UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 15, 2022

BETTER THERAPEUTICS, INC.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39864**	**85-3472546**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

548 Market Street #49404
San Francisco, California **94104**
(Address of principal executive offices) **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (415) 887-2311

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	**BTTX**	**Nasdaq Capital Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Information.

On March 15, 2022, Better Therapeutics, Inc. (the "Company") announced results from its clinical trial of BT-001, a prescription digital therapeutic platform that uses digitally delivered cognitive behavioral therapy to treat type 2 diabetes. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

On March 15, 2022, the Company expects to use a corporate presentation on primary endpoint data from its clinical trial of BT-001 for its investor call. A copy of the corporate presentation is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued by Better Therapeutics, Inc., dated March 15, 2022
99.2	Corporate Presentation of Better Therapeutics, Inc., dated March 15, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Better Therapeutics, Inc.

Dated: March 15, 2022

By: /s/ Mark Heinen
Name: Mark Heinen
Title: Chief Financial Officer

Exhibit 99.1

Better Therapeutics Announces Positive Primary Endpoint Data from Pivotal Clinical Trial of BT-001, a Prescription Digital Therapeutic (PDT) for Patients with Uncontrolled Type 2 Diabetes

Data Demonstrates Clinically Meaningful and Statistically Significant Results, Improving Glycemic Control by Reducing A1c 0.4% Versus the Control Group Receiving Standard of Care

SAN FRANCISCO, March 15, 2022 – Better Therapeutics, Inc. ("Better Therapeutics", NASDAQ: BTTX), a prescription digital therapeutics company developing nutritional cognitive behavioral therapy (nCBT) to address the root causes of cardiometabolic diseases, today announced primary endpoint data from its pivotal trial of BT-001, a first-in-class investigational PDT platform that is designed to use digitally delivered nCBT to treat type 2 diabetes.

The open label, randomized, controlled, parallel group trial enrolled 669 adults with type 2 diabetes and mean baseline A1c of 8.1%. Participants were randomized to receive standard of care with or without BT-001 and the primary efficacy endpoint was the difference in mean change from baseline in A1c after 90 days of treatment between the two groups. Following is an overview of key takeaways from the 90-day data:

- The clinical trial included a diverse, nationally representative patient population including participants from minority groups often underrepresented in diabetes studies. 40.2% of participants were non-white; 15.7% were Hispanic or Latin American.
- Participants had long-standing type 2 diabetes, high cardiovascular risk, multiple comorbidities with use of multiple medications.
- The primary efficacy endpoint (n=602) showed highly statistically significant improvement in A1c between the intervention and control groups (-0.4%, $p < 0.001$).
- Clinically meaningful changes (A1c reductions of 0.4% or more) occurred in 42.7% of the group receiving standard of care and BT-001 vs. 25.4% in the group receiving standard of care alone (difference of 17.3%, $p < 0.001$); we believe this demonstrates use of BT- 001 significantly improved A1c compared to standard of care alone.
- There was a clear dose-response between greater engagement in nCBT and greater reductions in A1c, supporting nCBT as a mechanism of action.
- Measures of patient engagement, adherence, persistence, and satisfaction were all positive.
- No meaningful differences in safety events were observed between groups.

The six-month trial is ongoing and is expected to be completed in Q2 2022. Given the compelling benefit-to-risk profile of BT-001 and highly statistically significant 0.4% reduction in A1c, Better Therapeutics intends to file a De Novo classification request with the FDA upon completion of the study.

“The data we’re unveiling today is a critical step in our journey to reimagine how cardiometabolic diseases are treated. By demonstrating that BT-001 can improve glycemic control at 90 days by addressing the behaviors that are root causes of type 2 diabetes, even in a very sick, poorly controlled population with long-standing diabetes, we not only open a new avenue of potential treatment, but a new horizon for non-pharmaceutical approaches to care,” said Dr. Mark Berman, chief medical officer of Better Therapeutics. “If these positive trends continue, we see the potential to advance PDTs to improve health and reduce reliance on medications.”

“The existing treatment paradigm for type 2 diabetes relies almost exclusively on the use of traditional medications to address the symptoms of the disease, while doing very little about the behaviors that are the underlying causes. We created nutritional CBT delivered as a prescription digital therapeutic to fill a known gap in clinical care,” said Kevin Appelbaum, co- founder and CEO of Better Therapeutics. “This primary endpoint data for BT-001 suggests that we are not only on the right track for creating a safe and effective treatment for type 2 diabetes, but that nutritional CBT may offer potential across a broad range of cardiometabolic conditions.”

