



MARCH 15, 2022

Primary Endpoint Day 90 Analysis

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THERAPEUTICS

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Baseline Characteristics

Diverse, nationally representative patient population recruited from 6 states

Parameter / Category	Statistic	Standard of Care (n=343)	BT-001 (n=326)	Overall (n=669)
Age (yrs)	Mean	57.5	57.6	57.5
% Female	%	56.3%	56.1%	56.2%
Race	%			
White		60.1%	59.5%	59.8%
Black or African American		28.3%	28.5%	28.4%
Asian		5.0%	4.0%	4.5%
American Indian or Alaskan Native		0.9%	1.2%	1.0%
Native Hawaiian or Other Pacific Islander		0.3%	0.3%	0.3%
Ethnicity - Hispanic or Latino	%	14.0%	17.5%	15.7%
Median Household Income	Median	\$61,330	\$64,228	\$62,723
% High school degree only, and some college but no degree	%	40.8%	37.7%	39.4%

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)	Overall (n=669)
BMI (kg/m ²)	Mean	35.0	35.0	35.0
Baseline HbA1c (%)	Mean	8.1%	8.2%	8.1%
Years Since Diagnosis	Mean	10.9	11.0	11.0
% on 2 or More Antihyperglycemic Medications	%	69.9%	69.0%	69.3%
Using Antihypertensive Medications	%	71.1%	67.5%	69.4%
% on 2 or More Number of Antihypertensive Medications ⁽¹⁾	%	66.5%	69.0%	67.7%
10 Year CV Risk Score	Mean	15.1%	15.1%	15.1%
Number of Comorbidities	Mean	2.7	2.8	2.7

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

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

	Statistic	Standard of Care (n=307)	BT-001 (n=295)	Difference	P-value
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%	<0.001
- Per Protocol Population	Mean (SD)	0.1% (1.1)	-0.3% (.9)	0.4%	<0.001
Decreased by 0.4% or more	% of Group	25.4%	42.7%	17.3%	<0.001

