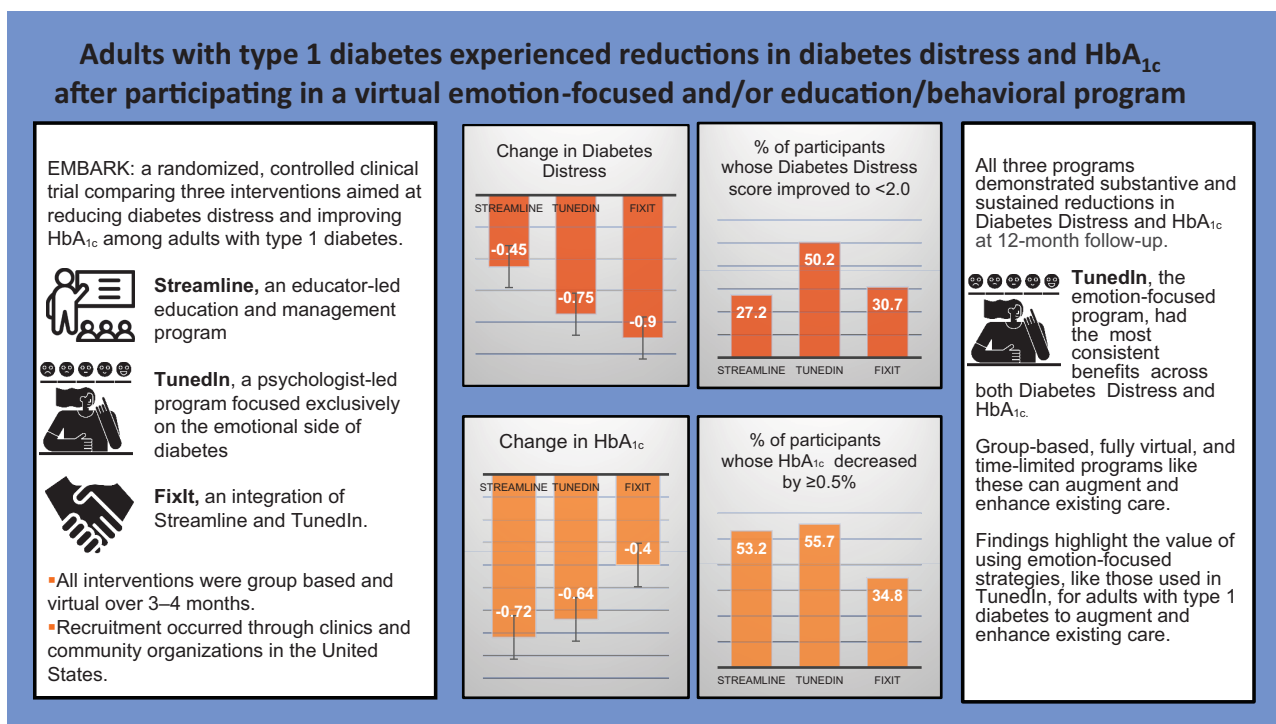


EMBARC: A Randomized, Controlled Trial Comparing Three Approaches to Reducing Diabetes Distress and Improving HbA_{1c} in Adults With Type 1 Diabetes

Danielle M. Hessler, Lawrence Fisher, Susan Guzman, Lisa Strycker, William H. Polonsky, Andrew Ahmann, Grazia Aleppo, Nicholas B. Argento, Joseph Henske, Sarah Kim, Elizabeth Stephens, Katherine Greenberg, and Umesh Masharani

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ARTICLE HIGHLIGHTS

- **Why did we undertake this study?**
To compare three approaches to reduce diabetes distress (DD) and improve HbA_{1c} among adults with type 1 diabetes.
- **What is the specific question we wanted to answer?**
Whether a virtual, group-based emotion-focused, educational/behavioral, or combination program resulted in the largest reductions in DD and HbA_{1c}.
- **What did we find?**
All three interventions were linked with clinically meaningful improvements in DD and HbA_{1c}; the emotion-focused program had the most consistent benefits.
- **What are the implications of our findings?**
The results suggest group-based and fully virtual programs are effective and there is value in the emotion-focused strategies used in TunedIn to enhance care for adults with type 1 diabetes.



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OBJECTIVE

To compare the effectiveness of three interventions to reduce diabetes distress (DD) and improve HbA_{1c} among adults with type 1 diabetes (T1D).

RESEARCH DESIGN AND METHODS

Individuals with T1D ($n = 276$) with elevated DD (a score >2 on the total Type 1 Diabetes Distress Scale) and HbA_{1c} ($>7.5\%$) were recruited from multiple settings and randomly assigned to one of three virtual group-based programs: 1) Streamline, an educator-led education and diabetes self-management program; 2) TunedIn, a psychologist-led program focused exclusively on emotional-focused DD reduction; or 3) FixIt, an integration of Streamline and TunedIn. Assessments of the primary outcomes of DD and HbA_{1c} occurred at baseline and at 3, 6, and 12 months.

RESULTS

All three programs demonstrated substantive and sustained reductions in DD (Cohen's $d = 0.58$ – 1.14) and HbA_{1c} (range, -0.4 to -0.72) at 12-month follow-up. TunedIn and FixIt participants reported significantly greater DD reductions compared with Streamline participants ($P = 0.007$). Streamline and TunedIn participants achieved significantly greater HbA_{1c} reductions than did FixIt participants ($P = 0.006$).

CONCLUSIONS

DD can be successfully reduced among individuals with T1D with elevated HbA_{1c} using both the educational/behavioral and emotion-focused approaches included in the study. Although both approaches are associated with significant and clinically meaningful reductions in DD and HbA_{1c}, TunedIn, the emotion-focused program, had the most consistent benefits across both DD and HbA_{1c}. The study findings suggest the overall value of group-based, fully virtual, and time-limited emotion-focused strategies, like those used in TunedIn, for adults with T1D.

