Randomized, Controlled Trial of a Digital Behavioral Therapeutic Application to Improve Glycemic Control in Adults With Type 2 Diabetes

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OBJECTIVE

To evaluate the efficacy and safety of a digital therapeutic application (app) delivering cognitive behavioral therapy (CBT) designed to improve glycemic control in patients with type 2 diabetes.

RESEARCH DESIGN AND METHODS

Adults with type 2 diabetes and an HbA_{1c} of 7 to <11% were randomly assigned to receive access to a digital therapeutic app delivering CBT (BT-001) or a control app, both on top of standard of care management. CBT is an established form of psychological treatment that endeavors to identify and change unhelpful thinking patterns. The primary study end point was treatment group difference in mean HbA_{1c} change from baseline to 90 days.

RESULTS

Among 669 randomly assigned subjects who completed app onboarding, the mean age was 58 years, BMI 35 kg/m^2, 54% were female, 28% Black, and 16% Latino. Baseline HbA_{1c} was 8.2 and 8.1% in the BT-001 and control groups, respectively. After 90 days of app access, change in HbA_{1c} was −0.28% (95% CI −0.41, −0.15) in the BT-001 group and +0.11% (95% CI −0.02, 0.23) in the control group (treatment group difference 0.39%; $P < 0.0001$). HbA_{1c} reduction paralleled exposure to the therapeutic intervention, assessed as the number of modules completed on the app (P for trend <0.0001). No adverse events in either group were attributed to app use and no adverse device effects reported.

CONCLUSIONS

Patients randomly assigned to the BT-001 arm relative to the control arm had significantly lower HbA_{1c} at 90 days. The digital therapeutic may provide a scalable treatment option for patients with type 2 diabetes.

In the U.S., about half of adults with diagnosed diabetes attain an HbA_{1c} <7% (1). Factors contributing to suboptimal glycemic control include inadequate self-care, lack of knowledge and ability to implement recommended behavior changes, and psychiatric comorbidities (2,3). Cognitive behavioral therapy (CBT) is an evidence-based treatment grounded in the idea that all behaviors are learned and that

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dysfunctional core beliefs contribute to errors in processing information, leading to emotional and behavioral dysfunction. Meta-analyses of randomized trials of CBT-based interventions in patients with diabetes have reported HbA_{1c} reductions ranging from 0.3 to 1.6% (4,5). The trials used individual counseling or group interventions delivered in person, by telephone, or internet for periods ranging from 2 weeks to 12 months. The improvement in glycemic control observed with CBT has been attributed to better adherence to lifestyle recommendations and hypoglycemic medication as well as alleviation of depression and anxiety (6,7).

Digital therapeutics delivering behavioral interventions without the need for human intervention have the potential to increase access due to their inherent scalability and reach beyond physical location and scheduling constraints. BT-001 is a digital therapeutic application (app) delivering CBT designed to improve glycemic control in adults with type 2 diabetes via smartphone. An earlier version of the app, when paired with health coaching, reduced self-reported HbA_{1c} by 1.1% after 3 months in a sample of 69 adults with type 2 diabetes (8). A separate pilot study (n = 80) using the BT-001 app alone demonstrated a 23 mg/dL (1.3 mmol/L) fall in fasting blood glucose in a similar time frame (9). We now report the results of a randomized, controlled, open-label trial assessing the efficacy and safety of BT-001 in a larger population.

RESEARCH DESIGN AND METHODS

The trial design and the intervention provided by the BT-001 app have been previously described (10). In brief, adults with type 2 diabetes, with HbA_{1c} 7 to <11% (53–97 mmol/mol) and access to a smartphone, were randomly assigned (1:1) to receive access to BT-001 or a control app for 180 days, both on top of standard of care management. Current smokers were excluded, as were those taking prandial insulin or oral corticosteroids or with active eating disorders. Subjects randomly assigned to both groups were instructed to download their assigned app from the Apple or Android app store and set up an account with username and password; those who did not complete this onboarding activity were excluded from the modified intention-to-treat (mITT) analysis population.

The predominantly automated recruitment process required potential subjects to provide electronic informed consent, complete an online screening questionnaire, and schedule a home visit for phlebotomy. The decentralized study required no in-person clinic visits; a mobile phlebotomy unit collected blood samples and physical measures during home visits using a standardized protocol. Standard of care management was provided via telehealth visits with investigators at days 90 and 180. Both the BT-001 and control groups provided patient-reported outcome data; BT-001–allocated subjects also received access to the CBT content. Antihyperglycemic medications could be adjusted as needed during the study consistent with standard of care, and all concomitant therapies were permitted.