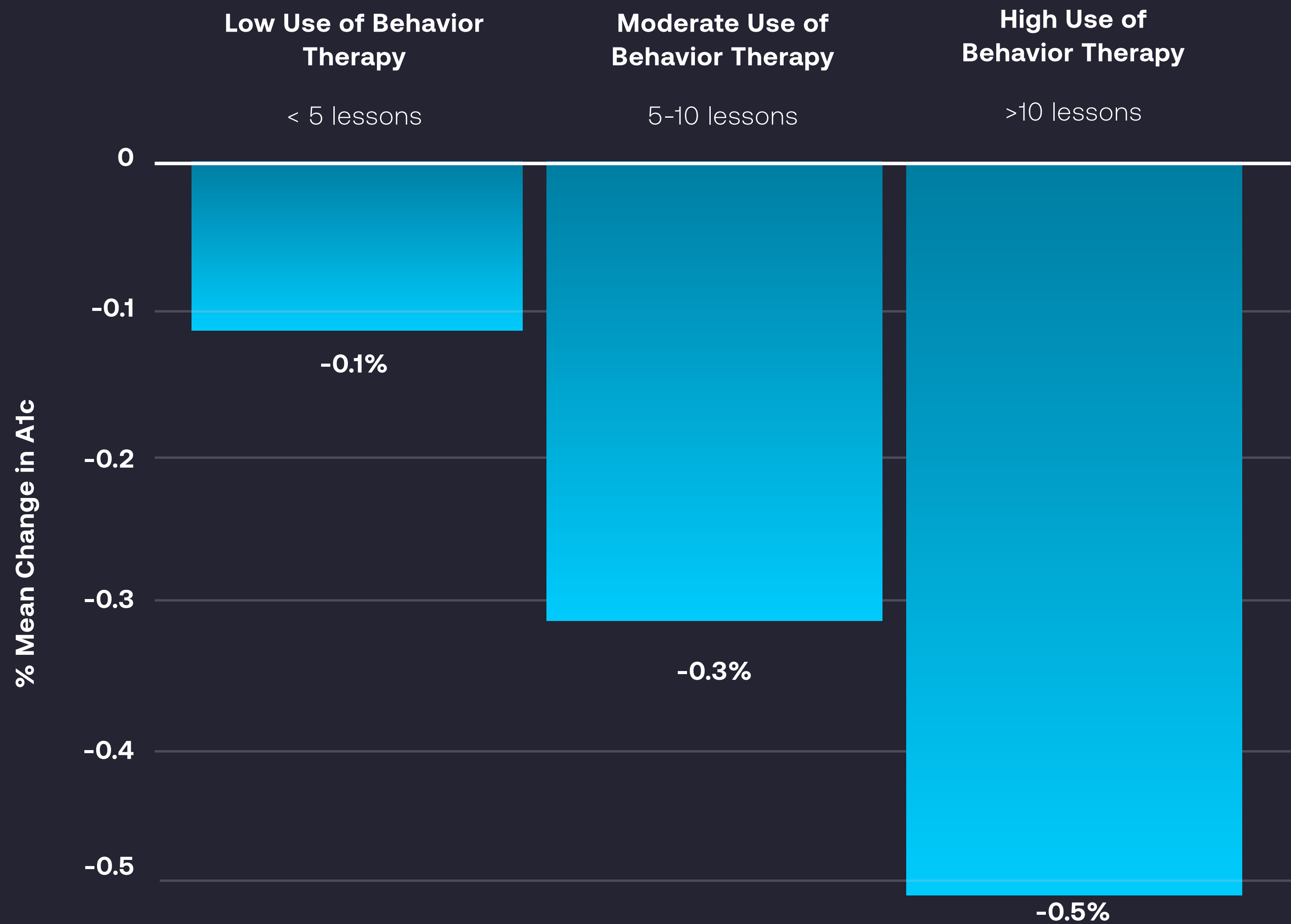
Safety Data Summary

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

Number of Subjects who Experienced:	Standard of Care (n=343)		BT-001 (n=326)		Overall (n=669)	
	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events 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

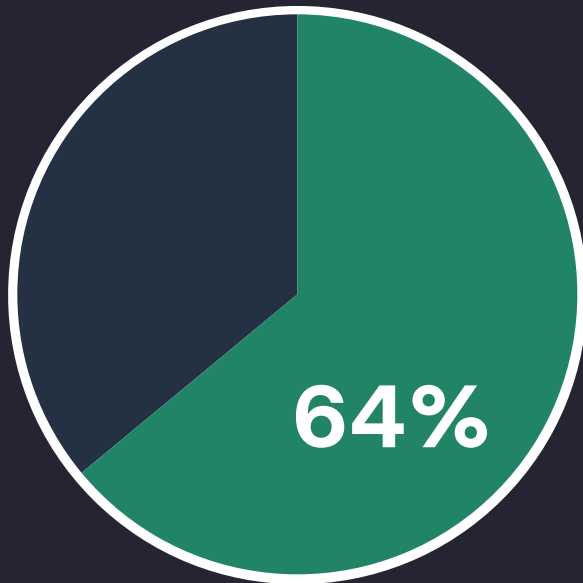
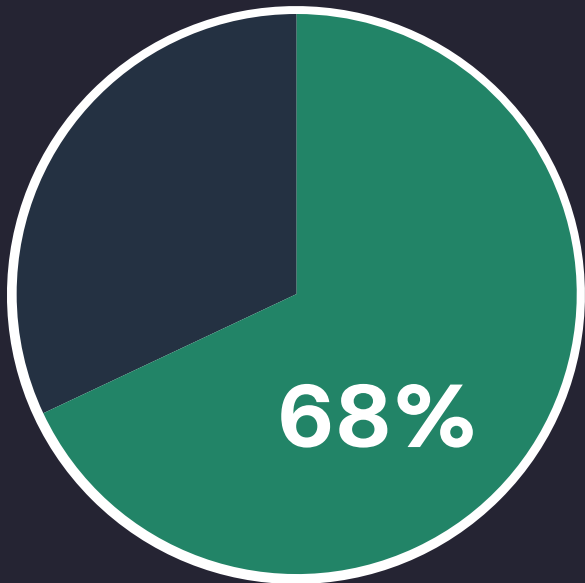
Dose Response of nCBT

Higher dose associated with larger improvements as compared with SOC, without increased adverse events

