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Economic Costs of Implementing Group Interventions to Reduce Diabetes Distress in Adults with Type 1 Diabetes Mellitus in the T1-REDEEM Trial

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Abstract

Aims—This study evaluated the implementation costs of two group interventions, one focused on diabetes education (KnowIt) and one focused directly on diabetes distress (OnTrack), that reduced diabetes distress and HbA1C in adults with poorly controlled type 1 diabetes (T1DM) in the T1-REDEEM trial.

Methods—Resources used to provide interventions were enumerated using activity-based micro-costing methods. Costs were assigned to resources in 2017 US dollars. US median wage and benefit rates were used to calculate costs of staff time. Cost per unit change was calculated for diabetes distress and HbA1C.

Results—For both interventions, per participant implementation costs were approximately $250 and cost per 1.0 percentage point (11 mmol/mol) change in HbA1C was $1,400. Cost per unit change in diabetes distress was $364 for KnowIt and $335 for OnTrack. No statistically significant differences in costs were observed.

Conclusions—This is the first study to examine the costs of implementing interventions targeting diabetes distress in the context of T1DM. Both interventions had per participant implementation costs in the lower end of the range of previously examined diabetes self-

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Conflict of Interest Statement

None of the authors have any conflicts of interest.

management interventions ($219 to $5,390). These inventions and their costs merit further attention because reducing diabetes distress may impact long term T1DM outcomes.

Clinical Trials Registration: ClinicalTrials.gov

Keywords

Type 1 Diabetes; Costs and Cost Analysis; Self-Management; Patient Education

1. INTRODUCTION

Diabetes distress refers to the often hidden emotional burdens, stresses, and worries that result from managing a demanding, chronic disease like type 1 diabetes mellitus (T1DM).[1] Diabetes distress is distinct from depression[2] and quality of life[3] and tends to be chronic, rather than episodic.[4] Diabetes distress is a significant clinical problem; it has been associated with poor glycemic control and problematic self-care behavior in both cross-sectional and longitudinal studies.[5–9] Approximately 42% of adults with T1DM manifest elevated diabetes distress.[4] Recent intervention studies demonstrate that diabetes distress is malleable, with the strongest effects coming from group programs that target emotional aspects of diabetes directly, rather than focusing exclusively on behavior change or education.[10–12]

The recent T1-REDEEM (Reducing Distress and Enhancing Effective Management) trial[12] compared two group interventions designed to reduce diabetes distress and HbA1C among highly distressed adults with poorly controlled T1DM. Both interventions, KnowIt and OnTrack, included a one-day, in-person workshop followed by four online video group meetings over the succeeding three months. KnowIt focused on diabetes education and management, while OnTrack focused directly on diabetes distress and the emotional side of diabetes. Statistically significant reductions in diabetes distress and HbA1C were observed with both interventions (d = 1.06 combined effect size for change in diabetes distress) and no between-group differences in outcomes were observed.[12]

It is increasingly recognized that adoption of new interventions depends on the medical providers who deliver care, and the decision makers who allocate resources and make reimbursement decisions, having information about real-world implementation costs. Implementation cost is a particular concern in the context of diabetes self-management interventions because interventions and their costs vary considerably. A recent systematic review found that per participant costs for effective self-management costs ranged from $219 to $5,390 in 2017 dollars.[13] Traditional economic analyses,[14–15] which focus on long-term, societal costs, typically do not provide the information about near-term implementation costs that medical providers and other decision makers need to consider as they implement a new evidence-based intervention. A targeted approach to cost analysis, that focuses specifically on implementation costs, has been promoted as a useful way to meet these information needs.[16–18] In this paper, we follow the approach of Ritzwoller and colleagues[16] to calculate the real-world implementation costs of KnowIt and OnTrack from the providers' perspective, and to evaluate the costs for unit reductions in diabetes distress and HbA1C.

2. MATERIALS AND METHODS

2.1. Participants

Using procedures detailed elsewhere,[12] a diverse sample of adults with T1DM were recruited through patient registries, support groups, and social media in California (San Francisco Bay Area, Los Angeles, Sacramento, San Diego); Tucson, Arizona; Portland, Oregon; and Toronto, Ontario, Canada. To be eligible, participants needed to be ≥19 years of age, diagnosed with T1DM for at least 12 months, able to read, write and speak English, have a mean item score ≥ 2 on the T1-Diabetes Distress Scale (T1-DDS), indicating elevated diabetes distress,[19] a recent HbA1c ≥ 7.5% (58 mmol/mol), have no severe diabetes complications (e.g., end-stage renal disease), no psychosis or dementia, and have a computer with Internet access. Participants provided written informed consent. Study procedures were approved by the Institutional Review Board of the University of California, San Francisco.

