REDEEM: A Pragmatic Trial to Reduce Diabetes Distress

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OBJECTIVE—To compare three interventions to reduce diabetes distress (DD) and improve self-management among non–clinically depressed adults with type 2 diabetes mellitus (T2DM).

RESEARCH DESIGN AND METHODS—In REDEEM, 392 adults with T2DM and DD were randomized to computer-assisted self-management (CASM), CASM plus DD-specific problem solving (CAPS), or a computer-administered minimal supportive intervention. Primary outcomes were Diabetes Distress Scale (DDS) total, the Emotional Burden (EB) and Regimen Distress (RD) DDS subscales, and diet, exercise, and medication adherence.

RESULTS—Significant and clinically meaningful reductions in DD (DDS, EB, and RD) and self-management behaviors occurred in all three conditions ($P < 0.001$), with no significant between-group differences. There was, however, a significant group × baseline distress interaction ($P < 0.02$), in which patients with high baseline RD in the CAPS condition displayed significantly larger RD reductions than those in the other two conditions. RD generated the most distress and displayed the greatest distress reduction as a result of intervention. The pace of DD reduction varied by patient age: older patients demonstrated significant reductions in DD early in the intervention, whereas younger adults displayed similar reductions later. Reductions in DD were accompanied by significant improvements in healthy eating, physical activity, and medication adherence, although not by change in HbA_{1c}.

CONCLUSIONS—DD is malleable and highly responsive to intervention. Interventions that enhance self-management also reduce DD significantly, but DD-specific interventions may be necessary for patients with high initial levels of DD. Future research should identify the minimal, most cost-effective interventions to reduce DD and improve self-management.

Diabetes Care 36:2551–2558, 2013

Diabetes distress (DD) refers to the often hidden emotional burdens, stresses, and worries that are part of managing a demanding, progressive, chronic disease like diabetes (1). The point prevalence of moderate and high DD is as high as 45.4% of type 2 diabetic (T2DM) adults in community settings (2), and DD has displayed significant linkages with poor glycemic control, self-management, and self-efficacy, independent of clinical depression (3–6). Approximately 70% of high-DD type 2 patients do not reach criteria for clinical depression (4).

DD is a critical, yet often neglected, area of comprehensive care for patients with diabetes. Because at least 70% of these patients are not clinically depressed (3), i.e., do not meet criteria for major depression or dysthymia, traditional behavioral and pharmacological interventions for depression may not be warranted. Interventions to reduce DD directly, based primarily on cognitive-behavioral approaches, have yielded mixed results (7,8). Several meta-analyses of this literature indicate that, even though some studies report reduced DD, the overall effect size on glycemic control is variable across studies and quite modest (9). Thus, few practical interventions directed specifically at adults with type 2 diabetes and DD without clinical depression have been developed and evaluated.

Our overview of the literature indicates that two strategies of DD intervention have been considered. One strategy suggests that, if effective, interventions to improve self-management behavior will also reduce DD, since the worries and concerns regarding poor disease management will be reduced as well. Programs to improve self-management have been shown to be effective, can be inexpensive, and are easily available for large patient populations (10), but their direct effects on reducing DD have not been demonstrated. A second strategy targets remediation of the very diabetes worries and concerns that underlie DD (7,11). Conceptually, this strategy suggests that as the distress that results from unsuccessful diabetes management increases over time (12), attention narrows, behavioral options become reduced, and alternative approaches and creative solutions become limited (13). An increasing spiral of poorer management and increased distress occurs that leads to even poorer coping (14,15). This pattern hampers the acquisition of new knowledge and skills, accelerates the development of unrealistic goals and expectations, and fosters inaccurate personal beliefs and perceptions that become self-defeating—all common reactions of distressed individuals facing a demanding and progressive chronic disease like diabetes (14). Thus, this perspective suggests that addressing the underlying emotional themes directly tied to DD may be crucial. It remains unclear, however, whether an intervention that targets DD directly will add significantly to the effects that result from improvements in disease-management programs alone (16).

Reducing Distress and Enhancing Effective Management (REDEEM) was a 12-month, three-arm comparative, pragmatic randomized clinical trial for distressed, non–clinically depressed adults with type 2 diabetes who reported difficulties with diet, physical activity, or

medication taking. We compared the effectiveness of a general, Web-based, behavioral self-management support program, computer-assisted self-management (CASM), with or without problem-solving therapy (PST), a program to reduce DD directly by improving diabetes-specific problem-solving skills (17), relative to a minimum, largely automated (18) general diabetes support and education condition (Leap Ahead). This additive approach was used to determine whether a combined behavioral and targeted DD intervention program, CASM plus PST (CAPS), was necessary to reduce DD or whether improved disease management alone was sufficient. We address the following research questions in this report: *1*) Does an intervention that addresses improvements in disease management also reduce DD, relative to a general, minimal intervention diabetes support and education program? *2*) Does an intervention that targets DD directly add significantly to a self-management program in reducing DD? *3*) Are programs to improve self-management (e.g., healthy eating, exercise) effective for distressed patients with type 2 diabetes?