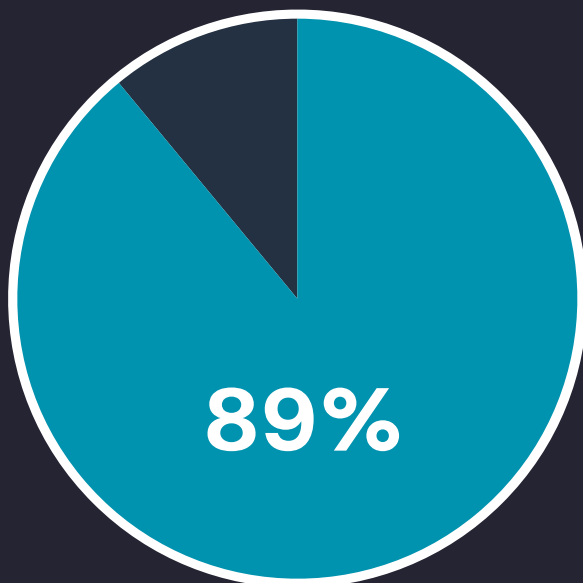
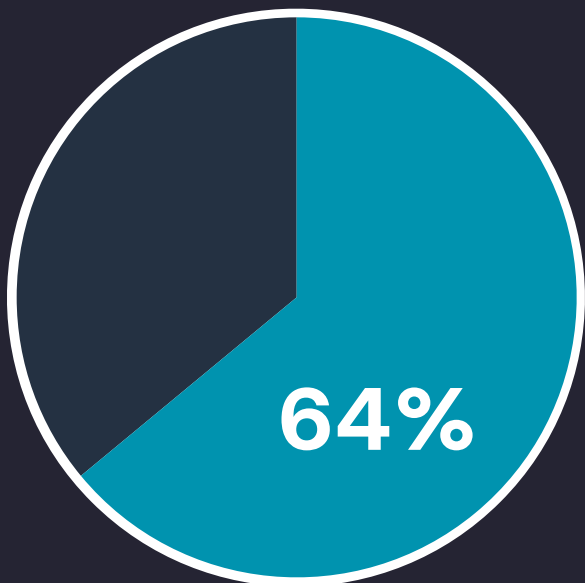