2.2. Interventions

The two study interventions, KnowIt and OnTrack, were similarly structured and required the same time commitment from participants. All participants attended a one-day, in-person workshop with a trained group leader, followed by four, one-hour, online video meetings with other group members and the leader over the following three months. Group leaders made phone contact with each group member between meetings. Technical assistance was available throughout the intervention.

KnowIt, led by a Certified Diabetes Educator, included an update on the causes and management of T1DM, including etiology, carb counting, and strategies to address specific disease management problems. Each online meeting reviewed individual action plans and addressed a specific topic: continuous glucose monitoring, islet and pancreas transplantation, hypoglycemia, and travel. Eighteen KnowIt groups were conducted that ranged in size from 5 to 13 participants.

OnTrack, led by a psychologist knowledgeable about diabetes, used examples and exercises specific to emotional aspects of diabetes and helped participants develop personalized action plans for managing emotions and getting “unstuck” about changing behavior. Plans included distress-related, emotion regulation strategies such as labelling feelings, keeping feelings in perspective, and separating feelings from appraisals of self-worth. Participants’ action plans targeted feelings that might accompany behavior change. Online meetings focused on action plans, dealing with diabetes, coping with frustrating blood glucose readings, and relationships with friends and family. Fifteen OnTrack groups were conducted that ranged in size from 7 to 14 participants.

2.3. Outcome measures

Diabetes distress was assessed via online surveys at study entry and at 3 and 9 months after the workshop using the Type 1-Diabetes Distress Scale (T1-DDS), a 28-item scale (alpha = .84).[20] The T1-DDS yields a total score and seven subscales: powerlessness (5 items), management distress (4 items), hypoglycemia distress (4 items), negative social perceptions (4 items), eating distress (3 items), physician distress (4 items), family/friend distress (4

items). Response options range from (1) “not a problem” to (6) “a very serious problem.” Blood was drawn for HbA1C testing at study entry and 3- and 9-months after the workshop.

Resource and cost measures

Using an activity-based micro-costing approach,[21] resources used to implement the two interventions were prospectively recorded using a database designed for the study. Resources linked to individual participants (phone and email contacts, individual technical support) were collected at the participant level. Resources associated with group activities (workshops, online meetings) were collected at the group level and allocated among participants. Most resource utilization data were obtained from existing records, including cell phone bills, web system logs, and invoices. Time devoted to supervision was obtained from project calendars and schedules. Staff time devoted to email and preparation were recorded in written staff logs. Research staff reviewed resource use data as it was received and confirmed values with group leaders as needed. The highly structured nature of the interventions made it possible to detect and follow-up on missing data and unexpected values.

In keeping with standard practice, resources used for research activities that are not relevant to real-world implementation were identified and excluded from cost calculations.[15,16] Excluded resources included time devoted to research participant recruitment, obtaining informed consent for research participation, and research assessments. Research staff were responsible for some tasks that are relevant to real-world implementation, such as providing support for workshops, sending reminders to group members, and providing technical assistance. These tasks were allocated to either group leaders or clerical assistants for cost calculations.

The scheduling requirements of the research project led to some variation in the number of participants and the set-up time required for some of the in-person workshops. To best approximate real-world implementation conditions, standard values for workshop size (8 participants) workshop set-up time (30 minutes) were used in all analyses. Costs associated with the web meeting system were collected but were not included in analyses because these resources are now available from multiple sources at no cost.

Staff training activities were considered separately from intervention activities because the frequency and quantity of staff training would differ widely in implementation. The costs of training individual group leaders and assistants were calculated so that practices can estimate their own costs given the number of staff that will be trained.

Costs were assigned to resources in US dollars as of 2017, the final year that study interventions were delivered. To maximize the generalizability of findings for broad implementation, national US median hourly wage rates were used to calculate the time costs of Certified Diabetes Educators ($37),[22] psychologists ($37),[23] social workers ($23),[23] and general office clerks (assistants) ($15).[23] Costs for supervision were calculated at 1.25 times salary costs of supervisees based on local experience. Benefit costs were calculated at 31.7% based on US Bureau of Labor Statistics National Compensation Survey data for 2017.[24] 2017 costs of printed materials were applied to materials purchased in all years.