Better Therapeutics intends to advance its product pipeline candidates BT-002 and BT-003, for the treatment of hypertension and hyperlipidemia, respectively, to pivotal trials after the completion of its pivotal trial in type 2 diabetes. The company will soon begin clinical research in fatty liver disease to understand the potential of nCBT as a potential treatment.

BT-001 is part of a new class of PDTs that are increasingly garnering interest from health care providers and payers. The Center for Medicare and Medicaid Services recently established new codes aimed at making it easier for providers to adopt and integrate these innovative therapies into their care regimens. And just last week, the bipartisan, bicameral *Access to Prescription Digital Therapeutics Act of 2022* was introduced in Congress. If passed, this legislation would create a new benefit category within Medicare to cover and reimburse PDTs. Type 2 diabetes is the largest cost driver among government payers, including Medicare, Medicaid, and the Veterans Health Administration, with 40% of type 2 diabetes patients obtaining their insurance through Medicare. Medicare coverage would represent upside to the company’s financial projections.

Investor Conference Call and Webcast

Better Therapeutics management will host an investor conference call and webcast today, March 15 at 8:30 a.m. ET to discuss the BT-001 data announcement and related corporate updates. The conference call may be accessed by dialing +1 (833) 945-2463 and entering the conference ID: 7299550. The live webcast may be accessed by visiting the event link at: https://edge.media-server.com/mmc/p/u4w9dpwb. Following the webcast, a replay of the webcast may be accessed from the Investor Relations section of the Better Therapeutics corporate website at: investors.bettertx.com.