Patient Engagement

Pilot



Pivotal



Minutes / Day

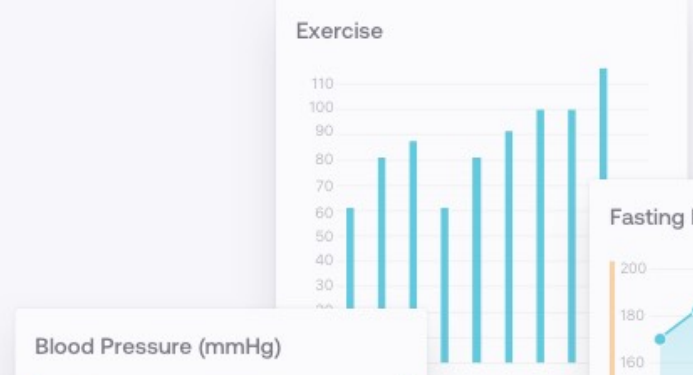
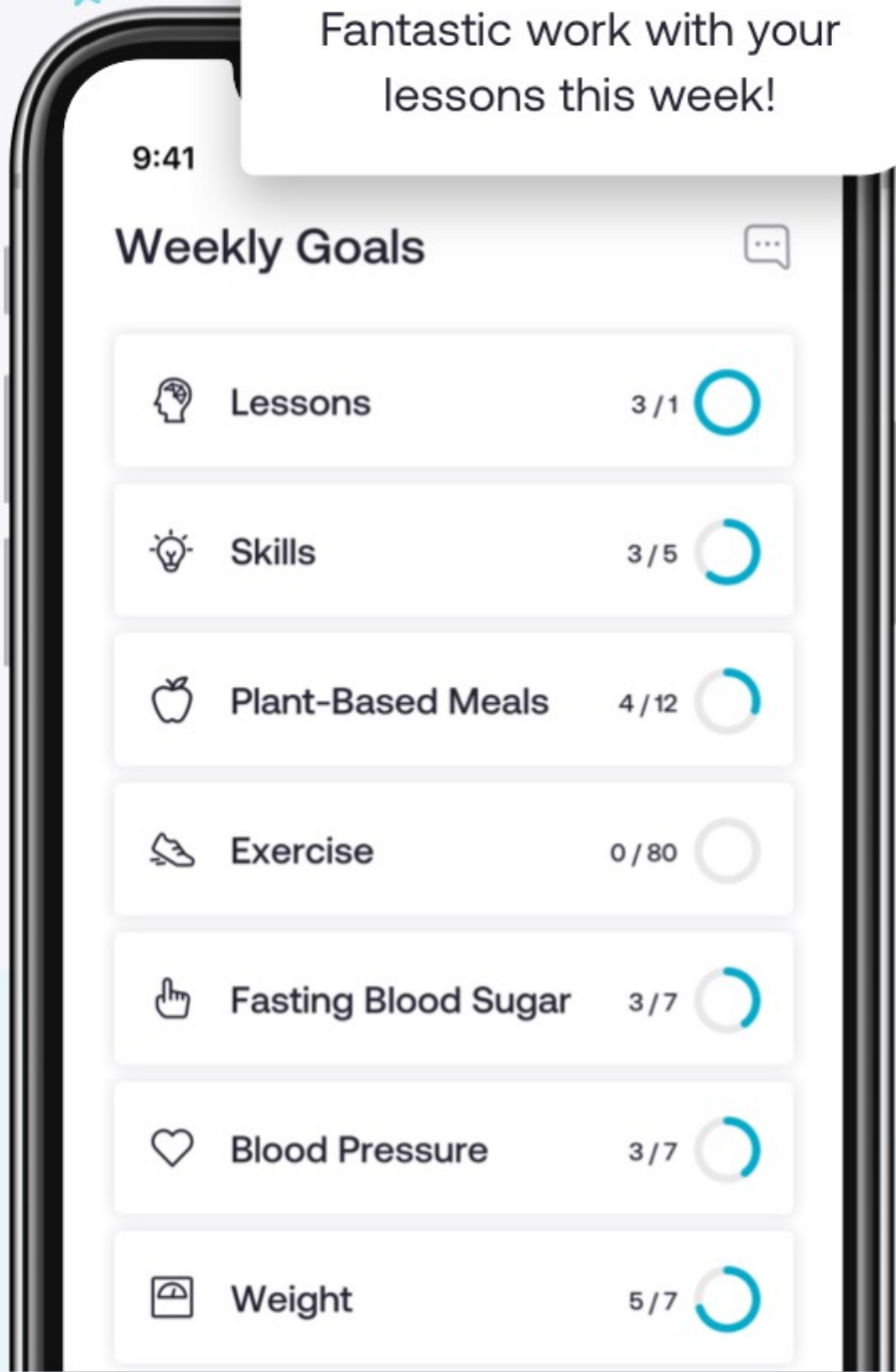
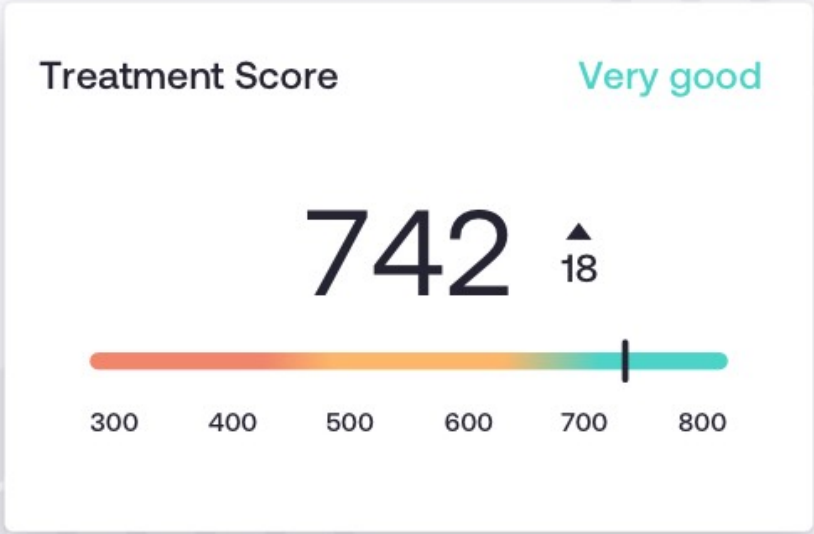
