Reductions in Regimen Distress Are Associated With Improved Management and Glycemic Control Over Time

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OBJECTIVE

Cross-sectional and longitudinal associations among regimen distress (RD), self-management, and glycemic control were undertaken to explore mechanisms of operation among these variables.

RESEARCH DESIGN AND METHODS

In a behavioral randomized control trial (RCT) to reduce RD, 392 adults with type 2 diabetes were assessed for RD, diet, exercise, medication adherence, and HbA_{1c} at baseline and at 4 and 12 months. Associations among RD, self-management, and HbA_{1c} were examined in cross-sectional analyses at baseline, in prospective analyses using baseline values to predict change over time, and in time-varying analyses.

RESULTS

At baseline, greater RD and poorer medication adherence were independently associated with higher HbA_{1c} ($P = 0.05$ and $P < 0.001$, respectively), and greater RD was associated with poorer medication adherence ($P = 0.03$). No consistent pattern of significant prospective associations was found. Significant time-varying findings showed that decreases in RD were associated with improvements in medication adherence ($P < 0.01$), physical activity ($P < 0.001$), and HbA_{1c} ($P = 0.02$) over time following intervention. Changes in self-management were not associated with changes in HbA_{1c} over time.

CONCLUSIONS

In the context of an RCT to reduce distress, RD, self-management, and HbA_{1c} were interrelated in cross-sectional and time-varying analyses. Decreases in RD were associated with improvements in both self-management and HbA_{1c} over 12 months. Findings point to the complex and likely multifaceted pathways of association among these key constructs, with results indicating significant linkages between RD and both self-management and glycemic control over time.

Diabetes distress refers to the often hidden emotional burdens, stresses, and worries that are part of managing diabetes (1). Regimen distress (RD) is a critical area of diabetes distress that focuses on daily disease management and is significantly associated with poorer diabetes outcomes, even after controlling for clinical depression (2–4). Although RD, self-management behavior, and glycemic control are core constructs central to the treatment of type 2 diabetes, the mechanisms underlying their interrelationships over time are not well understood. Cross-sectional studies have shown that high diabetes distress is associated with poor glycemic control and poor behavioral self-management (e.g., healthy diet, physical activity, medication adherence) (2–6), and to a lesser extent, poor self-management is associated with poor glycemic control (7,8). However, although critically important (9), little longitudinal research is available, severely restricting the identification of the causal and interactive mechanisms to explain these findings. Thus, how these constructs are causatively linked or how a potential third variable might be involved remain unclear. For example, it may be that RD interferes with behavioral management, which in turn affects glycemic control (10); that RD affects glycemic control directly through physiological mechanisms (11,12); or that poor glycemic control leads to low motivation for making behavioral lifestyle changes, which in turn increases RD. There is also some evidence that these constructs may influence one another bidirectionally and iteratively over time (3,13,14).

Randomized controlled trials (RCTs) provide a useful setting in which to study potential mechanisms among or between key constructs over time because the interventions themselves are developed to enhance change and to make the interactive patterns of change among the variables more visible. This approach stands in contrast to static, cross-sectional comparisons. Furthermore, RCTs enable an examination of individual subject change over time rather than focus exclusively on average differences between groups of patients over time.

Within the context of a 12-month RCT aimed at reducing diabetes distress, the current article explores potential linkages among RD, disease management, and glycemic control, making use of the following group- and patient-level changes over time: traditional group-level baseline cross-sectional comparisons, group-level prospective analyses in which baseline levels of one construct are used to predict change in another over time; and patient-level time-varying analyses in which change in one construct over time is associated with change in another over time. To explore potential mechanisms of interaction among the variables of interest, we hypothesized that *1*) concurrent associations will occur among high RD, high HbA_{1c}, and poor behavioral management; *2*) low distress at baseline will predict greater decreases in HbA_{1c} and increases in behavioral management over time; and *3*) decreases in RD will be associated with decreases in HbA_{1c} and increases in behavioral management over time. Addressing these questions will further our understanding of potential mechanisms of action among RD, self-management behavior, and glycemic control.