RESEARCH DESIGN AND METHODS

—Patients with type 2 diabetes and DD were recruited from the patient registries of several community medical groups and diabetes education centers. Inclusion criteria were a registry-recorded diagnosis of type 2 diabetes ≥12 months, a mean score of ≥1.5 on the two-item Diabetes Distress Screener (19) (confirmed later by the full scale) to indicate at least moderate DD (2,20), age ≥21 years, ability to read and speak English, at least moderate computer use facility, easy availability of a computer with internet access, comfort with internet use, and self-reported problems with diabetes management (healthy eating or exercise plan not followed in 3 of 4 days during the previous week or medications not taken 2 or more days during the previous week, based on the Summary of Diabetes Self-Care Activities [21]). Exclusion criteria included clinical depression (Patient Health Questionnaire 8 score ≥15 [22]) and severe diabetes complications or functional deficits (e.g., dialysis, blindness).Patients received a letter from their health care facility, signed by a facility clinician and project representative, informing them of the project. They were told that a REDEEM representative would telephone them to explain the project

further unless they opted out by calling an 800 number or by returning an enclosed postcard. During a follow-up call, the project was explained, patients were screened, and eligible patients were invited to a meeting at our project office or at another convenient location (e.g., library, patient's home). At the meeting, eligibility requirements were confirmed, informed consent was obtained, and a 1.5-h baseline assessment was completed (A0) that included height and weight, questionnaires, brief interview, and visit to a community laboratory for collection of biological data. Patients were then randomized individually to one of the three study arms using a computer-generated algorithm, and an intervention visit was scheduled within 2 weeks. In keeping with a pragmatic design and comparative effectiveness research (23), no usual care condition was included because of concerns about maintaining highly distressed patients in a noninterventional study arm. Assessments were repeated at 4 (A4) and 12 (A12) months postintervention. Three nonprofessional college graduate interventionists were trained and closely supervised by the investigators to deliver each of the three interventions and the telephone calls. A separate team of assistants undertook A0, A4, and A12 assessments.

CASM
Patients randomized to CASM were introduced to "My Path To A Healthy Life," a 40-min, previously validated, Web-based diabetes self-management improvement program (16,24). Patients selected achievable goals for medication adherence, diet, or exercise and were shown how to monitor their daily progress on the site. They received immediate feedback on their success over the past 7 days. The predominately Web-based intervention also provided an ask-the-expert forum to enhance engagement (25). After 6 weeks, patients completed an "action plan" for each previously prioritized management problem. Also included was a list of personalized barriers and strategies to overcome barriers. Patients received four live phone calls from their interventionist at weeks 2, 4, 7, and 12 to check progress and problems regarding their use of CASM and to provide encouragement to continue their efforts. At month 5, patients received an automated "behavior chain" booster program to reduce negative behavioral practices. This interactive component involved illustrative scenarios of prototypic patients

experiencing "chains of events," e.g., negative thinking that triggered overeating, followed by an exercise to help "break" the sequence (7,10). Finally, patients received four more live 15-min phone calls at weeks 24, 28, 34, and 48.

CAPS. Patients randomized to CAPS received a 60-min in-person intervention that included CASM plus PST. PST is an eight-step process to identify and define DD, establish realistic goals, generate ways to meet these goals, weigh the pros and cons of each, choose and evaluate solutions, create a DD action plan, evaluate outcome, and engage in pleasant activities (see pstnetwork.ucsf.edu) (26,27). As in CASM, CAPS patients received four live phone calls between A0 and A4 and between A4 and A12 to check progress on CASM and PST, respond to problems, and provide encouragement and a live supplemental booster session at month 5 (a review of the PST steps).

Leap Ahead
Patients randomized to Leap Ahead, a minimal intervention in comparison with the other two conditions, received a 20-min, computer-delivered health risk appraisal (e.g., seat belt and sunscreen use) along with diabetes information regarding healthy living, diet, and physical activity (28) preceding each of the eight calls between A0 and A12. The materials delivered diabetes information only, and patients were not directed to use the information to engage in a specific or structured program of self-management or DD change. Patients received a repeat of the risk appraisal at month 5, the same number and sequence of subsequent live phone calls to answer questions about provided diabetes management information, and assessments similar to those of CASM and CAPS.

The University of California, San Francisco, Institutional Review Board and the committees of collaborating institutions approved this study. Data were collected between 2008 and 2011 and analyzed in 2012.

