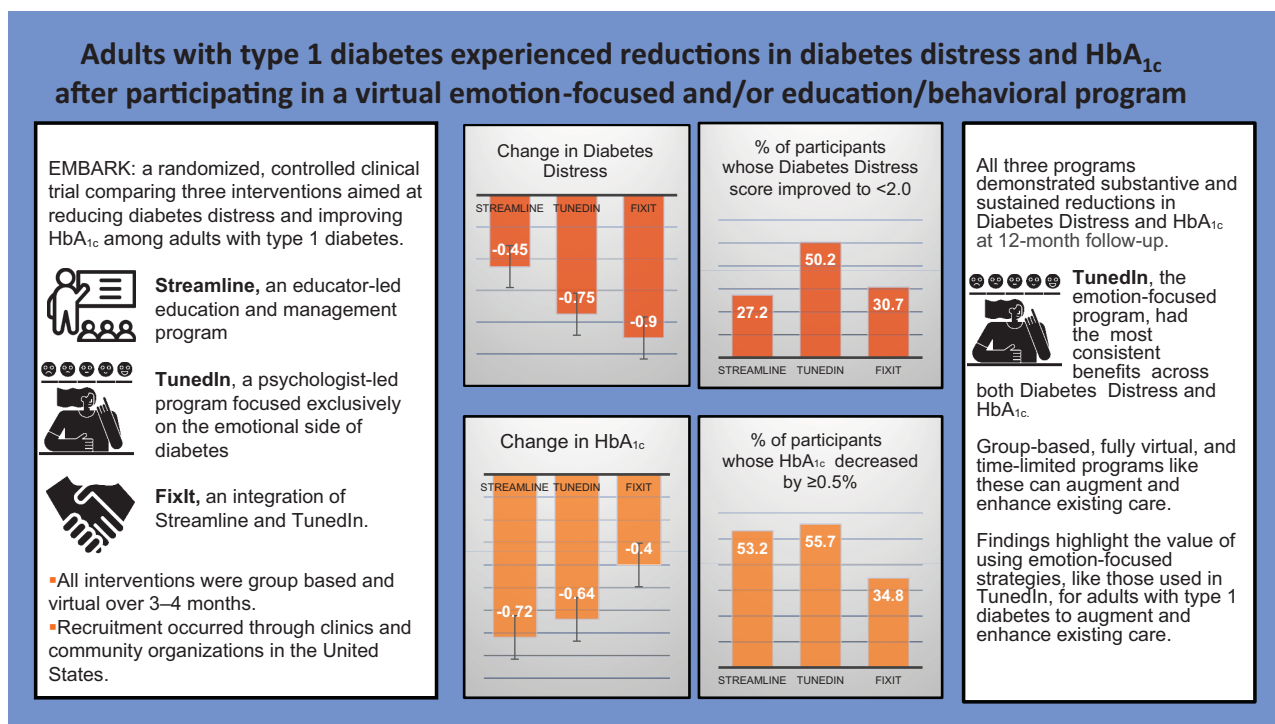


EMBARC: A Randomized, Controlled Trial Comparing Three Approaches to Reducing Diabetes Distress and Improving HbA_{1c} in Adults With Type 1 Diabetes

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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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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,