To permit providers to estimate implementation costs based on number of patients to be served, per participant costs were aggregated by intervention component (workshop, web meeting, communication with participants, supervision, printed materials, and training) and by role (group leader and assistant).

2.6. Statistical analysis

Baseline demographic and clinical characteristics of participants in the two intervention groups were compared using t-tests for continuous variables and chi-square tests for categorical variables. Given the focus on implementation costs and the finding that KnowIt and OnTrack did not differ in overall effectiveness, analyses focused on describing resource use and costs associated with the main components of each of the two interventions. Analyses were conducted from an intent-to-treat perspective and included all participants who attended the initial workshop. A t-test was used to compare the total costs of the two interventions. While resource use and costs often have skewed distributions, the highly structured nature of the interventions eliminated this skew. Some aspects of the interventions were so structured that little to no variation was observed in their costs, precluding comparison at the component level. For example, group leader supervision occurred at standard, pre-planned intervals and as a result, there was no variation in the supervision costs across leaders or treatment groups. The average, per participant cost per unit change in diabetes distress and HbA1C from baseline to 9 month follow-up, the cost-effectiveness ratio, was calculated by dividing mean total per participant intervention cost by mean change in each outcome measure.

As has been recommended[16] sensitivity analyses were conducted to examine intervention costs under plausible alternative intervention scenarios. While the KnowIt intervention is designed to utilize the specialized skills of Certified Diabetes Educators, the OnTrack intervention could be led by social workers, who often have training and expertise in delivering health-related behavioral interventions similar to that of psychologists, but have lower salaries. To examine the cost difference between these two group leaders, costs were compared again, assuming a social worker, rather than a psychologist as the OnTrack group leader.

3. RESULTS

3.1. Participants

As detailed previously,[12] 301 participants were randomized: 149 to KnowIt and 152 to OnTrack (see Table 1). On average, participants were in their forties, were white and female, and had been diagnosed with T1DM for over 20 years. KnowIt participants were slightly older (mean age 47.3) than OnTrack participants (mean age 42.8) (t_{299}=2.63, p=0.009), but there were no between-group baseline differences in diabetes distress or HbA1C.

3.2. Implementation Resources and Costs

Total intervention cost per participant was $251.4 for KnowIt and $251.5 for OnTrack, with no between-group differences in cost (t=1.71, ns) (Table 2). Although the structure of both interventions limited variation in resource use and costs, there was some variation in the key

intervention components (workshops, online meetings, and communication with participants) due to differences in the needs of participants. In both interventions, the four online meetings accounted for the largest percentage of resources and costs (42%−45%). In both interventions, group leader effort accounted for less than one half of the resources used and two-thirds of the costs incurred. The cost of a one unit decrease in diabetes distress (one point on the T1-DDS) was $364.4 for KnowIt ($251.4/(2.87–2.2)) and $335.3 ($251.5/(2.9–2.2)) for OnTrack. The cost of a 1.0 percentage point decrease in HbA1C (11 mmol/mol) was $1,396.7 for KnowIt ($251.4/(8.77–8.6)) and $1,397.2 for OnTrack ($251.5/(8.8–8.7)).

The length of the online meetings varied considerably, from 10.5 minutes to 77.0 minutes, with a mean length of 40.6 mins (SD=10.9). The actual time spent in each meeting was used to compute intervention cost and there were no differences in meeting length associated with intervention or with the number of participants attending. One component of the structured interventions where there was potential for individual variation in contact time and associated costs was in the telephone contacts between facilitators and participants. Scheduled telephone contacts between online meetings varied considerably in length, ranging from 0 minutes, for missed calls, to 44.0 minutes. However, the mean amount of time devoted to each of the four scheduled telephone contacts was 5.8 minutes (SD=3.1) and there were no statistically significant differences in contact time between KnowIt and OnTrack. Similarly, time devoted to unscheduled telephone contacts ranged from 0 to 41.0 minutes, but the mean per participant time devoted to unscheduled contacts was less than one minute and there were no statistically significant differences in unscheduled telephone contact time between KnowIt and OnTrack. The actual time devoted to each telephone contact was used to compute intervention cost.

