37 (7.41)	.056[a]	27.80 (8.83)	26.48 (8.56)	.406[a]

	Between groups comparisons after eight weeks		
	Intervention Group (*n* 19)	Control Group (*n* 25)	
	Mean (SD)	Mean (SD)	*P*
PSS	**19.00 (6.44)**	**25.64 (9.93)**	**.010**[a]
MHLC1	28.05 (3.01)	26.48 (4.35)	.185[a]
MHLC2	22.84 (5.20)	22.56 (6.04)	.872[a]
MHLC3	17.32 (10.11)	19.52 (7.76)	.418[a]
PSI-SF	73.68 (17.74)	75.24 (22.88)	.807[a]
PSI-SF1	28.00 (7.26)	28.32 (10.17)	.908[a]
PSI-SF2	19.32 (5.30)	20.44 (6.64)	.660[c]
PSI-SF3	26.37 (7.41)	26.48 (8.56)	.964[a]

PSS, perceived stress scale; MHLC1. internal health locus of control; MHLC2, external health locus of control; MHLC3, chance health locus of control; PSI-SF, parenting stress index total score; PSI-SF1, PSI-SF parental distress subscale; PSI-SF2, PSI-SF parent–child dysfunctional interaction subscale; PSI-SF3, PSI-SF difficult child subscale.

Significant differences at *P* < .05 are indicated in bold.

[a]Independent samples *t*-test (for between groups comparisons), paired-samples *t*-test (for within groups comparisons), significance level at .05.

[b]Wilcoxon test for dependent samples.

[c]Mann–Whitney test for independent samples.

intervention group (mean PSS 19.00, SD 6.44) reported lower mean level of perceived stress than the control group (mean PSS 25.64, SD 9.93): $t(41)$ 2.68, P .010, Cohen's d 0.84, which is indicative of a rather large difference.

Effects of the Intervention on Cortisol Levels

The comparison of means of salivary cortisol within groups and between groups before and after the intervention revealed no significant differences (Table 3).

Cortisol Levels at Baseline and at Two-Month Period Follow-Up

Before the intervention, cortisol levels tended to decrease (though, non-significantly) in the intervention group, compared to the control group, at all time points during the day: 08:00 (P .337), 12:00 (P .374), 15:00 (P .107), 18:00 (P .475), and 21:00 (P .687) (Table 3).

After the intervention, cortisol levels decreased non-significantly in the intervention group, compared to the control group, in the morning (08:00: P .455) and at noon (12:00: P .467), while there was a nonsignificant increase of cortisol levels in the intervention group, compared to the control group, in the evening (18:00: P .556) and night measurements (21:00: P .949) (Table 3).

Effects of the Intervention on Lifestyle Factors

Responses of parents of the intervention group in what concerns the quality of sleep ("Your sleep is") differed significantly before and after the intervention (χ^2 15.71, P .003). In particular, 36.8% described their sleep as "deep" before the intervention, while this percentage increased after the intervention (47.4%). Similarly, the percentage of participants who described their sleep "unquiet or disturbed" decreased after the intervention (21.1% vs. 31.6%). Responses of parents of the control group to the same question differed before and after the intervention but towards opposite direction (χ^2 33.52, P .005). The percentage of subjects who described their sleep "unquiet-other" increased after the intervention (28% vs. 24%) (Table 4). Moreover, significant improvement is reflected in responses of parents of the intervention group to other questions related to sleep ("In your opinion, do you sleep easily?" and "Are you happy with your sleep?"), while the responses of parents of the control group showed a significant differentiation in the opposite direction. Significant improvement was observed in the responses of parents of the intervention group to the question "Do you often have pain in the muscles/bones?" (15.8% answered "frequently" before the intervention vs. 10.5% χ^2 after the intervention 13.08, P .011), while significant deterioration occurred in the responses of parents of the control group to the same question (48% answered "sometimes" before the intervention vs. 52% χ^2 after the intervention 20.70, P .002) (Table 4). Similarly, for the questions "How often did you have stomach ache in the past three months?" and "How many times per day do you eat?" there were changes in the responses of the intervention group