Diabetes distress (DD) refers to the fears, worries, and burdens associated with living with and managing diabetes (1). Among adults with type 1 diabetes (T1D), elevated DD is highly prevalent (42–77%) (1–3). It is distinct from clinical depression (4), tends

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to be chronic rather than episodic (5,6), and has been significantly linked cross-sectionally and longitudinally with poor self-management (e.g., missed medication taking) and suboptimal glycemic outcomes (e.g., HbA_{1c}) (7–10). Thus, there is growing evidence of associative and causative linkages among DD, behavioral self-management, and glycemic outcomes, making DD an important clinical problem.

Systematic reviews of DD intervention studies have reported significant reductions in DD relative to controls, and parallel reductions in HbA_{1c} across these studies were significant but modest (11–13). Sturt et al. (12) and Schmidt et al. (13) concluded that DD is malleable and responsive to a range of intervention strategies, with the strongest effects resulting from those targeting the emotional side of diabetes directly, rather than focusing exclusively on disease management or education.

Three overriding intervention strategies underlie current DD reduction research. First, a diabetes education and management approach focuses on fostering self-management change. This strategy assumes that as people engage more effectively with their management, they will become less distressed. Second, an emotional approach suggests that the key to improving glycemic outcomes is to directly address the feelings, beliefs, and expectations that underlie DD and serve as barriers to management change (14–16). This strategy, supported by both emotion regulation theory and the Broaden-and-Build and Dynamic Models of Affect (17,18), suggests that, because of poor emotion regulation, DD acts as a brake on the application of existing diabetes knowledge and skills, and on one's ability to profit from new educational and behavioral interventions. By releasing the DD brake through emotion-focused intervention, the negative cycle can be efficiently ended. Third, an integrated approach suggests that combining an education and management approach with a DD emotion-centered approach capitalizes on the strengths of each, leading to a more effective and efficient strategy for reducing DD and improving glycemic management.

The T1-REDEEM (Reducing Distress and Enhancing Effective Management for T1D Adults) study provided a partial comparison among these strategies (19). It demonstrated that both a broadly based education-focused program and a general

emotion-focused program led to significant decreases in DD along with modest improvements in HbA_{1c} for adults with T1D. In support of DD serving as a brake, reduced DD was linked with improved management, which, in turn, was associated with lower HbA_{1c} (7). The emotion-focused program produced greater DD benefits for individuals with initially higher DD and poorer cognitive or emotion regulation skills than did the education-focused program, suggesting that different intervention strategies may be helpful for different individuals.

To date, however, to our knowledge, no study has directly compared the relative effectiveness of these three different approaches for reducing both DD and HbA_{1c} among adults with T1D. The EMBARK (Behavioral Approaches to Reducing Diabetes Distress and Improving Glycemic Control) study was designed as a 12-month randomized, controlled intervention trial for adults with T1D to fill this gap. It directly compared the impact of three highly focused interventions targeting clinically meaningful reductions in both DD and HbA_{1c} among adults with T1D: Streamline, a highly structured, focused, diabetes educator-led education and management program; TunedIn, a psychologist-led program that exclusively targeted the problematic feelings, beliefs, and expectations that underlie DD; and FixIt, a program that combined both Streamline and TunedIn into a single, integrated program. These interventions took the T1-REDEEM programs as a starting point, then uniquely concentrated and focused them directly according to the lessons learned from our previous experience. In the present report, we examine the effectiveness of each program individually over time, with between-group comparisons of DD and HbA_{1c} immediately after each intervention, and at 3 and 9 months after the intervention.

RESEARCH DESIGN AND METHODS

Sample and Recruitment

Adults with T1D were recruited by partnering with academic clinics' research registries and community-based organizations. Partnering organizations (two large research registries, Taking Control of Your Diabetes and T1D Exchange; four community clinics; and two community-based organizations) sent e-mails and/or social media posts to their members

with T1D to share information about the study. Interested individuals were directed to contact the research team via phone or e-mail. Additional diabetes clinics ($n = 5$) mailed letters to patients informing them of the study and letting them know that a project team member would contact them by phone within 2 weeks unless they opted out by returning an enclosed postcard or by calling a toll-free telephone number.

During initial contact through both recruitment procedures, the project was explained, informed consent was obtained, and initial screening was begun, including administration of the Type 1 Diabetes Distress Scale (T1-DDS) and obtaining permission to obtain participants' latest (within 3 months) clinic-recorded HbA_{1c} result. If a recent HbA_{1c} test was unavailable, a prepaid laboratory slip to a community laboratory or HbA_{1c} kit from DTI Laboratories, Inc. (Thomasville, GA) was mailed to the participant. All potentially eligible participants were then sent an electronic baseline survey to complete and then were given a \$40 gift card for their time. Inclusion criteria were as follows: ≥ 19 years of age; diagnosis of T1D for at least 12 months; ability to read, write, and speak English; a score of ≥ 2.0 on the total T1-DDS, indicating elevated DD (1); a recently recorded HbA_{1c} $\geq 7.5\%$; no severe complications (namely, end-stage renal disease, dialysis, blindness); absence of psychosis or dementia; and Internet access.

Eligible consenting participants were then randomly assigned by the research coordinator (1:1:1 allocation), using a computer-generated random number protocol in blocks of 15, to one of the three virtually delivered, group-based interventions ($n = 8$ –15 participants per group): Streamline, TunedIn, or FixIt. To address ethical concerns about keeping highly distressed participants in the study without intervention, a no-treatment control group was not included. Data were collected between 2019 and 2023 (recruitment 2019–2022, follow-up 2020–2023) and analyzed in 2023. All study activities were approved by the University of California, San Francisco Institutional Review Board and the trial was registered at ClinicalTrials.gov (identifier NCT04016558).