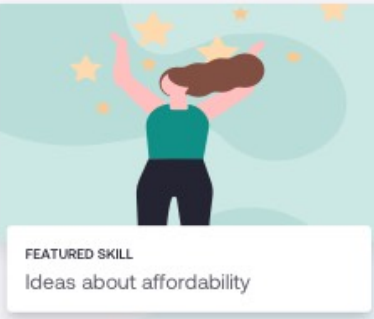
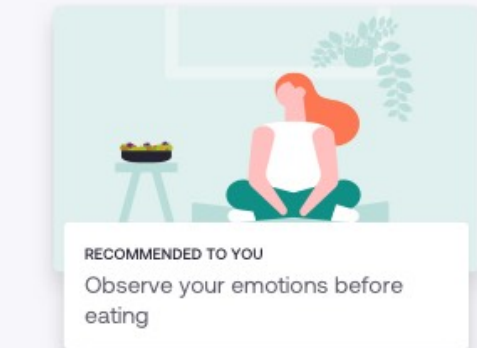
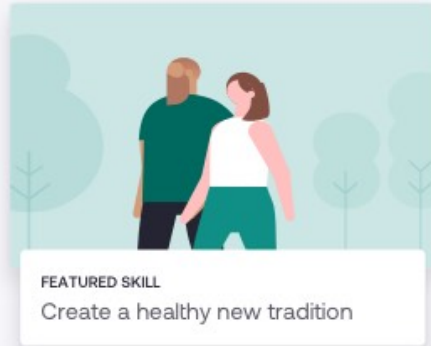
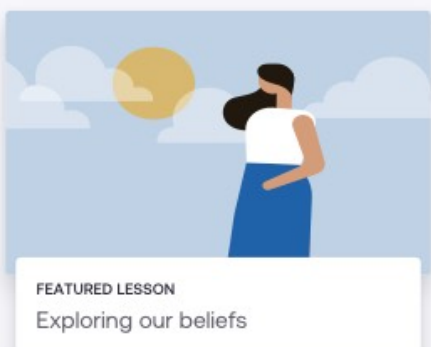
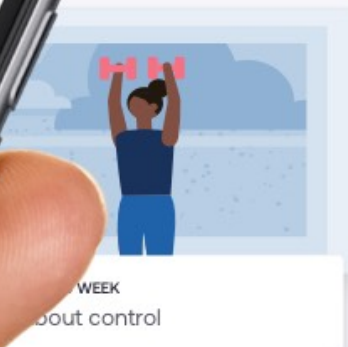