Table 3. Means and SDs (Within and Between Groups) of Cortisol Before and After Intervention

	Within Groups Comparisons					
	Intervention Group (n 19)			Control Group (n 25)		
	Before, Mean (SD)	After, Mean (SD)	P	Before, Mean (SD)	After, Mean (SD)	P
CORT 8.00	0.617 (0.309)	0.575 (0.252)	.936[b]	0.663 (0.271)	0.799 (0.642)	.696[b]
CORT 12.00	0.281 (0.215)	0.302 (0.237)	.605[b]	0.279 (0.157)	0.398 (0.503)	.670[b]
CORT 15.00	0.204 (0.081)	0.242 (0.175)	.438[b]	0.312 (0.270)	0.241 (0.082)	.977[b]
CORT 18.00	0.169 (0.087)	0.236 (0.211)	.309[b]	0.196 (0.147)	0.217 (0.121)	.555[a]
CORT 21.00	0.181 (0.200)	0.251 (0.274)	.122[b]	0.184 (0.173)	0.206 (0.164)	.949[b]
CORT 8.00–21.00	0.203 (0.109)	0.362 (0.462)	.535[b]	0.250 (0.151)	0.266 (0.159)	.277[b]
	Between groups comparisons after eight weeks					
	Intervention Group (n 19)		Control Group (n 25)			
	Mean (SD)		Mean (SD)		P	
CORT 8.00	0.575 (0.252)		0.799 (0.642)		.455[c]	
CORT 12.00	0.302 (0.237)		0.398 (0.503)		.467[c]	
CORT 15.00	0.242 (0.175)		0.241 (0.082)		.361[c]	
CORT 18.00	0.236 (0.211)		0.217 (0.121)		.556[c]	
CORT 21.00	0.251 (0.274)		0.206 (0.164)		.949[c]	
CORT 8.00–21.00	0.362 (0.135)		0.266 (0.159)		.578[c]	

[a]Independent samples t-test (for between groups comparisons), paired-samples t-test (for within groups comparisons), significance level at .05.
[b]Wilcoxon test for dependent samples.
[c]Mann–Whitney test for independent samples.

Table 4. Frequencies of the Lifestyle Questionnaire (Within and Between Groups) Before and After Intervention