Measures
Patient demographic variables included age (continuous variable), sex, race (white vs. nonwhite), and education (years); diabetes status included use of insulin (yes vs. no), years since diagnosis, and number of comorbidities and complications derived from a list of 22 common diabetes-related health problems.

The primary dependent variable was DD, which was assessed by the 17-item

Diabetes Distress Scale (DDS) (20) (α = 0.87), the five-item Regimen Distress (RD) DDS subscale (α = 0.90), and the five-item Emotional Burden (EB) DDS subscale (α = 0.88). RD and EB were selected because they were directly targeted by the interventions. Items that reflect areas of distress are rated on a 6-point Likert scale from "not a problem" to a "very serious problem." RD items include feeling that I am often failing with my diabetes regimen and feeling that I am not sticking closely enough to a good meal plan; EB items include feeling overwhelmed by the demands of living with diabetes and feeling that diabetes controls my life. Mean item scores from 2.0 to 2.9 reflect moderate distress, and scores ≥ 3 are considered high distress (2). Physical activity was assessed by the Community Health Activities Model Program For Seniors (29). It measures weekly caloric expenditure of light, moderate, and heavy physical activity. Only the light physical activity variable was used in the present analyses because it most frequently reflected levels reported by patients. Healthy eating was assessed by the NCI Percent Energy From Fat Screener (30), which estimates percent energy (calories) from fat based on consumption of 14 foods. Medication adherence was assessed by the eight-item Hill-Bone Compliance Scale (α = 0.80) (31) that assesses how often and why respondents miss taking medications, rated on a 4-point scale from "none of the time" to "all of the time." Glycemic control was assessed by HbA$_{1c}$, which was analyzed in a central laboratory for all participants and natural log transformed to reduce skew and kurtosis.

Data analysis

Descriptive statistics were computed to review score distributions. Missing data were imputed with multiple imputation procedures using NORM, version 2, software (32). NORM imputes data via an expectation-maximization algorithm, which provides efficient estimation of mean, variances, and covariances and uses a data-augmentation procedure that generates multiple imputations of missing values. Variables within a limited range were logit transformed to ensure that imputed values also fell within that range. The same imputed dataset was used for all analyses to ensure continuity of results.

One-way ANOVA and χ^2 tests, as appropriate, were conducted to test for baseline differences across the three treatment conditions and to examine differences in

outcomes between dropouts and continuing participants. Repeated-measures ANOVA models were used to test for change across time in the outcome variables (DDS, RD, EB, light physical activity, fat intake, medication adherence, and log-transformed HbA$_{1c}$). Difference scores were calculated for outcomes, with earlier scores subtracted from later scores: A0–A4, A0–A12, and A4–A12. For each difference-score outcome, a series of ANOVA models was specified to test for main treatment effects both in the absence of and with covariates, main effects of treatment and predictors, and interactions between intervention group and baseline demographic variables, disease status variables, and

baseline value of outcome. Given the large number of interactions tested, only variables for which a consistent pattern of significant interaction terms emerged were retained in the final models. Statistical analyses were performed using SPSS 19.0 (SPSS, Chicago, IL).

RESULTS—Of 2,606 patients identified from registries whom we could contact, 658 were eligible and 436 agreed to participate (66.6%) (Fig. 1). Problems with time and conflicting life demands were the most frequent reasons for nonparticipation. Of these, 392 completed baseline assessment and intervention (89.5%), with 150 randomized to