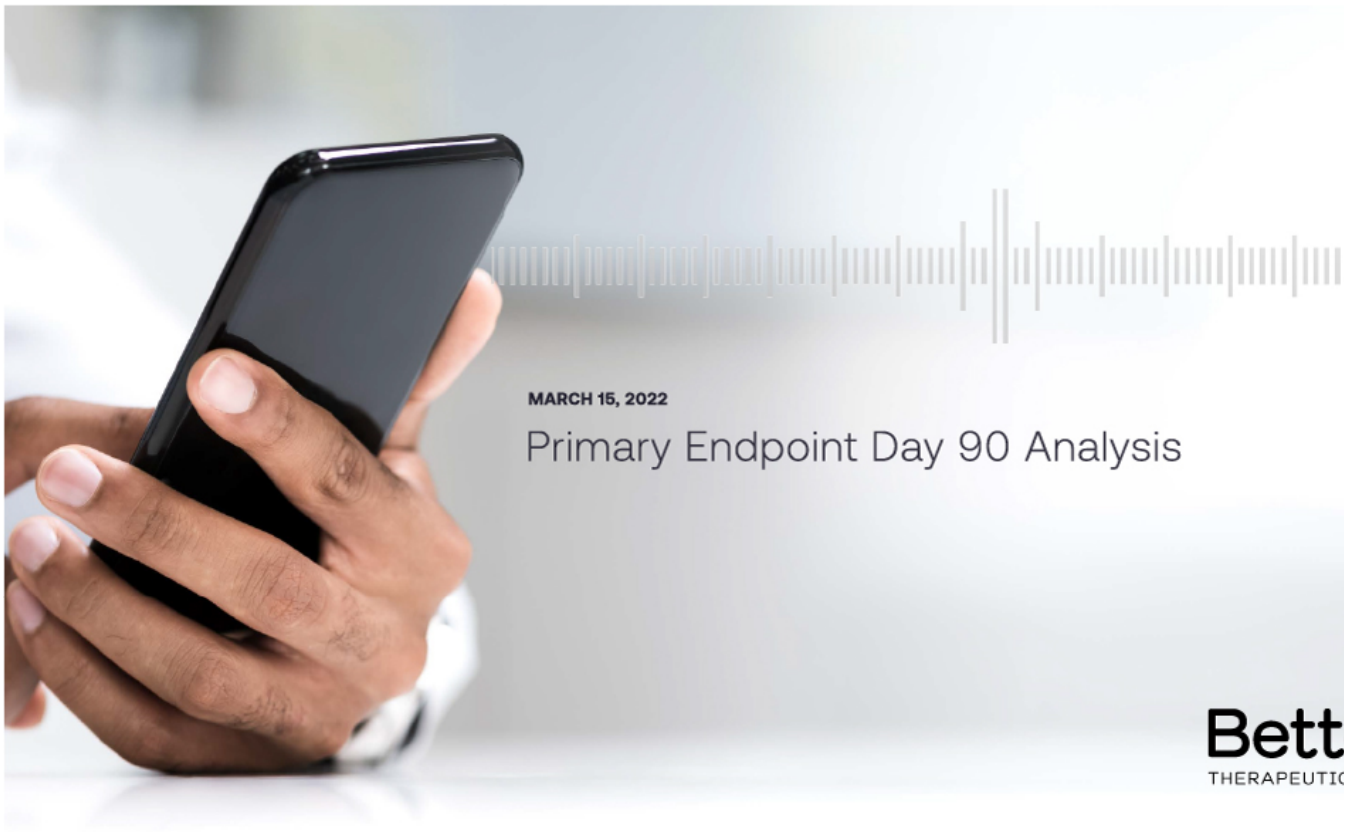
About Better Therapeutics

Better Therapeutics is a prescription digital therapeutics (PDT) company developing a novel form of cognitive behavioral therapy to address the root causes of cardiometabolic diseases. The company has developed a proprietary platform for the development of FDA-regulated, software-based solutions for type 2 diabetes, heart disease and other conditions. The cognitive behavioral therapy delivered by Better Therapeutics' PDT is designed to enable changes in neural pathways of the brain so lasting changes in behavior become possible. Addressing the underlying causes of these diseases has the potential to dramatically improve patient health while lowering healthcare costs. Better Therapeutics investigational mobile applications are intended, if authorized for marketing, to be prescribed by physicians and reimbursed like traditional medicines.

For more information visit: bettertx.com

Forward-Looking Statements

Certain statements made in this press release are "forward-looking statements" within the meaning of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements are typically identified by words such as "plan," "believe," "expect," "anticipate," "intend," "outlook," "estimate," "forecast," "project," "continue," "could," "may," "might," "possible," "potential," "predict," "should," "would" and other similar words and expressions, but the absence of these words does not mean that a statement is not forward-looking. The forward-looking statements in this press release include, but are not limited to, statements regarding the timing and results of the ongoing trial of BT- 001 in patients with type 2 diabetes, Better Therapeutics' plans regarding FDA submissions, expectations related to the potential benefits of BT-001 and CBT and their potential treatment applications, Better Therapeutics' plans regarding the research and advancement of its product candidates for additional treatments, expectations related to the interest of healthcare providers and payers in PDTs and legislative developments affecting PDTs and the outcome of such developments, among others. These forward-looking statements are based on the current expectations of the management of Better Therapeutics and are inherently subject to uncertainties and changes in circumstances and their potential effects and speak only as of the date of such statement. There can be no assurance that future developments will be those that have been anticipated. These forward-looking statements involve a number of risks, uncertainties or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements including: risks related to Better Therapeutics' business, such as the willingness of the FDA to authorize PDTs for commercial distribution and insurance companies to reimburse their use, market acceptance of PDTs, the risk that the results of previously conducted studies will not be repeated or observed in ongoing or future studies involving our product candidates and other risks and uncertainties included under the header "Risk Factors" in the definitive proxy statement/prospectus filed by us on October 12, 2021.


MARCH 15, 2022
Primary Endpoint Day 90 Analysis
Bett
THERAPEUTIC

Disclaimer

This presentation ("Presentation") is for informational purposes only. The information contained herein does not purport to be all-inclusive and neither Better Therapeutics, Inc. ("Better "Company") nor any of its respective affiliates nor any of its or their control persons, officers, directors, employees or representatives makes any representation or warranty, express or the accuracy, completeness or reliability of the information contained in this Presentation. You should consult your own counsel and tax and financial advisors as to legal and related r concerning the matters described herein, and, by accepting this Presentation, you confirm that you are not relying upon the information contained herein to make any decision. The re rely upon any statement, representation or warranty made by any other person, firm or corporation in making its investment or decision to invest in the Company. Neither the Compar respective affiliates nor any of its or their control persons, officers, directors, employees or representatives, shall be liable to the reader for any information set forth herein or any actior taken by any reader, including any investment in shares of the Company.

Certain information contained in this Presentation relates to or is based on studies, publications, surveys and the Company's own internal estimates and research. In addition, all of the included in this Presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while the C believes its internal research is reliable, such research has not been verified by any independent source. This meeting and any information communicated at this meeting are strictly c should not be discussed outside your organization.

Forward-Looking Statements.