Interventions

Streamline is an updated and refined, evidence-based diabetes-management

program delivered by a nurse certified in diabetes care and who was an education specialist. It included one 3-h virtual workshop followed by five one-on-one personal phone calls with each participant (typically, 10–25 min every 2–3 weeks over a 3 months; total intervention time was ≤ 4.5 h). The workshop provided a brief diabetes education review focused on proper basal insulin and bolus dosing and timing, followed by a structured five-step program to identify and resolve the specific glucose challenges identified by each participant. Steps included organizing their “diabetes toolkit” (i.e., diabetes devices, sensors, supplies); identifying a specific blood glucose problem and collecting data; exploring the problem through pattern recognition; deciding what to change and then making the change; and collecting new data to see what happened before reassessing the plan. In follow-up phone calls, participants reviewed their progress in working through these steps.

TunedIn exclusively addressed the emotional side of diabetes. It incorporates elements and strategies of Acceptance and Commitment Therapy (ACT) (20) specifically applied to diabetes. TunedIn included two 3-h virtual group workshops, four 1-h group Zoom calls, and one phone call with the group leader (10–15 min), who was a psychologist with diabetes training and experience (total intervention time was ≤ 10.5 h). The workshops gave participants information about DD, reviewed each participant’s DD profile from the T1-DDS, and included a structured five-step program to reduce DD. The steps included the participants 1) learning to recognize DD and its triggers and to illustrate how DD can lead to problematic choices and behaviors; 2) telling their “DD story” (i.e., the thoughts, beliefs, and feelings they tell themselves about their diabetes); 3) viewing their DD story through the lens of an observer, thus perceiving their thoughts and feelings in a more objective context; 4) developing a response to their DD story (from the perspective of a compassionate, objective, and helpful observer); and 5) exploring alternative choices or behaviors based on their values and goals. Participants selected an item from their T1-DDS survey results, identified a recent event that was distressing for them, and worked through the five steps. Follow-up individual and group calls allowed participants to report progress and share difficulties.

FixIt, a combination of Streamline and TunedIn, began with a modified version of TunedIn (two 3-h workshops, three 1-h group Zoom calls, and one 10-min individual phone call). Once completed, a modified version of Streamline was introduced, (one 3-h workshop, two 1-h group Zoom calls, four one-on-one phone calls). Last, the two group leaders delivered two, 1-h virtual calls to the entire group, integrating the combined TunedIn and Streamline experience (total intervention time was ≤ 16 h).

The interventions were designed to include the necessary time and content to address the primary goals of each program. As such, both the format (e.g., individual vs. group) and time varied somewhat among the interventions to maximize impact. Streamline and TunedIn were delivered over 3 months, whereas FixIt, because of its expanded content, occurred over 4 months. All assessments were conducted at baseline, immediately after intervention (3–4 months after baseline), 3 months after intervention (6–7 months after baseline), and 9 months after intervention (12–13 months after baseline). Hereafter, the follow-up time points are referred to as “3-month,” “6-month,” and “12-month.” Participants were sent gift cards for completed surveys and HbA_{1c} results at each follow-up point (\$55 at 3 months, \$65 at 6 months, and \$80 at 12 months). Facilitators received training (10 h) from an investigator, followed by observing an intervention. Each intervention was reviewed by the investigative team to provide supervision and support. To ensure fidelity, content-tracking checklists were developed for each program that were based on key areas of program content. Observers recorded a mean of 95% fidelity across all sessions, with no significant between-group differences; no “bleeding” across interventions was noted, because group leaders focused exclusively on the content of each program.

Measures

Participant self-reported data were collected on age, gender identity, ethnicity and racial identity, years with T1D, education, financial strain (21), emotion regulation assessed through the Non-Judging and Nonreactivity of Inner Experience Scales (22), and number of complications.

DD was assessed by the total score from the T1-DDS, a 28-item scale ($\alpha = 0.84$) (1) and by the seven subscales or DD “sources”: powerlessness, management, hypoglycemia, negative social perceptions, eating, physician, and family/friends. Response options ranged from 1 (not a problem) to 6 (a very serious problem). The total DD score (the average of 28 items) and seven source scores were analyzed as continuous variables. Also examined were the percentage of individuals whose total DD score dropped under the 2.0 threshold, as well as the percentage who decreased their mean total DD score by the minimal clinically important difference (MCID) equal to >0.19 (5).

HbA_{1c} values were obtained from clinic records. If the data were unavailable, participants received a laboratory slip for HbA_{1c} collection at a community site or a mailed HbA_{1c} kit. HbA_{1c} was analyzed as a continuous variable. Also examined were the percentages of individuals whose HbA_{1c} score dropped under the 7.5% threshold and whose HbA_{1c} score decreased by ≥ 0.5 .

Data Analysis

We used χ^2 or Student *t* tests to compare the three treatment conditions on participant characteristics and baseline values of outcome variables, and to document differences between dropouts and completers (SPSS Statistics software, version 26.0; IBM Corp.). Paired *t* tests were used separately for each group to determine change in DD and HbA_{1c} from baseline to each follow-up time point. Change in outcomes across groups was evaluated by ANCOVA. In these models, the follow-up value was specified as the outcome, the baseline value was the covariate, and treatment group was a fixed effect. When the treatment group effect was statistically significant ($P < 0.05$), Helmert contrasts were used to determine differences among the three groups. We also examined the effect of key moderators on outcomes (age, gender, race/ethnicity, baseline DD, emotion regulation, financial insecurity, and HbA_{1c}). Each moderator was included in a separate ANCOVA model as a main effect and as an interactive effect. Missing values were imputed with NORM software (version 2.0; The Methodology Center, Penn State,

University Park, PA) (23,24) using multiple-imputation procedures to create a stable, complete data set. Parallel analyses were performed with raw and imputed data sets; because the findings in all models were similar, we present only nonimputed results.