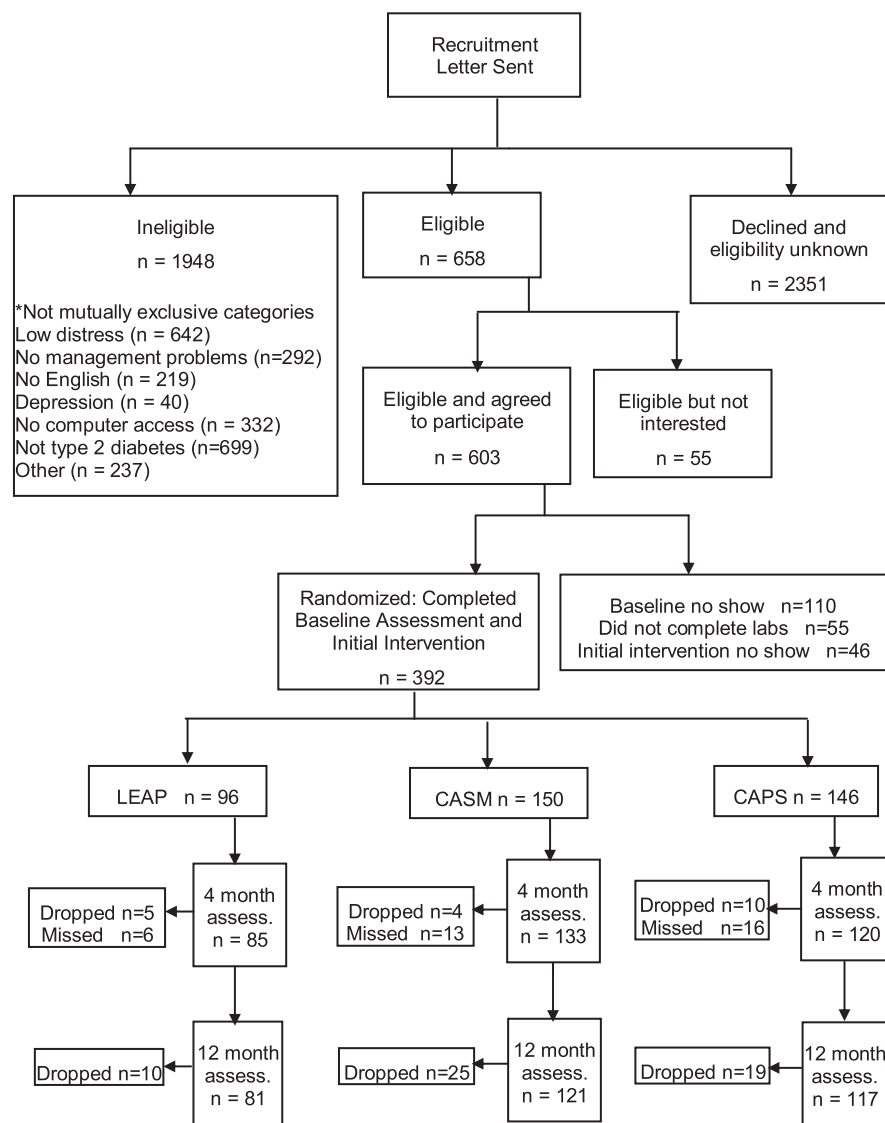

Figure 1—*Consort diagram of REDEEM study participation and retention. "Missed" indicates the participant missed the stage, but this did not preclude them from participating in a later stage of the project. assess., assessment.*

CASM, 146 to CAPS, and 96 to Leap Ahead. The smaller Leap Ahead sample was built into the randomization allocation algorithm to provide more power to compare the two active arms. Based on telephone screening data, there were no significant differences between those contacted who participated and those who refused.

Attrition was 13.8% from A0 to A4, 5.7% from A4 to A12, and 18.7% from A0 to A12. Only 8.4% of patients missed both A4 and A12 follow-up assessments. There were no significant between-group differences in attrition across any time period on any key study variable. There were also no significant baseline differences among the three study groups on any key demographic or diabetes status variable (Table 1). The diverse sample had a mean age of 56 ± 9.6 years (range 21–75), 53.8% of the sample was female, 8.7% of patients had ≤12 years of education, and mean (SD) baseline HbA$_{1c}$ was 7.4% (1.61) (57.0 mm/mol [17.6]).

Changes in DD
Significant and clinically meaningful reductions in DDS, RD, and EB occurred across the three study groups from A0 to A4 and A0 to A12 (Table 2). Also, significant reductions in DD scores between A4

and A12 occurred for all groups both after adjusting and not adjusting for changes between A0 and A4, indicating continued improvement over time. There were no significant between-group differences in these reductions at any time point for DDS, RD, or EB. Patients with higher DDS, RD, and EB baseline scores consistently displayed the largest reductions in distress from A0 to A4 and A0 to A12. Older patients showed larger reductions in RD and EB than younger patients from A0 to A4, but younger patients showed larger RD and EB score reductions than older patients from A4 to A12.

There was a significant group × baseline distress interaction for RD from A0 to A4 such that CAPS patients with high baseline RD displayed significantly larger RD reductions than high-baseline RD patients in Leap Ahead ($P = 0.005$) and marginally larger reductions than those in CASM ($P = 0.08$). Of patients classified as high DD on the DDS at baseline ($n = 95$), by 12 months 27.4% fell into the moderate range and another 34.7% displayed little or no DD. Thus, categorical changes in DDS occurred for 62.1% of initially high DD patients, with no between-group differences ($P = 0.92$). Among those who displayed moderate DD at baseline ($n = 147$), 60.5% reported

little or no DD at 12 months. Similar reductions occurred for both RD and EB.