Each week, BT-001 would ask subjects to complete a new behavioral module along with one or more related skill-based exercises. Modules addressed topics such as: personal beliefs and barriers (e.g., those related to a subject's ability to change and control his or her behaviors); beliefs about macronutrients and the importance of various food types; hedonic-related beliefs about pleasant or unpleasant sensations experienced by eating or exercising; and beliefs about exercise.

BT-001 is intended to be prescribed for use between clinic visits within 90-day treatment cycles, each of which includes 13 modules. The CBT content for the second treatment cycle was available during the first treatment cycle if subjects chose to work ahead. They were not required to complete any specific number of modules. BT-001–allocated subjects were asked to record information about their diet and exercise behaviors, perceptions, and beliefs, self-measured blood pressure, and glucose levels within the app. Based on these factors, the app presented a treatment plan summarizing daily and weekly goals to improve their glycemic control.

The primary efficacy end point was the difference in mean HbA_{1c} change from baseline to day 90 among BT-001–allocated subjects compared with those assigned to the control app. Safety assessments included adverse events and adverse device effects. An independent Data Safety Monitoring Committee reviewed data throughout the study.

Statistical Considerations

The planned sample size based on the primary end point was 648 subjects, 324 in each treatment group. The sample size (90% power; α = 0.05) was selected to detect a 0.4% difference in the change from baseline HbA_{1c} between the intervention and control arms assuming a dropout rate of 20%, SD of 1.4% based on prior studies conducted by the sponsor (8,9), and a common SD for the two treatment groups.

The primary end point was assessed in the mITT population by ANCOVA with baseline HbA_{1c} as a covariate. Treatment group differences in biomarker change from baseline were assessed in a similar manner. Change in antihyperglycemic medication was compared by χ^2. Subject-reported fasting blood glucose values were assessed as weekly change from baseline with baseline defined as the first three values after completion of onboarding. Weekly values were the mean of all values entered during the week. Fasting glucose trend was assessed by linear regression. The mITT population included all randomly assigned subjects who completed the onboarding process for their assigned app. Safety assessments were also conducted on the mITT population. Analyses for this study were independently conducted by CPC Clinical Research, an academic research organization affiliated with the University of Colorado, using the academic statistical analysis plan and SAS version 9.4.

RESULTS

Between April and December 2021, 725 subjects were randomly assigned at 12 sites in the U.S. App onboarding, which involved downloading the assigned app and setting up an account with an e-mail address and password, was completed by 669 subjects (BT-001, 326; control app, 343) who constituted the mITT population (Supplementary Fig. 1). Of these, 610 subjects (91%) had paired baseline and day 90 HbA_{1c} values (BT-001, 291; control app, 319). During the 90-day treatment period, 14 subjects in the BT-001 group (4%) withdrew consent and 12 (4%) were lost to follow-up; in the control app group, 9 (3%) withdrew consent and 6 (2%) were lost to follow-up.

Demographics and baseline characteristics are summarized (Table 1); no

Table 1—Baseline characteristics

	BT-001	Control app
N	326	343
Age, years, mean (SD)	57 (9)	58 (8)
Female, *n* (%)	176 (54)	190 (55)
Race, *n* (%)		
White	189 (59)	201 (59)
Black or African American	89 (28)	98 (29)
Asian	13 (4)	15 (4)
American Indian or Alaskan Native	3 (1)	3 (1)
Native Hawaiian or other Pacific Islander	1 (0.3)	1 (0.3)
Other (includes multiple races) or not reported	26 (8)	25 (7)
Hispanic or Latino ethnicity, *n* (%)	50 (17)	41 (13)
BMI, kg/m^2, mean (SD)	35 (7)	35 (7)
Weight, kg, mean (SD)	99 (20)	101 (24)
Systolic blood pressure, mmHg, mean (SD)	127 (15)	126 (14)
Diastolic blood pressure, mmHg, mean (SD)	78 (10)	78 (9)
Using antihypertensive medication, *n* (%)	202 (63)	233 (68)
Total cholesterol, mmol/L, mean (SD)	4.4 (1.1)	4.4 (1.2)
HDL-C, mmol/L, mean (SD)	1.2 (0.3)	1.2 (0.3)
LDL-C, mmol/L, mean (SD)	2.4 (0.9)	2.4 (0.9)
Triglycerides, mmol/L, mean (SD)	2.2 (1.5)	2.3 (4.3)
HbA_{1c}, %, mean (SD), mmol/mol, mean	8.2 (0.1), 66	8.1 (0.1), 65
Fasting blood glucose, mmol/L, mean (SD)	9.4 (3.2)	9.3 (3.0)
Years since diagnosis of diabetes, mean (SD)	11 (8)	11 (8)
Number of antihyperglycemic medications, mean (SD)	2.1 (1.1)	2.1 (1.1)