Sample size and power estimates are based on two-sided $\alpha = 0.05$ and Student *t* tests on change from baseline to each follow-up point. Estimating a 20% attrition rate, a sample of 90 per group allows for detection of moderate effect sizes ($d = 0.47$ SD unit differences) equating to mean changes in DD of ≥ 0.36 and mean changes in HbA_{1c} of $\geq 0.44\%$ based on the SDs in the current sample.

RESULTS

The final sample included 276 adults: 97 in Streamline, 91 in TunedIn, and 88 in FixIt (Fig. 1) across 29 groups ($n = 10$ each for Streamline and FixIt, $n = 9$ for TunedIn). Retention (82% at 3 months, 84% at 6 months, and 81% at 12 months) did not differ significantly by intervention group. Compared with study dropouts ($n = 51$), those who completed the study (hereafter, “completers”) ($n = 225$) reported lower mean baseline HbA_{1c} values (8.2% vs. 8.6%; $P = 0.02$) and fewer years living with diabetes (27.89 vs. 22.98 years; $P = 0.04$), and more participants self-identified as non-Hispanic White (85.3% vs. 70.6%; $P = 0.01$). The mean (SD) age was 46.8 (15.1) years, 79.6% identified as female, and the mean (SD) baseline HbA_{1c} was 8.3% (0.9%) (67.0 [9.8] mmol/mol). There were no between-group differences at baseline except that Streamline participants reported longer diabetes duration than those in the other groups (Table 1).

Change in DD

Large reductions in total DD were reported in all three groups from baseline to 3 months that were sustained over time, with the exception of minor, nonsignificant increases (e.g., a 6–12-month increase in total DD in Streamline from 2.32 to 2.34) at 6 and 12 months (Table 2). Nominal between-group differences in DD reductions occurred at 3 and 6 months ($P < 0.07$), with a significant difference among groups at 12 months ($P < 0.007$). In all cases, those participating in TunedIn and FixIt reported greater reductions in DD than those in Streamline. At 12 months, total DD reductions equated to a medium

effect size (Cohen's *d*) of 0.58 for Streamline and large effect sizes of 1.14 and 1.06 for TunedIn and FixIt, respectively.

The percentage of participants whose DD dropped under the 2.0 threshold (indicating nonelevated DD) and the percentage of a change of at least one MCID were also examined (Table 3). At 3 months, 22.1%, 38.9%, and 41.0% of Streamline, TunedIn, and FixIt participants, respectively, reduced their total DD below 2.0. At 12 months, 27.2%, 50.2%, and 30.7% of participants, respectively, passed this threshold. A significantly greater percentage of TunedIn participants passed this threshold than those in the other two groups ($\chi^2 = 0.01$, $P = 0.008$). Likewise, significant MCID improvements were seen immediately after the intervention and were sustained at 6 and 12 months, with most FixIt participants reporting at least one MCID improvement in total DD (82.4–85.5%), followed by TunedIn (74.6–78.9%) and Streamline (63.9–68.6%). At 12 months, a higher percentage of FixIt ($\chi^2 = 5.38$, $P = 0.02$) and TunedIn ($\chi^2 = 3.08$, $P = 0.079$) participants passed the MCID threshold compared with those in Streamline.

Similar significant reductions in T1-DDS source scales were reported immediately after the intervention and were generally sustained at 6 and 12 months, with the exception of Physician Distress in the Streamline group. Where between-group differences emerged, results mirrored those for total DD, with greater reductions in DD reported among those receiving the FixIt and TunedIn interventions compared with Streamline at 12 months in the areas of Powerlessness ($P < 0.001$), Hypoglycemia Distress ($P = 0.005$), and Physician Distress ($P = 0.001$). Overall, results indicated that, although all three intervention strategies yielded significant DD reductions, greater sustained reductions occurred in DD in TunedIn and FixIt than in Streamline.

Change in HbA_{1c}

HbA_{1c} decreased significantly in all three groups from baseline to immediately after the intervention (Streamline change [Δ] = -0.43 , $P < 0.001$; TunedIn $\Delta = -0.52$, $P < 0.001$; and FixIt $\Delta = -0.33$, $P = 0.003$) with no between-group differences (Table 2). Decreases in HbA_{1c} were maintained in all three groups at 6 months. At 12 months, however,

additional significant decreases occurred in Streamline ($\Delta = -0.65$ from baseline) and TunedIn ($\Delta = -0.59$ from baseline) (both $P < 0.001$), but not in FixIt. This resulted in statistically significant, though modestly greater, mean improvements in HbA_{1c} in the Streamline group compared with TunedIn and FixIt ($P = 0.032$) and greater improvements in TunedIn compared with FixIt ($P = 0.014$).

We also evaluated the clinical significance of HbA_{1c} change by examining the percentage of individuals who reported a reduction in HbA_{1c} to under the 7.5% threshold and the percentage who reported a decrease in HbA_{1c} of $\geq 0.5\%$ (Table 3). At 12 months, 40% of individuals in Streamline and TunedIn, compared with 28.8% in FixIt ($\chi^2 = 2.59$, $P = 0.108$ for Streamline; $\chi^2 = 2.47$, $P = 0.116$ for TunedIn) reduced their HbA_{1c} to $< 7.5\%$; there was no difference between the Streamline and TunedIn groups. Furthermore, at 12 months, just over half of Streamline and TunedIn participants (53.2% and 55.7%, respectively), compared with 34.8% in FixIt, achieved an HbA_{1c} decrease of $\geq 0.5\%$. More Streamline and TunedIn participants reached this threshold compared with FixIt participants ($\chi^2 = 6.29$, $P = 0.01$ for Streamline; $\chi^2 = 7.79$, $P = 0.005$ for TunedIn), with no significant difference between Streamline and TunedIn.