Changes in self-management behavior
Healthy eating. Significant reductions in percent of total calories from fat occurred across the entire sample from A0 to A4 and from A0 to A12 but not from A4 to A12 (Table 3). This suggests that gains that occurred primarily during the initial period of the intervention were maintained over time. There were no significant between-group differences. Older participants and those with higher baseline fat consumption showed the greatest improvements. There was a significant group × baseline percent fat interaction from A0 to A4 and A4 to A12. CAPS and Leap Ahead patients with higher percent fat at baseline demonstrated greater decreases from A0 to A4 than CASM patients. The converse was found from A4 to A12, during which stronger associations were found for CASM than Leap Ahead or CAPS ($P = 0.02$ and $P < 0.001$, respectively).
Physical activity. Physical activity increased significantly across the entire sample between A0 and A4 and between A0 and A12 but not between A4 and A12. This suggests that the gains that occurred during the initial part of the intervention were maintained between A4 and A12. Significant treatment group effects were found at A4–A12 and A0–A12, indicating that CASM and CAPS patients maintained their A0–A4 gains through 12 months, whereas Leap Ahead patients reverted back toward baseline levels during this period. Patients with lower baseline physical activity had the largest increases in physical activity from A0 to A4 and A0 to A12. From A4 to A12, there was a significant group × baseline physical activity interaction: among patients with relatively higher baseline physical activity, there were greater reductions in physical activity for patients in Leap Ahead than in CASM ($P = 0.005$) or CAPS ($P = 0.05$).
Medication adherence. Across the full sample, significant improvements in medication adherence occurred between A4 and A12 and A0 and A12 but not A0 and A4. These findings suggest that improvements in medication adherence occurred primarily in the later segments of the study. There was a significant A0–A12 treatment group effect, indicating that patients in CAPS had more improvement in medication adherence than those in CASM ($P = 0.02$) and Leap Ahead ($P = 0.006$).

Table 1—*Baseline characteristics of participants by intervention group* (N = 392)

	All	Leap Ahead	CASM	CAPS	Sig*
n	392	96	150	146	
Age (years)	56.11 (9.55)	55.23 (10.88)	56.96 (8.78)	55.82 (9.36)	0.34
Female	53.8	59.4	48.0	56.2	0.17
Race					0.64
American Indian/					
Alaska Native	0.8	0	1.3	0.7	
Asian	19.4	18.8	22.0	17.1	
African American	16.6	24.0	11.3	17.1	
Hispanic	11.2	10.4	12.7	10.3	
Pacific Islander	1.8	1.0	1.3	2.7	
White, non-Hispanic	40.1	35.4	41.3	41.8	
Multiple ethnicities	5.9	6.3	4.7	6.8	
Other	4.3	4.2	5.3	3.4	
Education					0.93
High school or less	8.7	10.4	8.0	8.2	
Technical school	30.4	28.1	30.0	32.2	
College	61.0	61.5	62.0	59.6	
Insulin use	17.9	19.8	15.3	19.2	0.59
Years since diagnosis	6.90 (5.93)	7.60 (6.44)	6.89 (6.04)	6.46 (5.46)	0.34
No. of comorbidities/					
complications	3.35 (2.58)	3.55 (2.75)	3.35 (2.62)	3.21 (2.43)	0.61
BMI (kg/m^2)	33.07 (7.78)	33.25 (8.41)	32.13 (7.17)	33.93 (7.90)	0.13

Data are means (SD) or percent unless otherwise indicated. Sig, significance. *One-way ANOVA or χ^2 test, as appropriate.

Patients who were female and who were nonwhite and those with poor baseline medication adherence showed the largest improvements.

HbA$_{1c}$. No significant time or group main effects were found for log-transformed HbA$_{1c}$. However, patients who were older (from A0–A4 and A0–A12), who had fewer comorbidities/complications (from A4–A12 and A0–A12), and who had higher baseline HbA$_{1c}$ (across all time points) showed the greatest HbA$_{1c}$ improvements over time.

CONCLUSIONS—Regarding our first two research questions, we found that DD and the distress specifically associated with diabetes regimen and emotion management are malleable and highly responsive to intervention. The reductions in DD are most apparent when viewing the categorical data. Approximately 33% of patients who reported high DD at baseline and 60% of patients who reported moderate DD at baseline reported little or no DD at 12 months. More specifically, we find that interventions that target enhanced self-management (CASM) reduce DD significantly but that DD-specific interventions (CAPS) may be necessary for patients with initially high levels of RD. RD generates the most distress and displays the greatest distress reduction as a result of intervention. Thus, for those with initially high RD (mean score ≥3), which is a significant portion of the type 2 diabetes population (31.2%) (33), programs that focus on improving disease management alone may be insufficient; a specific focus on RD may be required.

We also find in general that interventions decrease DD, especially RD, the most for patients with initially high DD. Because high DD is significantly correlated with poor disease management, HbA$_{1c}$, and functional deficits (1), patients displaying these characteristics are at greatest risk for high DD.