$P > 0.05$ for all treatment group comparisons. HDL-C, HDL-cholesterol; LDL-C, LDL-cholesterol.

statistically significant differences between treatment groups were observed. Mean age was 58 ± 9 years in both treatment groups (range 31–75 years), and BMI was 35 ± 7 kg/m^2. The cohort included 56% women and 28% Black, 5% Asian, and 16% Latino subjects with similar proportions in the two treatment groups. Baseline HbA_{1c} was 8.2 ± 1.0% (66 mmol/mol) in the BT-001 group and 8.1 ± 1.0% (65 mmol/mol) in the control group. The mean number of antihyperglycemic medications at baseline was 2.1 ± 1.1 in both groups. Metformin use was reported by 90%, sulfonylurea by 42%, basal insulin by 22%, glucagon-like peptide 1 agonists by 35%, and sodium–glucose cotransporter 2 inhibitors by 31% (Supplementary Table 1).

From baseline to day 90, HbA_{1c} decreased 0.28% (95% CI −0.41, −0.15) in the BT-001 group and increased 0.11% (95% CI −0.02, 0.23) in the control group (treatment group difference −0.39 [95% CI −0.57, −0.20]; $P < 0.0001$) (Fig. 1, left panel). The magnitude of HbA_{1c} reduction in the BT-001 group increased in parallel with exposure to the therapy, as indicated by the number of modules completed (Fig. 1, right panel) (P for trend <0.0001). Subjects completed an average of eight modules during the 90-day treatment period.

Subjects in the BT-001 group recorded physical activity, plant-based meals, and fasting glucose values an average of 5, 5, and 6 days/week, respectively. Fasting glucose recorded in the app trended downward (Fig. 2) (P for trend <0.0001), consistent with central laboratory glucose (Table 2) and HbA_{1c} results. During the 90-day treatment period, 48 subjects (7%) increased and 10 (1%) decreased the dose or number of their antihyperglycemic medications (increase: control, 28 and BT-001, 20; decrease: control, 7 and BT-001, 3; $P = 0.29$).

After 90 days of exposure to their assigned app, weight, blood pressure, and plasma lipids were lower in the BT-001 group compared with the control group, although none of the treatment group differences were statistically significant (Table 2).

Adverse events were reported by 76 (22%) of subjects in the control and 68 (21%) in the BT-001 group with most mild or moderate in severity. The most commonly reported adverse events were coronavirus disease 2019 (13 subjects in each group) and headache (BT-001, 3; control, 9). Hypoglycemia was reported by two subjects in the BT-001 group and none in the control group. No patient reported treatment-emergent depression; anxiety was reported by four and six subjects in the BT-001 and control groups, respectively. Serious adverse events were reported by 10 (3%) and 4 (1%) of patients in the control and BT-001 groups, respectively. The only category with more than one serious adverse event was for injury, poisoning, and procedural complications. None of the adverse events were attributed to app use, and no adverse device effects were reported.

CONCLUSIONS

In adults with type 2 diabetes, CBT delivered via a digital therapeutic app lowered HbA_{1c} by 0.39% ($P < 0.0001$) at 90 days compared with a control app, both on top of standard of care. A dose response was observed; subjects with greater exposure to the therapy demonstrated greater HbA_{1c} reduction (P for trend <0.0001). In parallel, glucose levels fell with exposure to BT-001 (P for trend <0.0001). Fewer adverse events were reported with BT-001 compared with the control app, and no adverse device effects were reported.