Overall, results show that all three groups had significantly reduced HbA_{1c}, with Streamline and TunedIn showing the largest improvements compared with FixIt.

Moderators of Intervention Impact on Total DD and HbA_{1c}

There was a significant interaction among intervention groups with baseline DD level at 12-month follow-up ($F = 6.05$, $P = 0.02$) and with baseline HbA_{1c} level at each follow-up (all $P < 0.01$). Having initial higher (worse) levels of DD and HbA_{1c} strongly predicted greater change in the Streamline group, but baseline levels were only modestly linked to, or were unassociated with, change in the TunedIn and FixIt groups. Thus, success among those receiving the TunedIn and FixIt interventions was less influenced by a person's initial DD or HbA_{1c} level than in Streamline. No other interactions reached statistical significance for either outcome, suggesting that reductions in DD and HbA_{1c} for all

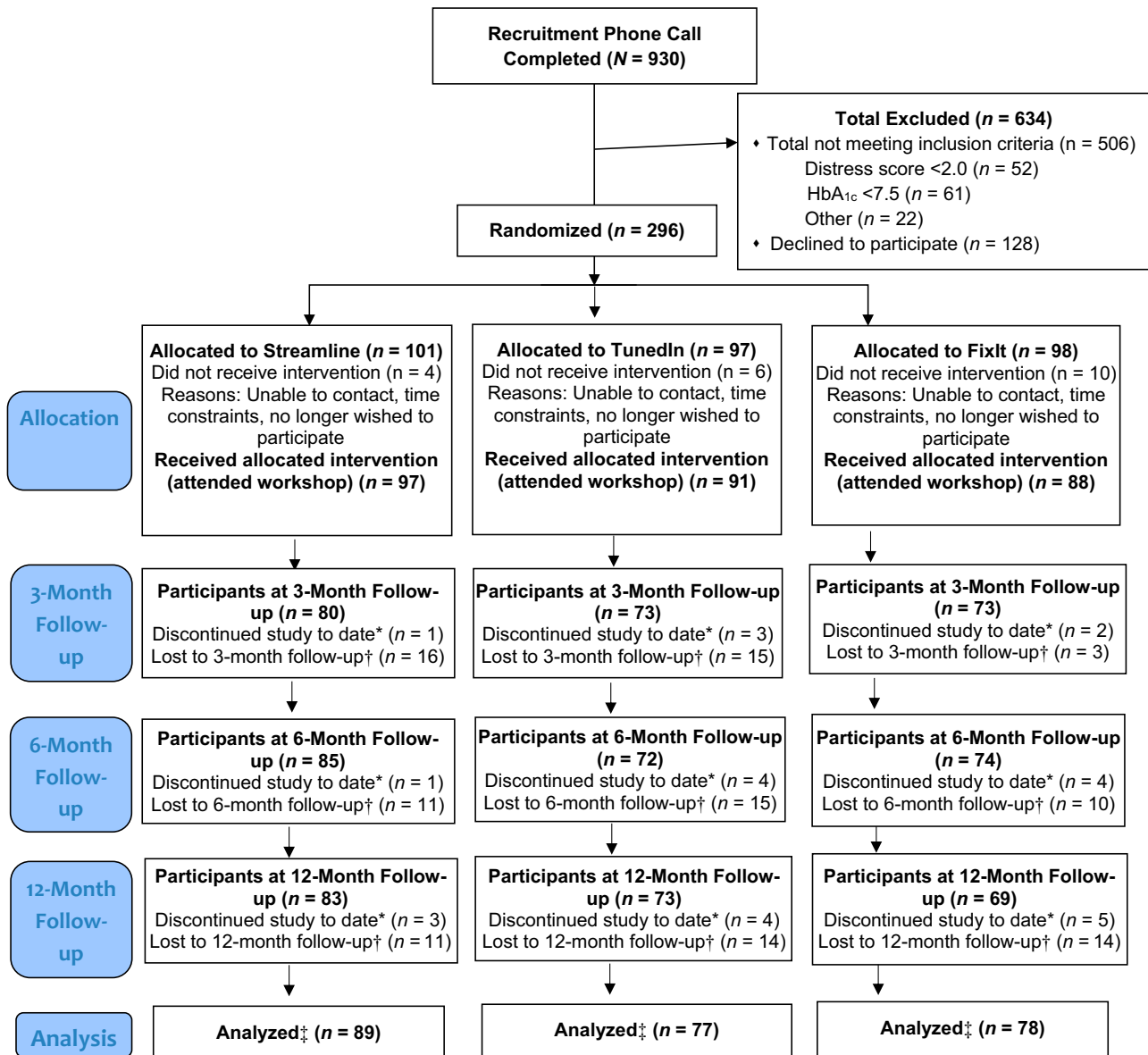


Figure 1—Consolidated Standards of Reporting Trials (CONSORT) diagram. *Discontinued study engagement and was no longer contacted at future follow-up assessment points. Counts are cumulative. †Completed neither the survey nor the blood sample collection at the assessment stage. ‡Completed, at minimum, the survey or the blood sample collection at any of the follow-up assessments.

interventions were generalizable across participants.

We also examined attendance across the intervention touchpoints, based on the requirements of each intervention. A high level of attendance at each activity was documented for all three interventions (see Supplementary Table 1). When examined in terms of the percentage of possible contacts completed, the highest participation was seen in Streamline (88%), followed by FixIt (75%), and then TunedIn (62%). Overall attendance was considered a measure of intervention exposure and was unrelated to reductions in DD and HbA_{1c} within any intervention group.