RESEARCH DESIGN AND METHODS
Subjects
Patients with type 2 diabetes were recruited from the patient registries of several community medical groups and diabetes education centers. The primary inclusion criterion was a mean score of ≥ 1.5 on the two-item Diabetes Distress Screener (15) (confirmed later by the full scale). Response options for the two items ranged from 1 (not a problem) to 6 (very serious problem), with a response of 2 defined as a little problem, thus including individuals with at least a modest level of diabetes distress (16). Additional inclusion criteria were a registry-recorded diagnosis of type 2 diabetes ≥ 12 months, age ≥ 21 years, ability to read and speak English, at least moderate computer use facility, easy availability of a computer with Internet access, and self-reported problems with adherence to diabetes management (healthy eating or exercise plan not followed for 3 of 4 days during the previous week or medications not taken ≥ 2 days during the previous week) based on the Summary of Diabetes Self-Care Activities (17). Exclusion criteria included clinical depression [Patient Health Questionnaire 8 score ≥ 15 (18)] and severe diabetes complications or functional deficits (e.g., dialysis, blindness). Thus, the sample included patients who had at least modest RD and some behavioral management difficulties so that change in one or more of these variables could be observed over time.

Procedures
A description of the study protocol and the intervention program have been previously published (19). Patients received a letter from their health-care facility informing them of the Reducing Distress and Enhancing Effective Management (REDEEM) study. During a subsequent call, the project was explained and patients were screened, and eligible patients were invited to a meeting where eligibility requirements were confirmed, informed consent was obtained, and a 1.5-h baseline assessment was completed. The assessment included height and weight, questionnaires, a brief interview, and visit to a community laboratory for collection of biological data. Patients were then randomized to one of the three interventions by a computer-generated algorithm, and an intervention visit was scheduled. In keeping with a pragmatic design and comparative effectiveness research (20), no usual care condition was included because of concerns about maintaining distressed patients in a noninterventional study arm. The interventions were *1*) Computer-Assisted Self-Management (CASM), which featured a 40-min, previously validated, web-based, diabetes self-management improvement program (21,22); *2*) CASM plus problem-solving therapy (CAPS) (23,24); and *3*) a minimal intervention that featured a 20-min, computer-delivered health risk appraisal and diabetes information (Leap Ahead) (25). In all conditions, patients received a live supplemental booster session at month 5, which included a repeated health risk appraisal for Leap Ahead patients and an automated program to reduce negative behavioral practices for patients in CASM and CAPS. Patients in all

conditions also received the same sequence of eight 15-min live phone calls (at weeks 2, 4, 7, 12, 24, 28, 36, and 44) to check progress and provide encouragement. Assessments were repeated at 4 and 12 months postintervention. 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, sex, ethnicity (dichotomized as white and nonwhite), and education (trichotomized as less than college, technical school, and college). Diabetes status included use of insulin (yes/no), years since diagnosis, and total number of comorbidities (e.g., asthma, rheumatoid arthritis) and complications (e.g., kidney problems, stroke).

RD was assessed by the five-item RD subscale ($\alpha = 0.90$) (16) from the Diabetes Distress Scale (16). RD was selected because it has the highest prevalence (19) and was directly targeted by the interventions. RD items were rated on a 6-point scale from 1 (not a problem) to 6 (very serious problem). Physical activity was assessed by the CHAMPS (Community Healthy Activities Model Program for Seniors) instrument (26,27), which measures weekly caloric expenditure of light, moderate, and heavy physical activity by assessing the frequency of engaging in various forms of physical activity. Only the light physical activity composite scale (eight items, e.g., walking, gardening, housework) was used in the present analyses because of its appropriateness for a primarily older age-group and because light physical activity was the area of focus targeted by the interventions. Healthy eating was assessed by the National Cancer Institute Percent Energy From Fat Screener (28), a validated instrument that estimates percent energy (calories) from fat based on the consumption of 14 foods (e.g., margarine or butter, rice, cheese) that is sensitive to change. Medication nonadherence was assessed by the eight-item Hill-Bone Compliance Scale ($\alpha = 0.80$) (29), which assesses how often and why respondents miss taking medications as rated on a 4-point scale from none of the time to all of the time. This scale yields a single nonadherence index score. Glycemic control was assessed by HbA_{1c}, which was analyzed in a central laboratory for all participants.