A strength of the study is the demographic profile of the cohort, which is generally representative of adults with diabetes in the U.S. (11). In particular, the cohort included 28% Black, 4% Asian, and 14% Latino subjects as well as 55% women. Another strength is the real-world setting of the study conduct, facilitated by the decentralized, pragmatic study design, including the lack of restrictions on concurrent diabetes management and entirely remote study conduct. The latter enabled participation of rural residents as well as persons with mobility, transportation, or childcare constraints. Despite the entirely remote

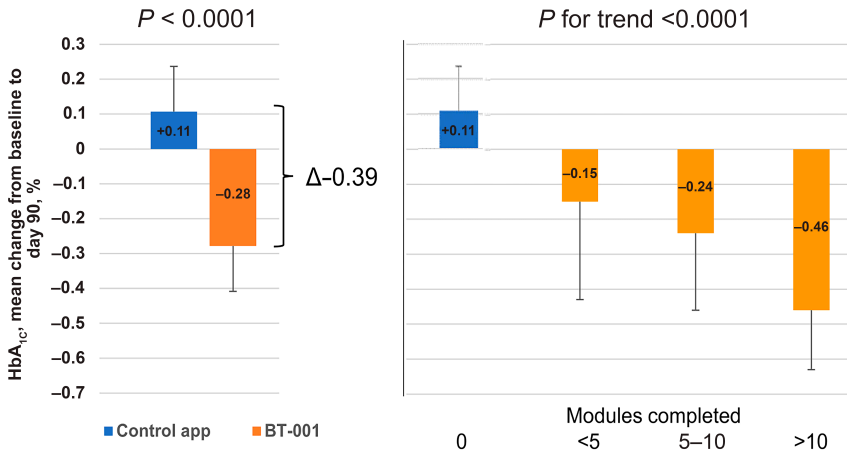

Figure 1—Treatment group difference in HbA_{1c} change from baseline to day 90. HbA_{1c} (mean, 95% CI) change from baseline to day 90 by randomized treatment group, adjusted for baseline HbA_{1c} (left panel). HbA_{1c} change from baseline to day 90, adjusted for baseline HbA_{1c}, by tertile of CBT modules completed in the BT-001 app (right panel). Subjects assigned to the control app completed no modules (blue bars; n = 319); orange bars show HbA_{1c} change among BT-001–allocated subjects by tertile of modules completed (n = 91, 99, and 101 for <5, 5–10, and >10 modules, respectively).

study conduct, rates of withdrawal and loss to follow-up were low. Although permitted, adjustments to antihyperglycemic medication were infrequent and similar between treatment groups during the 90-day treatment period. The impact of BT-001 on medication use may become clearer with longer follow-up.

A limitation of the study is the decentralized enrollment process, which may have selected a more motivated cohort than expected in clinical practice, potentially overestimating the efficacy of BT-001. The observation that subjects completing more modules had greater HbA_{1c} reduction supports the importance of engagement, consistent with in-person CBT (12) and behavioral interventions in general (3). Other limitations include the exclusion of non-English speakers, as the app is currently only available in English, and the exclusion of current smokers, a group comprising 14% of adults with diabetes (1), who might be expected to benefit from improved glycemic control. This gap will be addressed in ongoing studies of BT-001 (NCT05266625, NCT05302050, and NCT05094401), which include current smokers. Allowing adjustment of antihyperglycemic medication during the 90-day treatment period incurred the risk of attenuating the treatment group difference in HbA_{1c}, although medication changes were similar between groups. The fasting blood glucose levels reported within BT-001 reflect intrinsic limitations of glucometer measurements as well as potential reporting bias, although they are consistent with the central laboratory glucose results, suggesting that selective reporting was not an issue.

The observed HbA_{1c} reduction of 0.4% at 90 days with BT-001 can be assessed alongside randomized trials of in-person CBT for glycemic control. In a meta-analysis of 23 trials with 2,619 patients, HbA_{1c} change from baseline in patients with type 2 diabetes ranged from +0.2% to −1.09% with an overall difference of −0.3% (95% CI −0.4, −0.1; $P < 0.01$) (4). Another meta-analysis of 20 nonoverlapping trials with 2,900 patients found