CONCLUSIONS

We found that adults with T1D in all three intervention programs experienced substantive, clinically meaningful, and statistically significant reductions in both DD and HbA_{1c}. All reductions were generally sustained over time. More than 75% of participants experienced a clinically meaningful reduction in DD (5) with standardized effect sizes ranging from 0.58 to 1.14 at 12-month follow-up.

Significant differences among the interventions also occurred. TunedIn and FixIt participants reported significantly greater DD reductions in total, source, threshold, and MCID scores, compared

with Streamline participants. In contrast, Streamline and TunedIn participants had significantly greater HbA_{1c} reductions than did FixIt participants, with more than half experiencing an HbA_{1c} improvement >0.5%. Considering DD and HbA_{1c} in tandem, we suggest that those in TunedIn experienced the most consistent overall clinical benefits across both DD and HbA_{1c}, even though TunedIn did not directly address resolution of glucose problems. Instead, TunedIn exclusively used highly systematized and focused ACT-based techniques that foster awareness of how painful emotions and beliefs often drive unhelpful management behavior. Providing

Table 1—Participant characteristics at baseline by intervention group (N = 276)

Characteristic	All (N = 276)	Streamline (n = 97)	TunedIn (n = 91)	FixIt (n = 88)	F or χ^2 (P) values
Age (years)	46.81 (15.11)	48.88 (15.44)	47.34 (15.38)	43.99 (14.17)	2.52 (0.082)
Diabetes duration (years)	26.99 (15.30)	30.44 (15.47)	25.90 (14.74)	24.30 (15.15)	4.16 (0.017)
Uses an insulin pump, % (n)	72.8 (201)	73.2 (71)	72.5 (66)	72.7 (64)	0.01 (0.994)
Uses continuous glucose monitoring, % (n)	78.6 (217)	79.4 (77)	80.2 (73)	76.1 (67)	0.50 (0.781)
Highest education level achieved, % (n)					11.97 (0.063)
High school degree	2.6 (7)	1.5 (4)	0.4 (1)	0.7 (2)	
Some college	25.5 (70)	26.8 (26)	27.5 (25)	22.1 (19)	
Completed college	41.2 (113)	36.1 (35)	34.1 (31)	54.7 (47)	
Graduate school	30.7 (84)	33.0 (32)	37.4 (34)	20.9 (18)	
Gender, n (%)					1.67 (0.434)
Male	52 (18.9)	22 (22.7)	16 (17.6)	14 (16.1)	
Female	219 (79.6)	74 (76.3)	72 (79.1)	73 (83.9)	
Female to male (transgender)	3 (1.1)	1 (1)	2 (2.2)	0 (0)	
Male to female (transgender)	1 (0.4)	0 (0)	1 (1.1)	0 (0)	
Race/ethnicity, % (n)					0.84 (0.657)
Native American	0.4 (1)	1.0 (1)	0 (0)	0 (0)	
Asian	1.1 (3)	2.1 (2)	0 (0)	1.1 (1)	
Native Hawaiian	0 (0)	0 (0)	0 (0)	0 (0)	
Black	2.9 (8)	1 (1)	2.2 (2)	5.7 (5)	
White	88.7 (244)	87.6 (85)	91.2 (83)	87.4 (76)	
>1 Race	5.1 (14)	5.2 (5)	5.5 (5)	4.6 (4)	
Hispanic/Latino	10.4 (28)	11.7 (11)	12.2 (11)	7.0 (6)	1.58 (0.455)
Financially insecure, % (n)	41.3 (114)	42.3 (41)	35.2 (32)	46.6 (41)	2.47 (0.291)
Has taken a diabetes education class, % (n)					15.67 (0.110)
Never	11.6 (32)	6.2 (6)	16.5 (15)	12.5 (11)	
Past 12 months	13.0 (36)	15.5 (15)	13.2 (12)	10.2 (9)	
1–3 years ago	17.0 (47)	22.7 (22)	9.9 (9)	18.2 (16)	
4–7 years ago	21.7 (60)	23.7 (23)	19.8 (18)	21.6 (19)	
7–10 years ago	8.3 (23)	7.2 (7)	13.2 (12)	4.5 (4)	
>10 years ago	28.3 (78)	24.7 (24)	27.5 (25)	33.0 (29)	
Complications, n (%)	3.32 (2.57)	3.43 (2.67)	3.35 (2.49)	3.16 (2.57)	0.27 (0.762)
T1-DDS					
Total T1-DDS score	2.84 (0.76)	2.79 (0.83)	2.78 (0.73)	2.96 (0.73)	1.55 (0.214)
Powerlessness	3.93 (1.12)	3.75 (1.24)	3.92 (1.02)	4.13 (1.06)	2.66 (0.072)
Management	2.95 (1.13)	2.86 (1.12)	2.93 (1.12)	3.07 (1.15)	0.79 (0.455)
Hypoglycemia	2.81 (1.20)	2.93 (1.28)	2.66 (1.13)	2.84 (1.18)	1.28 (0.279)
Negative social perception	2.39 (1.26)	2.40 (1.28)	2.34 (1.26)	2.44 (1.24)	0.15 (0.861)
Eating	3.63 (1.33)	3.57 (1.35)	3.53 (1.33)	3.81 (1.30)	1.16 (0.317)
Physician	1.99 (1.17)	1.96 (1.15)	1.95 (1.13)	2.08 (1.24)	0.36 (0.696)
Family/friends	2.09 (1.09)	1.99 (1.07)	2.05 (1.07)	2.26 (1.14)	1.50 (0.224)
HbA _{1c} mean (%)	8.27 (0.93)	8.24 (0.86)	8.24 (0.87)	8.34 (1.07)	0.33 (0.719)
HbA _{1c} mmol/mol	67 (10.2)	67 (9.4)	67 (9.5)	68 (11.7)	0.33 (0.719)

Data reported as mean (SD) or %, unless otherwise indicated.

individuals with opportunities to recognize and observe these processes, and to “stand beside” those processes, may enable them to make better choices—choices more in line with what is best for them. These strategies have demonstrated considerable utility across a range of chronic diseases and other stress-related settings (25).