	Within Groups Comparisons					
	Intervention Group (*n* 19)			Control Group (*n* 25)		
	Before, F (%)	After, F (%)	*P*	Before, F (%)	After, F (%)	*P*
1. Your sleep is			**.003**[a]			**.0005**[a]
Deep	7 (36.8)	9 (47.4)		9 (36)	8 (32)	
Skin deep	6 (31.6)	6 (31.6)		10 (40)	10 (40)	
Unquiet/disturbed	6 (31.6)	4 (21.1)		6 (24)	7 (28)	
2. Sleep easily			**.004**[b]			**.0005**[b]
Yes	15 (78.9)	16 (84.2)		20 (80)	18 (72)	
No	4 (21.1)	3 (15.8)		5 (20)	7 (28)	
3. Happy with sleep			**.005**[b]			**.059**[b]
Yes	15 (60)	14 (56)		8 (42.1)	11 (57.9)	
No	10 (40)	11 (44)		11 (57.9)	8 (42.1)	
4. Pain in muscles/bones			**.011**[a]			**.002**[a]
Sometimes	11 (57.9)	12 (63.2)		12 (48)	13 (52)	
Frequently	3 (15.8)	2 (10.5)		6 (24)	6 (24)	
Never	5 (26.3)	5 (26.3)		6 (24)	6 (24)	
I don't know	–	–		1 (4)	–	
5. Stomach aches during past 3 months			**.023**[a]			.125[a]
Sometimes	7 (36.8)	8 (42.1)		7 (28)	8 (32)	
Frequently	3 (15.8)	2 (10.5)		4 (16)	5 (20)	
Never	9 (47.4)	8 (42.1)		12 (48)	12 (48)	
I don't know	–	1 (5.3)		2 (8)	–	
6. Eat per day			**.012**[a]			**.001**[a]
1–3 times	4 (21.1)	4 (21.1)		9 (36)	7 (28)	
4–6 times	14 (73.7)	15 (78.9)		15 (60)	15 (60)	
7–10 times	1 (5.3)	–		1 (4)	3 (12)	
7. You eat			**.002**[b]			**.021**[a]
Slightly	–	–		1 (4)	–	
Moderately	12 (63.2)	14 (73.7)		15 (60)	19 (76)	
Too much	7 (36.8)	5 (26.3)		9 (36)	6 (24)	
8. You eat			**.005**[a]			**.001**[a]
Slowly enough	–	2 (10.5)		1 (4)	–	
Normally	9 (47.4)	6 (31.6)		8 (32)	10 (40)	
Rather rapidly	6 (31.6)	6 (31.6)		10 (40)	10 (40)	
Very rapidly	4 (21.1)	5 (26.3)		6 (24)	5 (20)	
9. Daily smoking			**.030**[a]			**.001**[a]
1–10 cigarettes	4 (57.1)	4 (57.1)		3 (27.3)	4 (36.4)	
11–20 cigarettes	2 (28.6)	3 (42.9)		5 (45.5)	4 (36.4)	
31–40 cigarettes	1 (14.3)	–		2 (18.2)	2 (18.2)	
>41 cigarettes	–	–		1 (9.1)	1 (9.1)	

Table 4 (*continued*)

	Between groups comparisons baseline		
	Intervention Group (*n* 19)	Control Group (*n* 25)	
	F (%)	F (%)	*P*
Wake up refreshed			**.003**[a]
Yes	6 (31.6)	19 (76)	
No	13 (68.4)	6 (24)	

	Between groups comparisons after eight weeks		
	Intervention Group (*n* 19)	Control Group (*n* 25)	
	F (%)	F (%)	*P*
Eat organic products			.063[a]
Never-rarely	9 (47.4)	19 (76)	
Sometimes	10 (52.6)	5 (20)	
Always	–	1 (4)	

Significant differences at $P < .05$ are indicated in bold.
[a]χ^2, significance level at .05.
[b]Fisher's exact test.

towards positive direction (i.e., improvement), while in the control group changes in responses were towards negative direction (i.e., deterioration) (Table 4). Questions 7–9 in Table 4 revealed differences in the responses of parents of the intervention and control groups before and after the intervention towards positive direction (i.e., improvement) for both the groups.

Moreover, the responses of parents on sleep ("Do you wake up refreshed?") at baseline differed between the control group and the intervention group (χ^2 8.682, P .003) (Table 4). Finally, the responses of parents concerning diet after the intervention ("Do you eat organic products?") tended to differ between the control group and the intervention group, though not significantly (χ^2 5.52, P .063).

DISCUSSION

The pilot randomized controlled trial described in this article is the first to identify the short-term impact (eight weeks) of relaxation techniques (i.e., progressive muscle relaxation combined with diaphragmatic breathing exercises) on perceived stress, perception of health, parenting stress, and cortisol levels in parents of children and adolescents with DT1.

As far as the main results of this study are concerned, a statistically significant decrease was found in perceived stress among participants of the intervention group. The large effect size of this finding may demonstrate the beneficial impact of a stress management program on reducing stress. Additionally, a finding to be highlighted refers to the significant decrease of the total parental stress in parents of the intervention group. This finding is in line with other studies showing the positive effects of relaxation exercises on general anxiety and overall stress. These studies report reduction of psychological distress and improvement in the quality of life in clinical as well as in healthy populations.[27–30] It is important to note that the reduced stress levels reported in the intervention group of the present study, which was carried out in clinically healthy participants, are supported by findings of research examining the effect of relaxation exercises in clinical populations, as reviewed above.