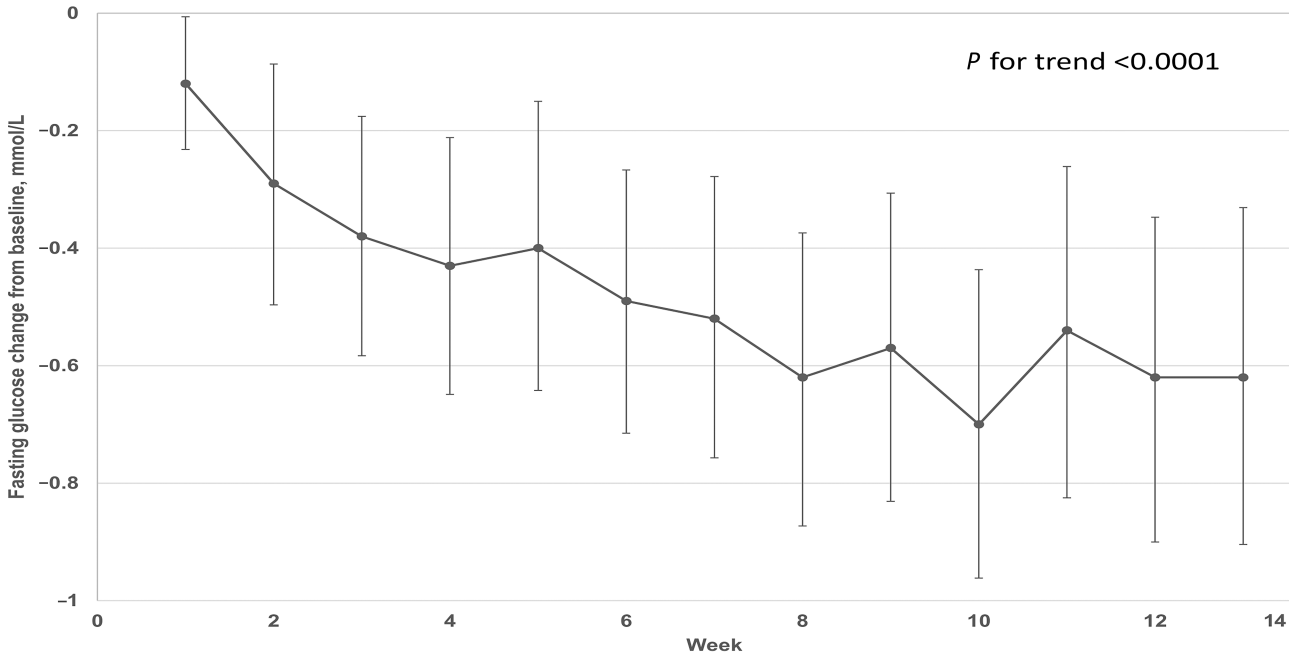

Figure 2—Fasting glucose levels change from baseline (mean, 95% CI). Fasting glucose levels reported in the BT-001 app are shown as the mean of each subject's change from baseline by week. Baseline glucose was defined as the mean of the first three values recorded. Weekly glucose levels are the mean of values recorded by individual subjects each week. Subjects were not required to record any particular number of glucose values; on average, subjects recorded six values per week.

Table 2—Weight, blood pressure, and plasma lipids: change from baseline to day 90 by treatment group

	BT-001		Control app	
	n	Change from baseline	*n*	Change from baseline
Weight, kg	200	−1.5 (6.3)	230	−1.0 (5.5)
Blood pressure, mmHg	200		228	
Systolic		−3.0 (15.4)		−1.0 (14.2)
Diastolic		−1.5 (9.7)		−1.0 (9.8)
Lipids, mmol/L	183		205	
Total cholesterol		−0.13 (0.74)		−0.08 (0.87)
HDL-C		−0.01 (0.15)		0.02 (0.15)
LDL-C		−0.11 (0.58)		−0.06 (0.70)
Triglycerides		−0.15 (0.90)		−0.05 (1.31)
Fasting glucose, mmol/L[a]	217	−0.68 (3.49)	232	−0.07 (3.28)

HDL-C, HDL-cholesterol; LDL-C, LDL-cholesterol. [a]$P < 0.05$.

treatment group differences ranging from +0.74 to −1.66% with an overall difference of −0.97 (95% CI −1.37, −0.57; $P < 0.0001$) (5). The duration of CBT in these studies ranged from 2 weeks to 12 months and was delivered individually or in group settings. Baseline HbA_{1c} levels varied, as did management of the control group. The magnitude of HbA_{1c} reduction observed with BT-001 appears generally in line with studies of CBT delivered in person. The relationship between improved glycemic control and increased consumption of plant-based meals as well as minutes of physical activity with CBT will be evaluated, as this trial completes 180 days of follow-up and in conjunction with ongoing studies of BT-001.