Under the assumption that a combined emotion- and management-based intervention would maximize change,

coupled with an extended exposure to intervention, the modest HbA_{1c} reductions in FixIt are surprising. We suggest two interrelated explanations. First, although overall attendance was 75%, the longer time frame for intervention delivery and the volume of content presented may have been overwhelming for participants, being far too much material to comprehend and process in a meaningful way. Second, the two parts of FixIt required a somewhat

different cognitive perspective that may not have been easily integrated. In the TunedIn portion, individuals focused on identifying and addressing the often-painful thoughts and feelings that underlie DD. They were then asked to make choices separate from these longstanding narratives. In contrast, in the Streamline portion of FixIt, participants were directed to shift from this novel emphasis on feelings to the mechanics of resolving very specific glucose problems. This shift

Table 2—Intervention group differences in HbA_{1c} and T1-DDS using continuous scores (N = 276)

Parameter	All (N = 276)	Streamline (n = 97)	TunedIn (n = 91)	FixIt (n = 88)	Treatment group effect: F (P) value (df = 2)
HbA_{1c} mean (%)					
Baseline	8.27 (0.056)	8.24 (0.095)	8.24 (0.098)	8.34 (0.100)	0.33 (0.719)
3 months	7.80 (0.061)	7.78 (0.103)	7.71 (0.111)	7.90 (0.105)	0.79 (0.457)
6 months	7.78 (0.062)	7.69 (0.106)	7.73 (0.111)	7.91 (0.107)	1.20 (0.304)
12 months	7.69 (0.056)	7.52 (0.092)	7.60 (0.098)	7.94 (0.101)	5.30 (0.006)*
T1-DDS					
Total DD score					
Baseline	2.84 (0.046)	2.79 (0.077)	2.78 (0.080)	2.96 (0.081)	1.55 (0.214)
3 months	2.20 (0.044)	2.34 (0.076)	2.18 (0.077)	2.08 (0.078)	2.73 (0.068)
6 months	2.22 (0.044)	2.32 (0.074)	2.19 (0.082)	2.17 (0.076)	1.01 (0.366)
12 months	2.15 (0.044)	2.34 (0.074)	2.03 (0.077)	2.06 (0.079)	5.10 (0.007)*
Powerlessness					
Baseline	3.93 (0.067)	3.75 (0.113)	3.92 (0.117)	4.13 (0.119)	2.66 (0.072)
3 months	2.97 (0.069)	3.31 (0.118)	2.90 (0.119)	2.71 (0.122)	6.56 (0.002)*
6 months	2.99 (0.070)	3.22 (0.118)	2.87 (0.129)	2.88 (0.120)	2.68 (0.071)
12 months	2.90 (0.069)	3.24 (0.116)	2.72 (0.120)	2.73 (0.124)	6.31 (0.002)*
Management distress					
Baseline	2.95 (0.068)	2.86 (0.115)	2.93 (0.119)	3.07 (0.121)	0.80 (0.455)
3 months	2.19 (0.055)	2.30 (0.094)	2.16 (0.095)	2.13 (0.097)	0.90 (0.409)
6 months	2.20 (0.061)	2.23 (0.101)	2.13 (0.112)	2.24 (0.103)	0.36 (0.701)
12 months	2.13 (0.058)	2.25 (0.097)	1.99 (0.101)	2.16 (0.103)	1.77 (0.174)
Hypoglycemia distress					
Baseline	2.81 (0.072)	2.93 (0.122)	2.66 (0.123)	2.84 (0.128)	1.28 (0.279)
3 months	2.07 (0.055)	2.24 (0.094)	1.99 (0.095)	1.99 (0.096)	2.21 (0.112)
6 months	2.08 (0.054)	2.10 (0.090)	2.09 (0.100)	2.03 (0.090)	0.18 (0.834)
12 months	2.04 (0.056)	2.26 (0.093)	1.96 (0.097)	1.91 (0.099)	4.03 (0.019)*
Negative social perceptions					
Baseline	2.40 (0.076)	2.40 (0.128)	2.34 (0.132)	2.44 (0.135)	0.15 (0.861)
3 months	1.89 (0.057)	1.96 (0.098)	1.88 (0.099)	1.83 (0.100)	0.42 (0.657)
6 months	1.90 (0.060)	1.95 (0.101)	1.93 (0.111)	1.81 (0.101)	0.59 (0.558)
12 months	1.86 (0.052)	2.01 (0.087)	1.75 (0.091)	1.81 (0.092)	2.33 (0.100)
Eating distress					
Baseline	3.64 (0.080)	3.57 (0.135)	3.54 (0.139)	3.81 (0.142)	1.16 (0.317)
3 months	2.80 (0.074)	2.82 (0.126)	2.87 (0.128)	2.72 (0.130)	0.32 (0.729)
6 months	2.93 (0.079)	2.93 (0.132)	2.84 (0.145)	3.03 (0.134)	0.47 (0.629)
12 months	2.71 (0.074)	2.79 (0.124)	2.62 (0.130)	2.73 (0.133)	0.45 (0.636)
Physician distress					
Baseline	2.00 (0.071)	1.96 (0.119)	1.95 (0.123)	2.08 (0.125)	0.36 (0.696)
3 months	1.73 (0.060)	1.88 (0.103)	1.75 (0.104)	1.56 (0.105)	2.32 (0.101)
6 months	1.76 (0.060)	1.98 (0.100)	1.68 (0.110)	1.61 (0.101)	3.85 (0.023)*
12 months	1.56 (0.063)	1.97 (0.106)	1.49 (0.110)	1.55 (0.113)	5.86 (0.003)*
Friends/family distress					
Baseline	2.10 (0.056)	1.99 (0.111)	2.05 (0.114)	2.26 (0.116)	1.50 (0.224)
3 months	1.73 (0.050)	1.82 (0.085)	1.72 (0.086)	1.65 (0.087)	0.96 (0.386)
6 months	1.71 (0.047)	1.72 (0.079)	1.70 (0.086)	1.70 (0.080)	0.01 (0.989)
12 months	1.71 (0.051)	1.79 (0.085)	1.66 (0.089)	1.68 (0.091)	0.66 (0.519)