Interestingly, the effects are not moderated by other patient demographic or diabetes-related variables, suggesting that the findings may generalize to most patients with diabetes. Furthermore, the pace of reduction in RD as a result of intervention appears different for older and younger patients: older patients show significant reductions in the early phases of the intervention, whereas younger patients respond later. This suggests that younger patients, who may be managing more non–disease-related stresses and life problems (34), may require greater

Table 2—Predictors of diabetes distress

| | Descriptive characteristics | | | | | | | | | Model results | | | | | | | | |
| | DDS | | | EB | | | RD | | | DDS | | | EB | | | RD | | |
	Baseline	4 months	12 months	Baseline	4 months	12 months	Baseline	4 months	12 months	0–4 months	4–12 months	0–12 months	0–4 months	4–12 months	0–12 months	0–4 months	4–12 months	0–12 months
All subjects (N = 392)	2.40 (0.89)	2.16 (0.86)	1.98 (0.81)	2.56 (1.18)	2.31 (1.07)	2.11 (1.00)	3.04 (1.19)	2.65 (1.08)	2.34 (1.02)									
Leap Ahead (n = 96)	2.48 (0.95)	2.27 (0.92)	1.98 (0.88)	2.65 (1.17)	2.41 (1.10)	2.19 (1.08)	3.17 (1.30)	2.80 (1.24)	2.36 (1.11)									
CASM (n = 150)	2.37 (0.86)	2.14 (0.86)	2.03 (0.83)	2.52 (1.17)	2.27 (1.07)	2.12 (1.00)	2.99 (1.08)	2.65 (1.06)	2.42 (1.04)									
CAPS (n = 146)	2.38 (0.89)	2.11 (0.82)	1.92 (0.75)	2.53 (1.18)	2.29 (1.05)	2.05 (0.94)	3.02 (1.22)	2.56 (0.98)	2.24 (0.94)									
Time (years)										40.85 (<0.001)	18.43 (<0.001)	110.34 (<0.001)	24.84 (<0.001)	17.21 (<0.001)	79.20 (<0.001)	60.60 (<0.001)	34.00 (<0.001)	139.92 (<0.001)
Group										0.18 (0.84)	1.26 (0.29)	1.53 (0.22)	0.01 (0.99)	0.45 (0.64)	0.33 (0.72)	0.51 (0.60)	1.14 (0.32)	1.53 (0.22)
Group										0.52 (0.60)	0.87 (0.42)	1.20 (0.30)	0.06 (0.94)	0.25 (0.78)	0.45 (0.64)	2.17 (0.12)	0.61 (0.55)	1.50 (0.23)
Sex										1.11 (0.29)	0.28 (0.60)	0.11 (0.74)	2.48 (0.12)	2.31 (0.13)	0.09 (0.77)	0.43 (0.51)	0.00 (0.99)	0.42 (0.52)
Insulin										0.77 (0.38)	0.37 (0.54)	0.02 (0.89)	0.02 (0.89)	0.06 (0.80)	0.15 (0.70)	0.06 (0.81)	0.77 (0.38)	0.51 (0.48)
Ethnicity										0.06 (0.81)	0.87 (0.35)	0.87 (0.35)	2.18 (0.14)	0.09 (0.77)	3.63 (0.06)	0.86 (0.35)	0.55 (0.46)	0.01 (0.96)
Education										0.09 (0.92)	0.84 (0.36)	1.26 (0.26)	0.33 (0.72)	0.42 (0.52)	0.30 (0.56)	0.46 (0.63)	2.91 (0.09)	6.40 (0.01)
Years since diagnosis										0.51 (0.47)	0.28 (0.60)	0.01 (0.91)	0.11 (0.75)	0.15 (0.70)	0.01 (0.98)	0.80 (0.37)	0.00 (0.96)	0.71 (0.40)
Comorbidities/complications										0.61 (0.44)	2.52 (0.11)	1.39 (0.24)	1.85 (0.18)	7.52 (0.006)	3.35 (0.07)	1.40 (0.24)	2.43 (0.12)	0.32 (0.57)
Age										2.37 (0.12)	6.33 (0.01)	2.65 (0.10)	2.65 (0.10)	7.18 (0.008)	1.96 (0.16)	4.07 (0.04)	3.83 (0.05)	0.10 (0.76)
Baseline distress										100.06 (<0.001)	1.08 (0.30)	125.82 (<0.001)	139.59 (<0.001)	0.03 (0.85)	142.40 (<0.001)	145.51 (<0.001)	10.51 (<0.001)	230.30 (<0.001)
Baseline distress × group															4.13 (0.02)			

Data are means (SD) for descriptive characteristics and F (P) for model results.