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Better


Better
THERAPEUTICS

Baseline Characteristics

Diverse, nationally representative patient population recruited from 6 states

Parameter / Category	Statistic	Standard of Care (n=343)	BT-001 (n=326)	Ov (n=
Age (yrs)	Mean	57.5	57.6	5
% Female	%	56.3%	56.1%	56
Race	%			
White		60.1%	59.5%	59
Black or African American		28.3%	28.5%	28
Asian		5.0%	4.0%	4
American Indian or Alaskan Native		0.9%	1.2%	1.
Native Hawaiian or Other Pacific Islander		0.3%	0.3%	0
Ethnicity - Hispanic or Latino	%	14.0%	17.5%	15
Median Household Income	Median	$61,330	$64,228	$6
% High school degree only, and some college but no degree	%	40.8%	37.7%	39

Better

Baseline Characteristics

Participants had long-standing T2 diabetes, high cardiovascular risk, multiple comorbidities and extensive medication use

Parameter / Category	Statistic	Standard of Care (n=343)	BT-001 (n=326)	Ov (n=
BMI (kg/m²)	Mean	35.0	35.0	3
Baseline HbA1c (%)	Mean	8.1%	8.2%	8
Years Since Diagnosis	Mean	10.9	11.0	1
% on 2 or More Antihyperglycemic Medications	%	69.9%	69.0%	69
Using Antihypertensive Medications	%	71.1%	67.5%	69
% on 2 or More Number of Antihypertensive Medications (1)	%	66.5%	69.0%	67
10 Year CV Risk Score	Mean	15.1%	15.1%	15
Number of Comorbidities	Mean	2.7	2.8	2

(1) For those treated for hypertension (67.5% of participants)

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Change in A1c (-0.4%) was Clinically Meaningful and Highly Statistically Significant

	Statistic	Standard of Care (n=307)	BT-001 (n=295)	Difference	P-valu
Baseline	Mean (SD)	8.1% (0.9)	8.2% (0.9)		
Day 90	Mean (SD)	8.2% (1.4)	7.9% (1.3)		
Day 90, Change From Baseline					
- Intent to Treat Population	Mean (SD)	0.1% (1.2)	-0.3% (1.1)	0.4%	<0.00
- Per Protocol Population	Mean (SD)	0.1% (1.1)	-0.3% (.9)	0.4%	<0.00
Decreased by 0.4% or more	% of Group	25.4%	42.7%	17.3%	<0.00

Better+

Safety Data Summary

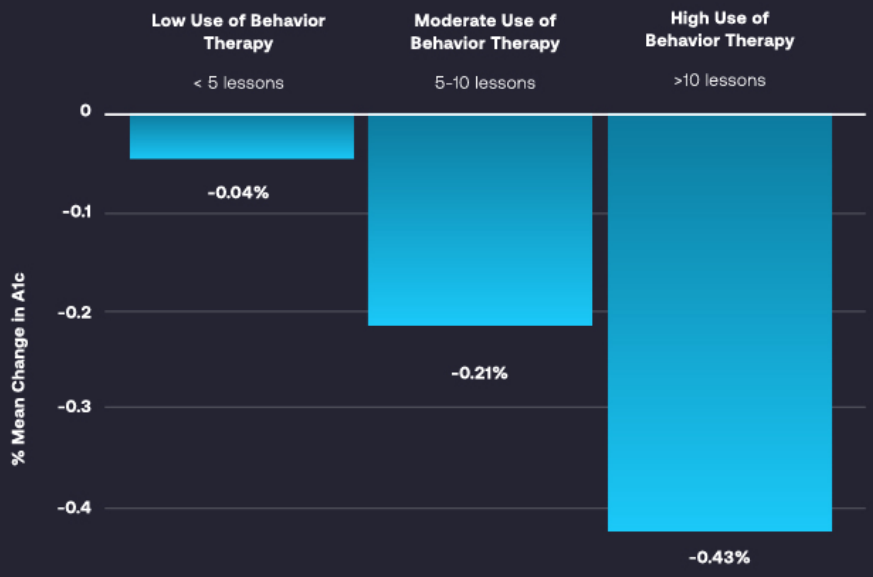
Study demonstrates expected profile in T2DM population. No meaningful differences between groups. No events related to BT-001 device.