Sensitivity analyses examined the impact of replacing the psychologist group leader used in OnTrack with a lower cost social worker with similar expertise. With a social worker as OnTrack leader and a CDE as KnowIt leader, the per participant cost of OnTrack was reduced to $192.4, a cost statistically significantly lower than the cost of KnowIt ($t=32.88$, $p<0.0001$). The associated costs of a unit change in diabetes distress would be $256.5 and in HbA1C was $1,068.9.

In T1-REDEEM, leaders of both OnTrack and KnowIt programs received 14 hours of training. The total cost of training a group leader was $1,535, which included $682 in leader time and $853 in supervisor time. Training a social worker to deliver the OnTrack intervention would cost $954. Project assistants also received 14 hours of training. Six hours of this training was supervised; the assistant's supervisor did not attend the workshop. The total cost of training an assistant was $329 which included $232 in assistant time and $97 in supervisor time.

4. DISCUSSION

This study is the first to examine the costs associated with implementing interventions directly targeting diabetes distress among adults with T1DM. Costs of the two effective group interventions implemented in the T1-REDEEM trial were calculated to be generalizable to implementation in real-world clinical care. No statistically or practically

significant differences in per-participant costs or cost per unit change in diabetes distress or HbA1C were observed between the KnowIt and OnTrack interventions. The per participant cost for both interventions was about $250. The mean cost of a unit decrease in diabetes distress was $364.4 for KnowIt and $335.3 for OnTrack. The cost of a 1.0 percentage point (11 mmol/mol) decrease in HbA1C was about $1,400 for both interventions. Group leader time accounts for two-thirds of intervention costs. Training a single group leader in either intervention cost $1,535. These overall costs are quite modest, especially given the documented effect on distress reduction

As delivered in the T1-REDEEM study, with KnowIt groups led by a certified diabetes educator and OnTrack groups led by a psychologist, both interventions offer similar effectiveness at a similar cost. Sensitivity analyses showed that changing leadership from a psychologist to a social worker would reduce the per participant cost for OnTrack from $256.5 to $192.4, a 24% reduction in cost. Employing social workers as group leaders for OnTrack seems promising. Many social workers receive training in delivering group interventions that are similar to the training psychologists receive. Additionally, most social workers receive training in working in medical care settings and the focus of social work training on “person in environment,” may make them particularly well suited to helping participants develop personal action plans in OnTrack.

The costs of implementing KnowIt and Ontrack compare favorably to published costs of other self-management interventions for diabetes mellitus: in a recent systematic review of similar studies,[13] 5 of 8 studies presented costs comparable to the costs calculated for the T1-REDEEM interventions. Per participant costs ranged from $219, for a telephone intervention delivered by lay health educators,[25] to $5,390, for an intensive intervention that included a residential retreat, and 6 months of weekly, 4-hour, in-person meetings.[26] At a cost of approximately $250 per participant, KnowIt and OnTrack fall in the lower end of the distribution of per participant costs. Three studies included in the systematic review and another study published since the review,[27] considered costs in relation to reduction in HbA1C. The approximately $1,400 cost of a 1.0 percentage point (11 mmol/mol) reduction in HbA1C observed in T1-REDEEM falls near the lower range of costs reported in these studies which, in 2017 dollars, ranged from $605 in the telephone intervention delivered by lay interviewers[25] to $9,539 in the intensive, in-person intervention.[26] None of these studies examined intervention implementation costs in relation to long term outcomes and future research examining the payoff from varying investments in intervention would be of value.

The cost analysis presented here is limited in several respects. The T1-REDEEM study did not examine medical outcomes or medical utilization, thus the associated costs cannot be considered. However, given the similar clinical outcomes observed with both interventions, differences in other, unmeasured clinical outcomes seem unlikely. Also, the focus on implementation costs precluded the examination of costs incurred by patients to participate in the interventions, e.g., time and transportation. The use of online group meetings, however, likely limits patient costs. While the group format used for KnowIt and OnTrack is advantageous in terms of cost, it is not clear how intervention impact might differ in an individualized format. To maximize generalizability, we used national salary costs in our calculations. As a result, areas with lower or higher salary costs would experience somewhat

different implementation costs. Nonetheless, the relative costs of the two interventions and their components are likely to remain the same. Additionally, we did not include staff training costs on a per-participant basis because they are not easily generalizable to different clinical settings where the number of staff trained, and the number of patients they serve, can vary considerably. We have, however, provided these costs so that programs can use them to calculate their training costs taking number of trainees, staff turnover, and number of patients into consideration.