Data Analysis

Descriptive statistics were computed to review score distributions. Missing data were imputed with multiple imputation procedures using NORM version 2 software (30). NORM imputes data through the expectation-maximization algorithm, which provides an efficient estimation of means, variances, and covariances, and uses a data augmentation procedure that generates multiple imputations of missing values.

One-way ANOVA and χ^2 tests, as appropriate, were conducted to test for baseline differences across the three treatment conditions and to examine potential differences in outcomes between dropouts and continuing participants. For all cross-sectional, prospective, and time-varying analyses, sex, age, insulin use, ethnicity (white vs. other), education (three levels), years since diabetes diagnosis, and number of comorbidities and complications were included as covariates. Intervention group was also included as a covariate in all analyses. Continuous variables were grand mean centered to facilitate interpretation of results.

Baseline Cross-sectional Models
A multivariable linear regression model was specified for each outcome: HbA_{1c}, RD, medication nonadherence, diet, and physical activity. Predictors included intervention group, sociodemographic variables, and baseline values of the other four outcomes. Additional models were conducted to examine whether results differed when each outcome was predicted by baseline level of only one other outcome at a time.

Prospective Models
These analyses examined whether change over time was associated with baseline values of key variables. The outcome variables were change from baseline within each individual using five random-intercept general linear mixed models, one for each outcome. Predictors included time code (0 at baseline, 0.33 at 4 months, and 1.00 at 12 months), each individual's personal mean across three time points to adjust for between-person differences in the outcome, intervention group, sociodemographic variables, and baseline values of the other four outcomes. Additional random-intercept mixed models examined whether results differed when each change-scored outcome was predicted by the baseline level of only one other outcome at a time.

Time-Varying Covariate Models
Five random-intercept linear mixed models were specified to determine whether change from baseline in each outcome was associated with change from baseline among the other outcomes, using approaches that completely partition between- and within-participant effects (31,32). Additional analyses examined whether results differed when each outcome was predicted by change in only one other outcome at a time. Statistical analyses were performed with SPSS version 19.0 (IBM Corporation, Chicago, IL).

RESULTS

Preliminary Analyses
Of 2,606 patients identified from registries who could be contacted, 658 were eligible, and 436 agreed to participate (66.6%). Problems with time and conflicting life demands were the most frequent reasons for nonparticipation. Of these, 392 (89.5%) completed baseline assessment and intervention, with 150 randomized to 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. According to telephone screening data, there were no significant differences between those who participated and those who refused on the basis of sex, age, ethnicity, education level, and years since diagnosis.

Attrition was 13.8% from baseline to 4 months, 5.7% from 4 to 12 months, and 18.7% from baseline to 12 months. Only 8.4% of patients missed both 4- and 12-month assessments. There were no

significant between-group differences in attrition across either time period on any key study variable. There were no significant baseline differences among the three study groups on any key demographic or diabetes status variable (Table 1) or differences on key variables based on recruitment source (community group vs. diabetes education center). The diverse sample had a mean age of 56 (SD 9.6) years, 53.8% of the sample was female, 8.7% of patients had $\leq$ 12 years of education, and mean baseline HbA_{1c} was 7.4% (1.6%) [57.0 (17.6) mmol/mol].

Cross-sectional Analyses
In models that included all the primary predictors at baseline, both higher RD and poorer medication adherence were associated with higher HbA_{1c}, and higher RD was associated with poorer medication adherence (Table 2). Age and comorbidities/complications were the only background characteristics consistently related to the outcomes. Younger patients reported higher RD, HbA_{1c}, and medication nonadherence.

Patients with more comorbidities/complications had higher RD, higher medication nonadherence, and higher fat diets. These patients also reported greater physical activity. The same pattern was found when each of the four key predictors was entered in separate models, indicating that these associations were independent of one another. Thus, we found significant baseline cross-sectional associations among RD, medication nonadherence, and HbA_{1c}.