Table 3—Predictors of behavioral and HbA$_{1c}$ outcomes

Descriptive statistics

	Percent fat			Physical activity			Medication nonadherence*			HbA$_{1c}$		
	Baseline	4 months	12 months	Baseline	4 months	12 months	Baseline	4 months	12 months	Baseline	4 months	12 months
All subjects (N = 392)	31.42 (3.87)	30.75 (2.95)	30.56 (3.34)	1,401.67 (1,112.91)	2,150.44 (1,826.71)	1,955.95 (1,847.31)	1.20 (0.28)	1.20 (0.40)	1.14 (0.21)	1.98 (0.19)	1.98 (0.20)	1.99 (0.19)
Leap Ahead (n = 96)	32.08 (4.21)	31.25 (2.79)	30.78 (3.50)	1,368.61 (1,017.33)	2,249.52 (1,833.55)	1,497.78 (1,515.84)	1.19 (0.27)	1.18 (0.35)	1.17 (0.23)	1.99 (0.20)	1.97 (0.20)	1.98 (0.18)
CASM (n = 150)	31.46 (3.95)	30.70 (3.22)	30.33 (3.19)	1,508.55 (1,203.51)	2,116.56 (1,750.76)	2,164.42 (1,898.73)	1.18 (0.23)	1.19 (0.37)	1.14 (0.20)	1.99 (0.19)	1.99 (0.20)	2.00 (0.20)
CAPS (n = 146)	30.94 (3.50)	30.46 (2.74)	30.64 (3.40)	1,313.60 (1,073.80)	2,120.10 (1,907.11)	2,043.20 (1,949.47)	1.23 (0.32)	1.23 (0.46)	1.13 (0.19)	1.97 (0.19)	1.97 (0.20)	1.98 (0.18)

Model results

	Percent fat			Physical activity			Medication nonadherence*			HbA$_{1c}$		
	0–4 months	4–12 months	0–12 months	0–4 months	4–12 months	0–12 months	0–4 months	4–12 months	0–12 months	0–4 months	4–12 months	0–12 months
Time	17.86 (<0.001)	0.72 (0.40)	10.98 (<0.001)	73.90 (<0.001)	2.82 (0.09)	38.63 (<0.001)	0.01 (0.95)	9.39 (0.002)	21.62 (<0.001)	0.45 (0.50)	1.11 (0.29)	0.16 (0.69)
Group	0.42 (0.66)	0.84 (0.44)	1.40 (0.25)	0.86 (0.42)	3.92 (0.02)	3.80 (0.02)	0.17 (0.84)	2.15 (0.12)	4.55 (0.01)	0.96 (0.38)	0.02 (0.98)	0.67 (0.51)
Group	8.50 (<0.001)	6.30 (0.002)	0.45 (0.64)	0.67 (0.51)	0.22 (0.81)	3.93 (0.02)	0.07 (0.93)	1.19 (0.31)	2.77 (0.06)	1.61 (0.20)	0.05 (0.95)	1.20 (0.30)
Sex	0.26 (0.61)	0.12 (0.73)	0.51 (0.47)	2.60 (0.11)	2.91 (0.09)	0.01 (0.94)	4.57 (0.03)	6.84 (0.01)	2.32 (0.13)	13.49 (<0.001)	5.69 (0.02)	1.80 (0.18)
Insulin	5.92 (0.02)	3.35 (0.07)	0.23 (0.63)	0.77 (0.38)	0.80 (0.37)	0.01 (0.98)	0.01 (0.93)	0.82 (0.37)	2.80 (0.10)	0.49 (0.48)	1.64 (0.20)	0.31 (0.58)
Ethnicity	0.47 (0.49)	0.66 (0.42)	2.49 (0.12)	0.11 (0.74)	0.07 (0.79)	0.01 (0.93)	3.58 (0.06)	0.17 (0.68)	5.88 (0.02)	0.03 (0.86)	0.17 (0.68)	0.10 (0.75)
Education	1.27 (0.28)	3.50 (0.06)	1.39 (0.24)	0.78 (0.46)	0.02 (0.88)	0.11 (0.74)	0.25 (0.78)	0.25 (0.62)	1.03 (0.31)	4.29 (0.01)	0.07 (0.79)	3.21 (0.07)
Years since diagnosis	0.26 (0.61)	0.13 (0.72)	0.61 (0.44)	2.51 (0.11)	0.68 (0.41)	0.04 (0.84)	1.85 (0.18)	2.98 (0.09)	1.26 (0.26)	0.04 (0.83)	0.88 (0.35)	0.33 (0.57)
Comorbidities/ complications	0.24 (0.62)	1.63 (0.20)	1.23 (0.27)	2.94 (0.09)	0.44 (0.51)	0.60 (0.44)	5.76 (0.02)	2.30 (0.13)	1.35 (0.25)	0.58 (0.47)	3.76 (0.05)	6.95 (0.009)
Age	1.51 (0.22)	4.80 (0.03)	13.22 (<0.001)	0.96 (0.33)	0.62 (0.43)	0.01 (0.94)	2.34 (0.13)	0.56 (0.45)	1.05 (0.31)	3.99 (0.05)	0.33 (0.57)	7.52 (0.006)
Baseline of outcome	321.87 (<0.001)	72.97 (<0.001)	537.04 (<0.001)	18.43 (<0.001)	1.55 (0.22)	22.43 (<0.001)	2.26 (0.13)	69.49 (<0.001)	351.02 (<0.001)	29.21 (<0.001)	9.98 (0.002)	67.50 (<0.001)
Baseline of outcome × group	8.29 (<0.001)	6.62 (<0.001)			4.22 (0.02)							