For baseline analyses, the univariate linear model with baseline value of outcome was the dependent variable and treatment group was the independent variable. For 3-, 6-, and 12-month outcome analyses, the univariate general linear model with follow-up value of outcome was the dependent variable, treatment group was an independent variable, and baseline value of outcome was the covariate. Baseline indicates original values; 3, 6, and 12 months indicate estimated values adjusted for baseline. * $P < 0.05$.

may have been experienced as wrenching, leading to less engagement in the Streamline portion of FixIt. This view is supported by the finding that, despite the significant but relatively smaller HbA_{1c} reductions for this group, participants maintained their large reductions in DD over time. The pace, ordering, and intensity of a combined intervention

need to be re-evaluated, with special attention paid to addressing the novel and different lenses that each strategy requires.

With the positive impact of TunedIn on both DD and HbA_{1c}, three additional considerations are noteworthy. First, TunedIn, like all interventions tested in EMBARK, was delivered virtually, which

may extend the program's reach and reduces cost. Although many pathway efforts are in place to increase the number of mental health professionals with diabetes expertise (26), a workforce shortage is likely to remain (27), and virtual group-based programs such as those used in EMBARK can make use of limited existing resources. Relatedly, our previous cost

Table 3—Intervention group differences in HbA_{1c} and T1-DDS using threshold and MCID measures of change (N = 276)

Parameter	All (N = 276)	Streamline (n = 97)	TunedIn (n = 91)	FixIt (n = 88)
T1-DDS total score improved $\geq +1$				
MCID on difference score, %				
From baseline to 3 months	73.6	63.9	74.6	82.6
From baseline to 6 months	76.6	68.6	75.9	85.5
From baseline to 12 months	75.9	67.5	78.9	82.4
T1-DDS total score improved to <2.0, %				
From baseline to 3 months	33.8	22.1	38.9	41.0
From baseline to 6 months	33.3	24.7	36.8	39.6
From baseline to 12 months	39.4	27.2	50.2	30.7
HbA_{1c} improved to <7.5, %				
From baseline to 3 months	32.3	31.4	36.7	29.4
From baseline to 6 months	30.4	31.1	32.8	27.4
From baseline to 12 months	36.7	40.5	40.0	28.8
HbA_{1c} decreased by ≥ 0.5, %				
From baseline to 3 months	42.4	37.1	48.3	42.6
From baseline to 6 months	43.5	41.9	49.3	39.7
From baseline to 12 months	48.4	53.2	55.7	34.8

analysis of an in-person program of similar length or time was estimated to cost \$335 per person, suggesting a cost-efficient strategy (28). Second, the results of the moderator analyses indicated that the effects of TunedIn were largely unrelated to patient characteristics, including initial levels of DD and HbA_{1c}. Thus, the positive outcomes of TunedIn appear applicable to a broad range of adults with T1D. Third, notwithstanding the magnitude of HbA_{1c} reductions in Streamline, the HbA_{1c} reductions in TunedIn were far greater than those reported in previous DD intervention research, including our own (19). We suggest that our previous experience enabled us to further refine and focus TunedIn to conform more closely with diabetes-related ACT principles and techniques. We suspect that this level of increased precision likely enhanced TunedIn's more clinically meaningful findings. These findings need to be replicated and generalized to the T1D population at large in future research.

Several limitations to this study need to be considered. First, data were collected between 2019 and 2023, during the COVID-19 pandemic, which may have affected outcomes because of unusually high levels of participant stress, social isolation, and problems accessing health care. Second, the programs differed in terms of total contact hours, and this could have contributed to findings, though it is notable that FixIt included the greatest number of contact hours but was not linked with the largest overall benefits. Third, eligibility criteria

required Internet access, and a high percentage of participants self-identified as non-Hispanic White and as female, all of which may limit generalizability. Relatedly, eligibility criteria included a threshold for both DD (≥ 2.0) and HbA_{1c} ($\geq 7.5\%$), but many individuals with relatively low HbA_{1c} also report elevated DD (1). Future studies should include individuals whose HbA_{1c} is below the 7.5% threshold, because related work has documented important benefits to an individual's quality of life in reducing DD across a range of glycemic levels (12). Future work should continue to examine other outcomes beyond DD and HbA_{1c} and to investigate the degree to which and the mechanisms by which changes in DD are linked to changes in HbA_{1c} (e.g., opening the door to new diabetes-related perspectives, yielding greater engagement with management of glycemic problems [29]).

Our results suggest that both management- and emotion-focused group programs for adults with T1D can lead to significant and clinically meaningful reductions in DD and HbA_{1c}. TunedIn, an emotion-focused program, had the most consistent overall benefits when considering both DD and HbA_{1c}. Findings suggest the value of using emotion-focused strategies, like those in TunedIn, to reduce DD and enhance management among adults with T1D.

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Author Contributions. D.M.H. and L.F. conceptualized the study and drafted the manuscript. D.M.H., L.F., S.G., W.H.P., and U.M. contributed to the study design, implementation, and critical review. D.M.H., L.F., and L.S. analyzed and interpreted the data. All authors critically reviewed, edited, and approved the final version of the manuscript. D.M.H. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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