Prospective Analyses
Significant improvements over time were found among RD, medication nonadherence, physical activity, and dietary fat intake. Although the average change in HbA_{1c} over time was not significantly different from zero for the sample as a whole, there was significant variation in change in HbA_{1c} over time, with some patients showing significant increases and others significant decreases. There were only two models in which the baseline value of a construct predicted change in an outcome over

time: Higher baseline RD and higher medication nonadherence significantly predicted greater improvement in physical activity over time (Table 3). Male patients, those with fewer comorbidities/complications, and those with less education had larger decreases in HbA_{1c} over time. Men showed less improvement in physical activity, and younger patients demonstrated greater decreases in medication nonadherence but less improvement in dietary fat intake. The same results were observed in models that included only one of the primary predictors at a time. Thus, few significant prospective associations occurred in which the baseline level of one core construct predicted change over time in another.

Time-Varying Analyses
Decreases in RD over time were significantly associated with decreases in HbA_{1c} (Table 4). None of the changes among the three self-management variables were associated with changes in HbA_{1c} over time. Reductions in RD over time were significantly related to

Table 1—Baseline characteristics of participants by intervention group

Characteristic or variable	All (n = 392)	Leap Ahead (n = 96)	CASM (n = 150)	CAPS (n = 146)	P value[1]
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
Number 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
RD	3.04 (1.19)	3.17 (1.30)	2.99 (1.08)	3.02 (1.22)	0.50
Energy from fat (%)	31.42 (3.87)	32.08 (4.21)	31.46 (3.95)	30.94 (3.50)	0.08
Calories/week expenditure, light PA	1,402 (1,113)	1,367 (1,017)	1,509 (1,204)	1,314 (1,074)	0.31
Medication nonadherence	1.20 (0.28)	1.19 (0.27)	1.18 (0.23)	1.23 (0.32)	0.18
HbA_{1c} (%)	7.41 (1.61)	7.45 (1.71)	7.45 (1.53)	7.34 (1.62)	0.81

Data are mean (SD) or %. PA, physical activity. [1]One-way ANOVA or χ^2 test, as appropriate.

decreases in medication nonadherence, and improvements in physical activity were marginally associated with decreases in medication nonadherence. Likewise, reductions in RD were significantly associated with increases in physical activity, and there was a marginal association between decreases in medication nonadherence and improvements in physical activity. None of the time-varying variables were associated with change in fat intake over time. The same pattern of results was found in models that included only one time-varying predictor at a time. Thus, two sets of significant time-varying associations were found: Improvement in RD was associated with improvement in self-management over time (i.e., medication adherence, physical activity), and improvement in RD but not self-management was associated with decreases in HbA$_{1c}$.

CONCLUSIONS

We examined cross-sectional, prospective, and time-varying associations among RD, self-management behavior, and glycemic control in a sample of adults with type 2 diabetes within the context of an RCT aimed at reducing distress. In line with previous reports (5,6,8), we found significant cross-sectional associations among RD, medication nonadherence, and HbA$_{1c}$: Higher RD was associated with higher medication nonadherence and higher HbA$_{1c}$. We found no consistent support for prospective longitudinal relationships among any of the key constructs: Baseline levels of RD, self-management behaviors, and HbA$_{1c}$ did not predict change among the key constructs over time. Finally, in line with previous findings (3,13,14), consistent and significant time-varying associations were found: After controlling for demographics, disease status, and intervention group, decreases in RD over time were significantly associated with improvements in self-management (physical activity, medication adherence) and reductions in HbA$_{1c}$. Changes in self-management, however, were not significantly associated with changes in HbA$_{1c}$. Thus, not only was the intervention successful in reducing distress but also the reductions in

distress were significantly associated with improved disease management and improved glycemic control.

The significant time-varying relationships between RD with disease management and glycemic control within a sample of adults with type 2 diabetes exposed to a distress intervention suggests that disease-related distress may have important consequences for management in clinical settings. Distress appears to be malleable, even with modest intervention, if it is addressed regularly and directly (19). Thus, including an affective component within diabetes education and regular clinical assessment can lead to improved clinical outcomes (1). Furthermore, the relationships reported here were found in a sample of patients without clinical depression, which may help patients and clinicians to view distress as part of the spectrum of diabetes, distinct from a diagnosed mood disorder.