The subjects of the control group showed a statistically significant increase in the "chance" category of the Health Locus of Control questionnaire, while no significant difference was revealed in the instruments testing other lifestyle variables. These findings underline the importance of implementing a relaxation program to reduce stress levels, which were evident in the participants of the control group.

Pre-intervention measures of parental stress showed high stress levels in the intervention group, thus confirming the literature that identifies the parent as the "real patient" in a family with a diabetic patient.[38,39]

However, no statistically significant improvement was noted in cortisol levels in either the intervention or the control group. This finding is in line with another study showing no significant improvement in cortisol levels after the implementation of relaxation techniques in healthy adult population.[40] All subjects' salivary cortisol levels were within low–normal range and did not change significantly. This can be attributed to the demographic composition of participants—healthy individuals with no indication of poor adaptation to stress or adrenal fatigue. Studies designed for people with systematic diseases may lead to different results. In addition, since the measurement of cortisol levels appears not to be a valid marker for healthy populations, future researchers should include the measurement of other biomarkers of stress, such as heart rate or blood pressure, in healthy populations.

Additionally, the implementation of the stress management program showed statistically significant differences within the intervention group in various lifestyle characteristics.

Specifically, the subjects of the intervention group reported better quality of sleep, fewer physical stress-related symptoms (e.g., pain in the muscles/bones, chest pain or pain in the heart area, and upset stomach), and healthier eating habits (e.g., frequency of daily meals). The above findings indicate the positive impact of the stress management program on lifestyle factors. However, the present study showed no significant between-group differences with respect to lifestyle parameters. Possibly, a research design that would include long-term interventions may assist in developing and maintaining a healthy lifestyle. Therefore, non-significant differences between the intervention and control groups could be attributed to the short-term nature of the intervention (eight weeks).

Furthermore, within-group comparisons, both in the intervention and control groups, showed reduced daily cigarette consumption and improved dietary patterns. These findings may indicate the favorable effect of parental involvement in the control group in this research, as well as the positive role of the education in healthy lifestyles (i.e., exercise advice and diet) without necessarily learning specific relaxation techniques. A statistically significant improvement was also found in the control group, as compared to the intervention group, in variables related to experiencing stress or physical discomfort (e.g., waist pain, back pain, and headaches). A possible explanation for this finding could be that parents of the control group attempted to comply with the perceived expectations of the researcher by responding in a socially desirable manner.

This pilot study presents some methodological issues: (a) small sample size, which reduced the power of analysis and limits the generalization of findings; (b) self-reported questionnaires; (c) no control for possible confounders, such as other related factors (e.g., personality and health); (d) more systematic attention to the intervention group compared with the control group, which could be a determinant for between-group differences; (e) short-term intervention (eight weeks) and lack of follow-up over longer periods, which would reveal the stability of therapeutic effects over time and would lead to more reliable conclusions on the reduction of stress.

It is worth noting that the examination of the implementation of relaxation techniques (i.e., progressive muscle relaxation in combination with the diaphragmatic breathing) in the population of parents of children with DT1 is a first-studied area. For this reason, it has not always been easy to extensively discuss our findings in the light of relevant literature. However, this pilot study may motivate researchers for future investigation in order to replicate these results.

Acknowledgments

We would like to thank Pinelopi Papadopoulou, MSc, for editing this article.