	Standard of Care (n=343)		BT-001 (n=326)		Overall (n=669)	
Number of Subjects who Experienced:	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Even n
A TEAE (Treatment-Emergent Adverse Event)	76 (22.2%)	113	68 (20.9%)	111	144 (21.5%)	224
A Serious TEAE	10 (2.9%)	10	4 (1.2%)	4	14 (2.1%)	14
A TEAE Possibly/Probably Related to Study Intervention	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0
A TEAE that is Related to Medical Software	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0

Better+

Dose Response of nCBT

Higher dose associated with larger improvements, without increased adverse events



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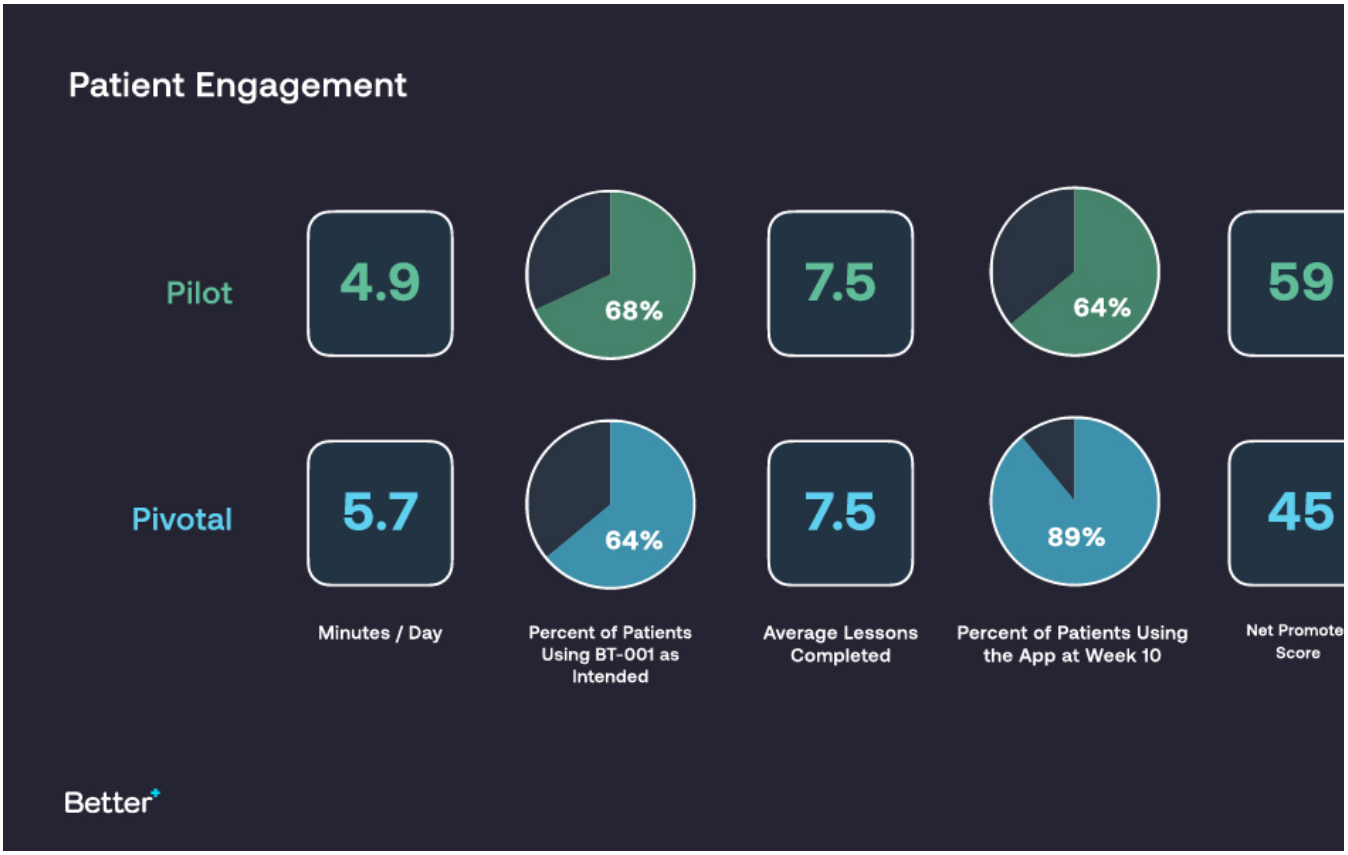