The absence of significant time-varying associations between change in self-management behaviors and change in HbA$_{1c}$ is worth noting. Two explanations may be relevant. First, a link between co-occurring changes in behavior and HbA$_{1c}$ may have occurred if the sample had contained a wider range of initial HbA$_{1c}$ values. Mean baseline HbA$_{1c}$ was only 7.4%, making significant reductions as a function of an intervention difficult to achieve. Second, the assessment of diet, physical activity, and medication nonadherence may not have been sufficiently comprehensive or sensitive to document relevant change.

The multiple linkages found among RD, disease management behavior, and glycemic control over time as a result of intervention suggest that a search for a single mechanism or causative pathway that explains all the observed dynamic relationships may not be realistic. It is most likely the case that multiple factors and pathways link these variables to one another. These may include biological (e.g., hypothalamic-pituitary-adrenal axis), behavioral (e.g., medication nonadherence), and affective (e.g., burden of management) mechanisms (12). Moreover, other findings suggest

Table 2—Baseline cross-sectional associations

Baseline	RD B (SE)	RD P value	Medication nonadherence B (SE)	Medication nonadherence P value	Diet B (SE)	Diet P value	Physical activity B (SE)	Physical activity P value	HbA$_{1c}$ B (SE)	HbA$_{1c}$ P value
RD			0.02 (0.01)	0.03	−0.11 (0.18)	0.53	−27.95 (50.51)	0.58	0.13 (0.07)	0.05
Medication nonadherence	0.50 (0.23)	0.03			1.16 (0.79)	0.14	−433.53 (224.69)	0.06	1.20 (0.31)	<0.001
Diet	−0.009 (0.01)	0.53	0.004 (0.003)	0.14			4.17 (14.65)	0.78	−0.006 (0.02)	0.74
Physical activity	−0.00003 (0.00005)	0.58	−0.00002 (0.00001)	0.06	0.00005 (0.0001)	0.78			0.00008 (0.00007)	0.24
HbA$_{1c}$	0.07 (0.04)	0.05	−0.03 (0.008)	<0.001	−0.04 (0.13)	0.74	43.74 (37.25)	0.24		

All models controlled for the following variables: group (Leap Ahead, CASM, CAPS), sex, insulin, ethnicity, education level, years since diagnosis, number of comorbidities/complications, and age.

Table 3—Baseline predictors of change in outcomes over time

Baseline	RD B (SE)	P value	Medication nonadherence B (SE)	P value	Diet B (SE)	P value	Physical activity B (SE)	P value	HbA$_{1c}$ B (SE)	P value
Time	−0.67 (0.05)	<0.001	−0.06 (0.02)	<0.001	−0.08 (0.02)	<0.001	0.45 (0.15)	0.003	0.01 (0.05)	0.82
RD			−0.01 (0.01)	0.22	0.01 (0.01)	0.48	0.20 (0.07)	0.005	−0.04 (0.03)	0.16
Medication nonadherence	−0.17 (0.13)	0.18			−0.01 (0.05)	0.76	0.60 (0.32)	0.06	−0.01 (0.12)	0.95
Diet	−0.08 (0.08)	0.31	−0.02 (0.02)	0.17			0.06 (0.21)	0.78	−0.11 (0.08)	0.17
Physical activity	−0.002 (0.01)	0.90	0.001 (0.003)	0.73	−0.01 (0.01)	0.14			−0.01 (0.01)	0.45
HbA$_{1c}$	−0.002 (0.02)	0.93	−0.005 (0.005)	0.31	0.01 (0.01)	0.06	−01 (0.05)	0.86		

All models controlled for the following variables: group (Leap Ahead, CASM, CAPS), sex, insulin, ethnicity, education level, years since diagnosis, number of comorbidities/complications, and age.

that the impact of change in one variable on another over time is complex and most likely reciprocal and iterative. This process is most likely not uniform across individuals and may vary as a function of both stage in the disease process (33,34) and other contextual factors (e.g., age, sex, disease burden, comorbidities) (35). Thus, it may make little sense to search for a simple, causative magic bullet that accounts for all these complex relationships; instead, consistent with precision medicine approaches, it may make better sense to seek multiple causative pathways that operate differently among different patient groups. This strategy may increase complexity but have a greater chance of identifying causal mechanisms.