REFERENCES

1. Craig ME, Hattersley A, Donaghue KC. Definition, epidemiology and classification of diabetes in children and adolescents. *Pediatr Diabetes*. 2009;10(suppl 12):3 12 [10.1111/j.1399 5448.2009.00568.x, Review].
2. Malerbi FE, Negrato CA, Gomes MB. Assessment of psychoso cial variables by parents of youth with type 1 diabetes mellitus. *Diabetol Metab Syndr*. 2012;4(1):48.
3. Thernlund G, Dahlquist G, Hagglof B, et al. Psychological reactions at the onset of insulin dependent diabetes mellitus in children and later adjustment and metabolic control. *Acta Paediatr*. 1996;85(8):947 953.
4. Cochlami T, Bor R. Family relationships in Greek insulin dependent diabetics. *Couns Psychol Q*. 1993;6(4):267 279.
5. Almeida MC. Grief among parents of children with diabetes. *Diabetes Educ*. 1995;21(6):531 532.
6. Antisdel EJ. Diabetes specific distress among parents of youth with type I diabetes. Unpublished doctoral dissertation. New York, NY: Yeshiva University; 2000.
7. Stoppelbein L, Greening L. Brief report: the risk of posttraumatic stress disorder in mothers of children diagnosed with pediatric cancer and type I diabetes. *J Pediatr Psychol*. 2007;32(2):223 229.
8. Powers SW, Byars KC, Mitchell MJ, et al. Parent report of mealtime behavior and parenting stress in youth children with type I diabetes and in healthy control subjects. *Diabetes Care*. 2002;25(2):313 318.
9. Hatton DL, Canam C, Thorne S, et al. Parents' perceptions of caring for an infant or toddler with diabetes. *J Adv Nurs*. 1995;22 (3):569 577.
10. Kassiou K, Tamasiros J. Family management of insulin dependent diabetes mellitus. A practical problem solving approach. *Acta Paediatr Suppl*. 1999;88(427):47 51.
11. Müller Godeffroy E, Treichel S, Wagner VM. German Working Group for Paediatric Pump Therapy. Investigation of quality of life and family burden issues during insulin pump therapy in children with type 1 diabetes mellitus a large scale multicentre pilot study. *Diabet Med*. 2009;26(5):493 501.
12. McConnell EM, Harper R, Campbell M, Nelson JK. Achieving optimal diabetic control in adolescence: the continuing enigma. *Diabetes Metab Res Rev*. 2001;17(1):67 74.
13. Murphy HR, Wadham C, Hassler Hurst J, Rayman G, Skinner TC. Families and AdolescentsCommunication and Teamwork Study (FACTS) Group. Randomized trial of a diabetes self management education and family teamwork intervention in adolescents with type 1 diabetes. *Diabet Med*. 2012;29(8):e249 e254.
14. Jackson C, Richer J, Edge JA. Sibling psychological adjustment to type 1 diabetes mellitus. *Pediatr Diabetes*. 2008;9(4 Pt 1):308 311.
15. Mullins LL, Wolfe Christensen C, Pai AL, et al. The relationship of parental overprotection, perceived child vulnerability, and parenting stress to uncertainty in youth with chronic illness. *J Pediatr Psychol*. 2007;32(8):973 982.
16. Dashiff CJ. Parents' perceptions of diabetes in adolescent daughters and its impact on the family. *J Pediatr Nurs*. 1993;8:361 369.
17. Gold PW, Chrousos GP. Organization of the stress system and its dysregulation in melancholic and atypical depression: high vs low CRH/NE states. *Mol Psychiatry*. 2002;7(3):254 275.
18. Contoreggi C, Herning RI, Na P, et al. Stress hormone responses to corticotropin releasing hormone in substance abusers without severe comorbid psychiatric disease. *Biol Psychiatry*. 2003;54(9):873 878.
19. Miller GE, Chen E, Parker KJ. Psychological stress in childhood and susceptibility to the chronic diseases of aging: moving toward a model of behavioral and biological mechanisms. *Psychol Bull*. 2011;137(6):959 997.
20. Mosbah AA, Abd Ellatif NA, Sorour EI. Influence of serum cortisol levels on glycemic control in children with type 1 dia betes. *J Egypt Soc Parasitol*. 2011;41(3):777 784.
21. Murphy HR, Wadham C, Rayman G, Skinner TC. Approaches to integrating paediatric diabetes care and structured education:

experiences from the Families, Adolescents, and Children's Teamwork Study (FACTS). *Diabet Med*. 2007;24(11):1261 1268.
22. Guthrie DW, Sargent L, Speelman D, et al. Effects of parental relaxation training on glycosylated hemoglobin of children with diabetes. *Patient Educ Couns*. 1990;16(3):247 253.
23. Matam P, Kumaraiah V, Munichoodappa C, et al. Behavioral intervention in the management of compliance in young type I diabetics. *J Assoc Physicians India*. 2000;48(10):967 971.
24. Harris MA, Freeman KA, Beers M. Family therapy for adoles cents with poorly controlled diabetes: initial test of clinical significance. *J Pediatr Psychol*. 2009;34(10):1097 1107.
25. Brand S, Holsboer Trachsler E, Naranjo JR, et al. Influence of mindfulness practice on cortisol and sleep in long term and short term meditators. *Neuropsychobiology*. 2012;65(3):109 118.
26. Urizar GJ, Munoz RF. Impact of a prenatal cognitive behavioral stress management intervention on salivary cortisol levels in low income mothers and their infants. *Psychoneuroendocrinology*. 2011;36(10):1480 1494.
27. Vancampfort D, Corell CU, Scheewe TW, et al. Progressive muscle relaxation in persons with schizophrenia: a systematic review of randomized controlled trials. *Clin Rehabil*. 2012;27 (4):291 298.
28. Jacobson E. *Progressive Relaxation*. Chicago, IL: University of Chicago Press; 1938.
29. Wilk C, Turkoski B. Progressive muscle relaxation in cardiac rehabilitation: a pilot study. *Rehabil Nurs*. 2001;26(6):238 242.
30. Dehdari T, Heidarnia A, Ramezankhami A, et al. Effects of progressive muscular relaxation training quality of life in anxious patients after coronary artery bypass graft surgery. *Indian J Med Res*. 2009;129(603):8.
31. Leea JS, Leea MS, Lee JY, et al. 3rd international symposium workshop on circadian rhythms and clinical chronotherapy. *Biomed Pharmacother*. 2003;57(1):87 91.
32. Prem V, Sahoo RC, Adhikari P. Effect of diaphragmatic breath ing exercise on quality of life in subjects with asthma: a system atic review. *Physiother Theor Pract*. 2012;29(4):271 277.
33. Pervanidou P, Kolaitis G, Charitaki S, et al. The natural history of neuroendocrine changes in pediatric posttraumatic stress disorder (PTSD) after motor vehicle accidents: progressive divergence of noradrenaline and cortisol concentrations over time. *Biol Psychiatry*. 2007;62:1095 1102.
34. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Soc Behavior*. 1983;24(4):386 396.
35. Andreou E, Alexopoulos EC, Lionis C, et al. Perceived stress scale: reliability and validity study in Greece. *Int J Environ Res Public Health*. 2011;8(8):3287 3298.
36. Abidin RR. *Parenting Stress Index: Professional Manual*. 3rd ed. Odessa, FL: Psychological Assessment Resources Inc; 1995.
37. Wallston BS, Wallston KA. Development of the multidimen sional health locus of control (MHLC) scales. *Health Educ Behav*. 1978;6(2):160 170.
38. Sullivan Bolyai S, Deatrick J, Gruppyso P, et al. Constant vigilance: mother's work parenting young children with type I diabetes. *J Paediatr Nurs*. 2003;18(1):21 29.
39. Kovacs M, Finkelstein R, Feinberg TL, et al. Initial psychologic responses of parents to the diagnosis of insulin dependent diabetes mellitus in their children. *Diabetes Care*. 1985;8(6): 586 595.
40. Galvin JA, Benson H, Deckro GR, et al. The relaxation response: reducing stress and improving cognition in healthy aging adults. *Complement Ther Clin Pract*. 2006;12(3):186 191.