Cardiovascular risk reduction is one goal of glycemic control; HbA_{1c} reductions >0.3% have been associated with reductions in major cardiovascular events, with the magnitude of fall in HbA_{1c} paralleling risk reduction (13). The least squares mean HbA_{1c} 0.39% reduction observed with BT-001 was for the overall cohort. In the current study, patients who engaged more with the app, using modules completed as a surrogate for engagement, achieved greater HbA_{1c} reduction. As data accrue from ongoing real-world clinical studies of the app, characteristics of patients likely to engage with the app will be sought with the potential aim of targeting those likely to achieve the greatest benefit. Cardiovascular risk reduction occurs over a lengthy period. Whether the digital therapeutic app has a durable effect on behavior is currently being assessed. If HbA_{1c} reduction persists after completion of one or more cycles of treatment, this would contrast with medications that are only effective while being taken. The current study is assessing use of the app through 180 days, whereas ongoing real-world clinical studies will collect follow-up data for up to 2 years.

Modest, nonstatistically significant reductions in body weight, blood pressure, and lipids were observed with BT-001 compared with the control app. The magnitude of change in these biomarkers may reflect the limited duration of the intervention as well as the fact that average values for most exploratory markers were near normal at baseline, likely due to significant concurrent medication use, and thus, the study was not powered to detect significant changes in these biomarkers at 90 days. These findings do provide reassurance that BT-001 is not having an unwished-for impact.

In contrast to diabetes-focused smartphone apps that catalog foods' nutritional content or organize individuals' finger-stick glucose or physical activity data (14), digital therapeutic apps delivering CBT are therapeutic. The intervention is complementary to concurrent pharmacotherapy and has the potential advantage of leveraging the close relationship people have with their smartphones (15). Engagement is built and reinforced by manual input of biomarker values, reporting of plant-based meals (10) and minutes of physical activity, completion of modules and skill exercises, and by receiving individualized encouragement and feedback from the app.

In contrast to in-person CBT, the digital therapeutic is available at any time in the user's pocket. Delivery of a cognitive behavioral intervention via smartphone app can provide a scalable option for improving glycemic control.

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Better Therapeutics, Inc. reviewed the manuscript before submission, but the co-authors maintained the authority of final approval of the manuscript to submit for publication. Statistical analyses were independently conducted by CPC Clinical Research.

Duality of Interest. Study funding was provided by Better Therapeutics, Inc., J.H. owns AstraZeneca stock. N.L.G. and M.A.B. are employees of Better Therapeutics, Inc. and own stock in the company. P.L. is a consultant for Better Therapeutics, Inc., D.D. is an employee of Clinical Trials of Texas, which receives research funding from Better Therapeutics, Inc. J.H., A.G., and M.P.B. are employees of CPC Clinical Research, a nonprofit academic research organization affiliated with the University of Colorado that receives research grant/consulting funding from: Abbott Laboratories, Agios, Alexion Pharmaceuticals, Alnylam Pharmaceuticals, Amgen, Angionetics, Anthos Therapeutics, ARCA Biopharma, Array BioPharma, AstraZeneca, Atentiv Health, Audentes, Bayer, Better Therapeutics, Inc, Bristol-Myers Squibb, Cardiol Therapeutics, CellResearch Corp., Cook Medical, Cook Regentec, CSL Behring, Eidos Therapeutics, EP Trading Co., Esperion Therapeutics, Everly Health, Faraday Pharmaceuticals, Fortress Biotech, Inc, HDL Therapeutics, Inc., HeartFlow, Hummingbird Bioscience, Insmed, Janssen, Kowa Research Institute, Inc., Lexicon Pharmaceuticals, Inc., Merck, Medtronic, Moderna, Novate Medical, Novo-Nordisk, Pfizer, PhaseBio, PPD Development, Prothena Biosciences, Regeneron Pharmaceuticals, Regio Biosciences, Sanifit Therapeutics, Sanofi, Smith+Nephew, Stealth BioTherapeutics, and WraSer Pharmaceuticals. M.P.B. receives consulting fees from Audentes and owns stock in Medtronic and Pfizer. No other potential conflicts of interest relevant to this article were reported.

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