Several options should be considered. These include the use of more-frequent longitudinal assessments (e.g., daily or weekly assessment) to tease out the direction and pace of influence for different patient groups. For example, in a 21-day diary study, negative affect was associated with next-day fasting glucose, whereas fasting glucose failed to predict next-day negative affect, suggesting a unidirectional linkage (35). Another option is to stimulate change in one variable and observe changes in the others. For example, studies have shown that the emotional distress that frequently accompanies class III obesity subsides dramatically after bariatric surgery, even before significant weight loss and HbA$_{1c}$ change occur (36). This differential timing and rate of change among the relevant variables over time suggest the operation of a potential third variable. Similarly, it may be helpful to observe whether changes in biological variables (e.g., hypothalamic-pituitary-adrenal axis) occur at the same rate and within the same time period as changes in affect or behavior. Finally, variations in personal behavioral styles and traits may moderate many of these processes. For example, considerable data on conscientiousness, neuroticism, positive affect, and other trait-like variables have been shown to influence disease management, distress, and health outcomes (37,38) and may attenuate or intensify hypothesized relationships among these variables over time. Thus, when exploring potential causal mechanisms, it may be helpful to explore alternative methods that stimulate change and to consider the contributions of biological, behavioral, affective, and other variables that provide the context in which these mechanisms operate.

This study has several strengths, including a relatively large community sample, use of validated measures, 12-month longitudinal data with modest attrition, and replication of earlier findings with a different patient sample. Several limitations should be kept in mind. First, although validated measures were used to assess behavioral self-management, the study could have been strengthened by the use of a more comprehensive battery of behavioral measures. Second, because level of HbA$_{1c}$ was not an eligibility criterion, the mean baseline

Table 4—Time-varying predictors of change in outcomes over time

	RD B (SE)	P value	Medication nonadherence B (SE)	P value	Diet B (SE)	P value	Physical activity B (SE)	P value	HbA$_{1c}$ B (SE)	P value
Time	−0.62 (0.05)	<0.001	−0.04 (0.02)	0.02	−0.06 (0.02)	0.01	0.15 (0.17)	0.35	0.08 (0.06)	0.19
RD			0.03 (0.01)	0.006	0.02 (0.01)	0.18	−0.35 (0.10)	<0.001	0.08 (0.03)	0.02
Medication nonadherence	0.33 (0.12)	0.006			0.03 (0.05)	0.60	−0.65 (0.34)	0.06	0.15 (0.12)	0.21
Diet	0.21 (0.98)	0.18	0.01 (0.03)	0.60			−0.25 (0.25)	0.32	−0.25 (0.13)	0.52
Physical activity	−0.04 (0.01)	<0.001	−0.01 (0.004)	0.06	−0.01 (0.01)	0.32			−0.003 (0.01)	0.83
HbA$_{1c}$	0.09 (0.04)	0.02	0.01 (0.01)	0.21	−0.01 (0.01)	0.52	−02 (0.10)	0.83		

All models controlled for the following variables: group (Leap Ahead, CASM, CAPS), sex, insulin, ethnicity, education level, years since diagnosis, number of comorbidities/complications, and age.

level was relatively low (7.4%), thus limiting potential group change over time. Third, the study sample was relatively well educated and had computer access. Both the study eligibility criteria and the larger study context, an RCT aimed at reducing distress, may limit the generalizability of the findings.

With the use of both cross-sectional and longitudinal analyses, this study provides additional evidence for a relationship among RD, behavioral self-management, and glycemic control. Multiple explanatory pathways are likely among these variables, including biological, behavioral, and affective mechanisms. The findings suggest that improvements in management and HbA$_{1c}$ co-occur with improvements with RD. The findings underscore the importance of addressing RD in clinical care as a routine part of diabetes management.

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