Data are means (SD) for descriptive characteristics and F (P) for model results. Treatment group effects are interpreted in models that include group as a single predictor. Group should not be interpreted, however, in models that include a significant group interaction because the higher-order interaction supersedes a main effect. *HbA$_{1c}$ was natural log transformed for analysis.

exposure to distress-reduction programs over time than older patients. Last, we find that reductions in DD are maintained over time. Unlike many behavioral programs, in which return to baseline levels over time is common (35), reductions in DD can be sustained even with limited patient contact.

Where between-group differences emerged, those in CAPS displayed the greatest gains. Although several studies show that improved disease management is accompanied by reduced DD (10,36,37), younger patients, those with many comorbidities and complications, those with poorer initial functioning, and those having less education may require direct DD assistance. The cumulative effects of multiple stressors, life demands, and functional deficits may place substantive ongoing burdens on patients that reduce internal resources and require more distress-focused attention in clinical care (1).

Reductions in DD were accompanied by significant improvements in healthy eating, physical activity, and medication adherence, although not by change in HbA_{1c}, a more distal and nontargeted outcome. Thus, even highly distressed, nondepressed patients with type 2 diabetes respond to disease-management interventions. Interestingly, consistent with other studies (38), improvements in healthy eating and physical activity occur early in the intervention for CASM and CAPS patients and are maintained subsequently without returning to baseline levels, whereas gains in medication adherence occur later in the intervention. Although these findings bear replication, among DD patients it may take longer for the behavioral contingencies that support medication taking to emerge than for diet and exercise. Furthermore, those in CAPS displayed significantly greater improvements in medication adherence than those in the other two groups, underscoring the important contribution of distress-focused interventions for highly distressed patients.

A somewhat surprising finding is that significant reductions in DDS, RD, and EB occur without a significant overall treatment group main effect, suggesting that the pattern of change in DD over time for all three groups is similar. This finding provides evidence that Leap Ahead, a minimal general health and diabetes education intervention (18), is for many patients as effective in reducing distress as CASM and CAPS. Taking about the same time as CASM and CAPS, Leap Ahead did not require, suggest, or encourage patients to change behavior; its goal was only to provide attention and modest health-related information delivery. Excluding initially highly distressed patients, for whom more distressed–focused interventions may be necessary, these findings suggest that most distressed patients are highly responsive to clinical staff attention, concern, and support both with and without the structure of formal programs to change behavior or enhance DD-related problem solving. Reducing distress, therefore, may have less to do with providing patients with programs of action and behavioral change and more to do with health care professionals listening to, understanding, acknowledging, and normalizing DD so that patients' internal resources can become freer of internal distress–related constraints (1,14,15,39). Thus, programs to reduce DD may be relatively easy to implement and disseminate and require less skilled staff to administer, thus lowering potential costs.

This study had several strengths: a randomized comparative design; a validated, pragmatic, and low-cost Web-based intervention; delivery by nonprofessional staff; high program representativeness and reach (40); and use of a large community sample. Attrition from baseline to 12 months in a highly distressed sample was moderate (18%), was not differential among groups, and did not affect outcomes. Several issues, however, may reduce the impact of the results. First, the study design was additive, comparing CASM to CASM plus PST. We did not test the impact of PST alone (7). It may be that focused interventions to reduce DD may be most efficacious for many patients. We also did not include a usual care arm. Thus, we could not test the effect of attention alone. Finally, inclusion criteria did not include an HbA_{1C} cut point. Mean baseline HbA_{1c} was low (7.4%), making improvement as a result of intervention relatively difficult to demonstrate.

In conclusion, DD is highly prevalent among patients with type 2 diabetes and is linked with poor disease management and glycemic control, independent of clinical depression. This investigation showed that DD is highly responsive to intervention and that although interventions that improve self-management can also reduce distress, distress-specific interventions need to be delivered for patients with initially high levels of DD. Greater attention to DD within the context of self-management improvement programs and general clinical care is warranted.

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