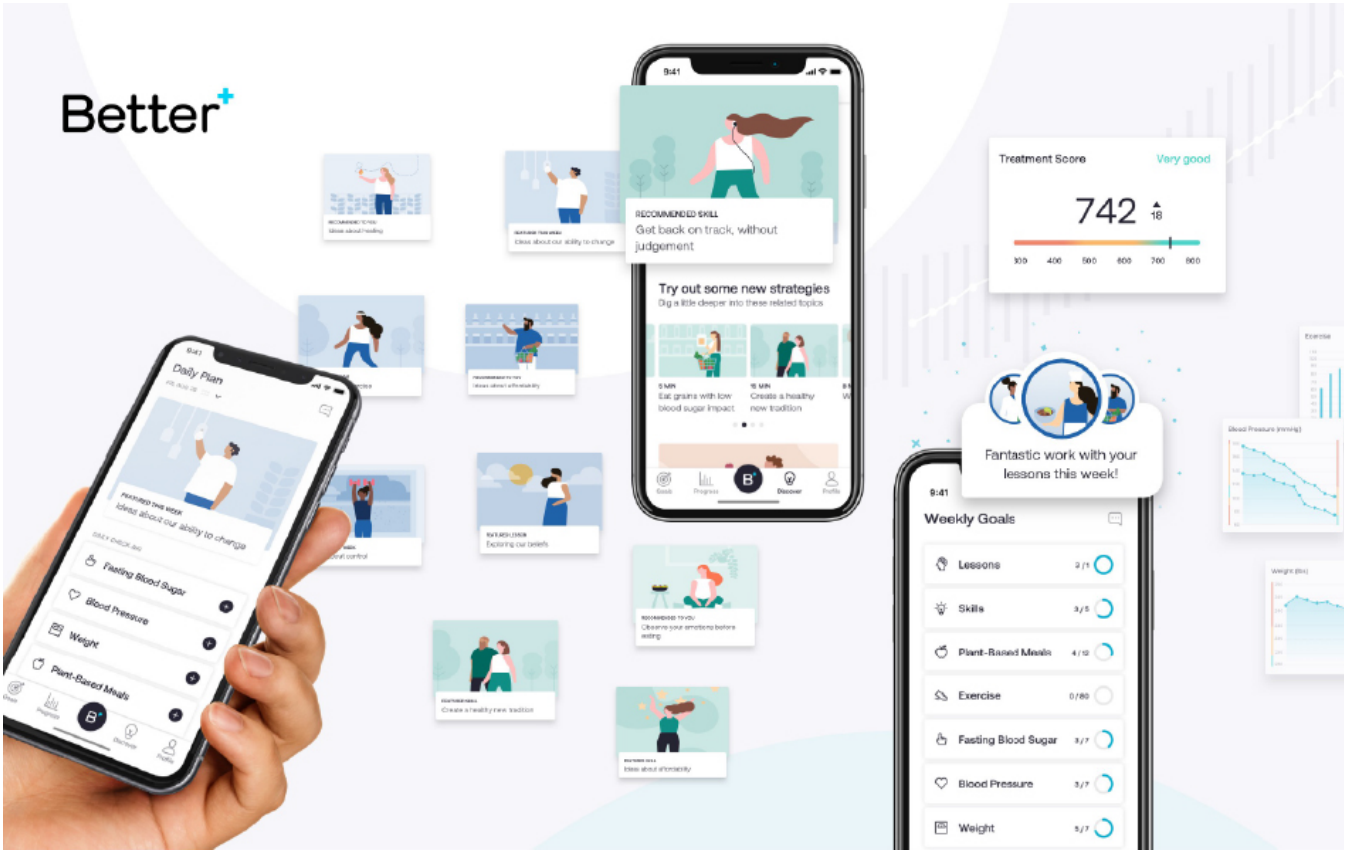

Patient Engagement
Pilot
4.9
68%
7.5
64%
59
Pivotal
5.7
64%
7.5
89%
45
Minutes / Day
Percent of Patients Using BT-001 as Intended
Average Lessons Completed
Percent of Patients Using the App at Week 10
Net Promote Score
Better


Better
Daily Plan
Fasting Blood Sugar
Blood Pressure
Weight
Plant-Based Meals
RECOMMENDED SKILL
Get back on track, without judgement
Try out some new strategies
Dig a little deeper into these related topics
5 MIN
Eat grains with low blood sugar impact
15 MIN
Create a healthy new tradition
Treatment Score
Very good
742
18
Fantastic work with your lessons this week!
Weekly Goals
Lessons
Skills
Plant-Based Meals
Exercise
Fasting Blood Sugar
Blood Pressure
Weight