These findings also point to opportunities to optimize the interventions to reduce costs. The T1-REDEEM study initiated both interventions with in-person group workshops. As web-based group interactions become more ubiquitous, participants may be comfortable using web meetings from the beginning, a change that would reduce all costs substantially. Similarly, the number of online meetings could be examined to determine if fewer meetings would yield comparable results.

5. CONCLUSIONS

In conclusion, results show that two group interventions significantly reduce diabetes distress and HbA1C in distressed adults with poorly controlled T1DM, and that both can be implemented at a cost comparable to the costs of telephone interventions delivered by health educators. These two interventions and their costs merit further attention because results of the T1-REDEEM study suggest that high diabetes distress acts as a “barrier” to improved self-management.[12] Thus, interventions like KnowIt and OnTrack that specifically target diabetes distress merit future study to determine whether they have significant effects on long term outcomes.

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Highlights

1. This is the first examination of the implementation costs of interventions targeting diabetes distress and HbA1C in Type 1 diabetes mellitus.
2. Costs were similar for an interventions focused on diabetes education (KnowIt) and diabetes distress (OnTrack).
3. Both interventions, led by professional facilitators, had implementation costs of approximately $250, similar to costs of interventions led by lay health educators.
4. The mean cost of a unit decrease in diabetes distress was $364 for KnowIt and $335 for OnTrack. The mean cost of a 1.0 percentage point (11 mmol/mol) decrease in HbA1C was approximately $1,400 for both interventions.

Table 1

Baseline demographic and clinical characteristics of participants

Characteristic	KnowIt (n=149)	OnTrack (n=152)
	Mean (sd) / n (%)	Mean (sd) / n (%)
Age*	47.3 (14.5)	42.8 (15.1)
Education (years)	15.7 (3.6)	15.2 (3.6)
Age at T1DM diagnosis	21.2 (14.4)	19.5 (13.7)
Years with T1DM	26.1 (14.0)	23.2 (13.3)
Female	105 (70.5%)	103 (67.8%)
White	123 (8.26%)	118 (77.6%)
Diabetes distress (total score)	2.87 (0.63)	2.90 (0.60)
HbA1c %	8.8 (1.13)	8.8 (1.11)
HbA1c mmol/mol	72 (15)	73 (15)

* $p<0.01$

Table 2

Resources and Costs Per Participant

Intervention Component	KnowIt											
	Group Leader				Assistant				Total			
	Minutes		$		Minutes		$		Minutes		$	
	mn	sd	mn	sd	mn	sd	mn	sd	mn	sd	mn	sd
Workshop	57.6	2.9	46.8	2.4	68.6	0	22.6	0	126.1	2.9	69.3	2.4
Online meetings	89.8	18.5	73.0	15.0	108.1	11.8	35.6	3.9	197.9	23.8	108.5	16.2
Communication with participants	28.7	5.2	23.3	4.2	67.7	11.6	22.3	3.8	96.4	12.7	45.6	5.7
Group leader supervision	26.3	0	24.0	0	-	-	-	-	26.3	0	24.0	0
Printed Materials	-	-	-	-	-	-	-	-	-	-	4.0	0
Total	202.3	18.9	167.0	15.4	244.3	18.3	80.4	6.0	446.65	28.1	251.4	17.3
	OnTrack											
	Group Leader				Assistant				Total			
	Minutes		$		Minutes		$		Minutes		$	
	mn	sd	mn	sd	mn	sd	mn	sd	mn	sd	mn	sd
Workshop	57.6	2.3	46.8	1.9	66.2	0	21.8	0	123.9	2.3	68.6	1.9
Online meetings	86.1	18.5	70.0	15.0	115.8	17.1	38.1	5.6	202.0	29.9	108.1	18.0
Communication with participants	28.1	3.1	22.9	2.5	72.0	10.6	23.7	3.5	100.2	11.1	46.6	4.4
Group leader supervision	26.8	0	24.5	0	-	-	-	-	26.8	0	24.5	0
Printed Materials	-	-	-	-	-	-	-	-	-	-	3.7	0
Total	198.7	18.8	164.2	15.2	254.1	23.2	83.7	7.6	452.8	34.6	251.5	19.3