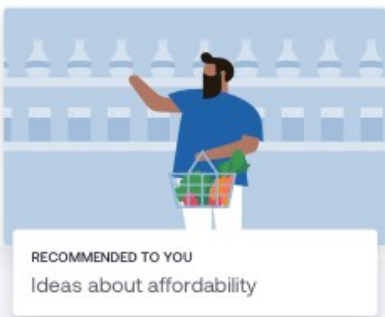
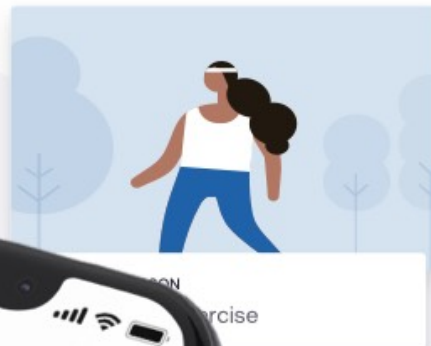
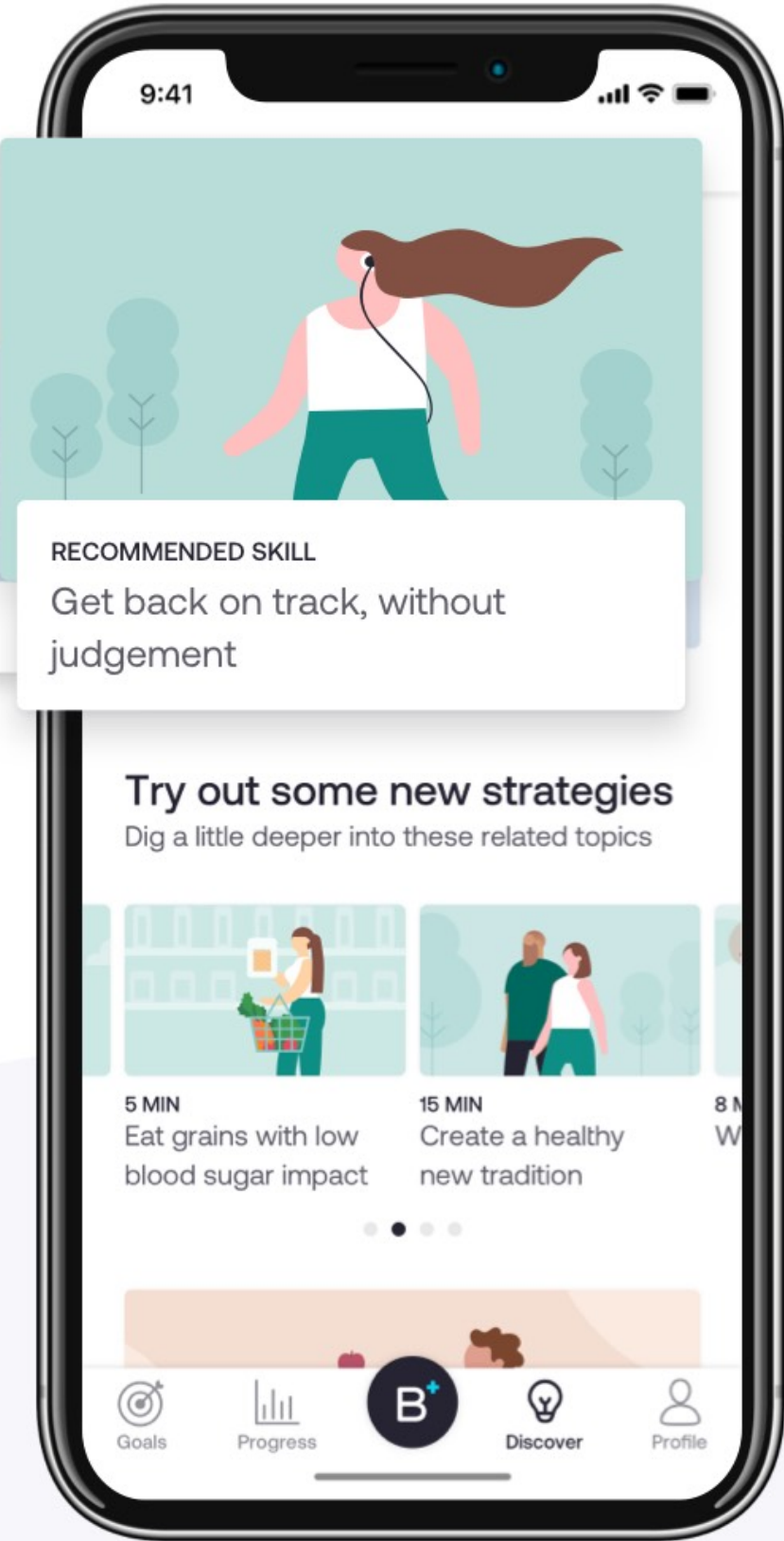
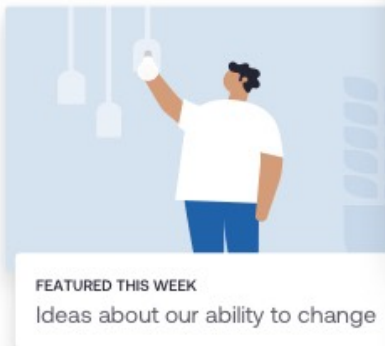
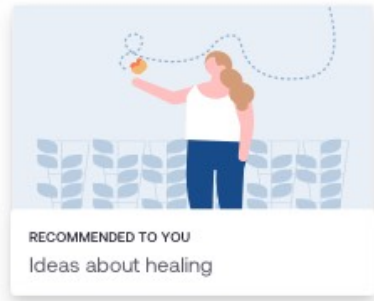
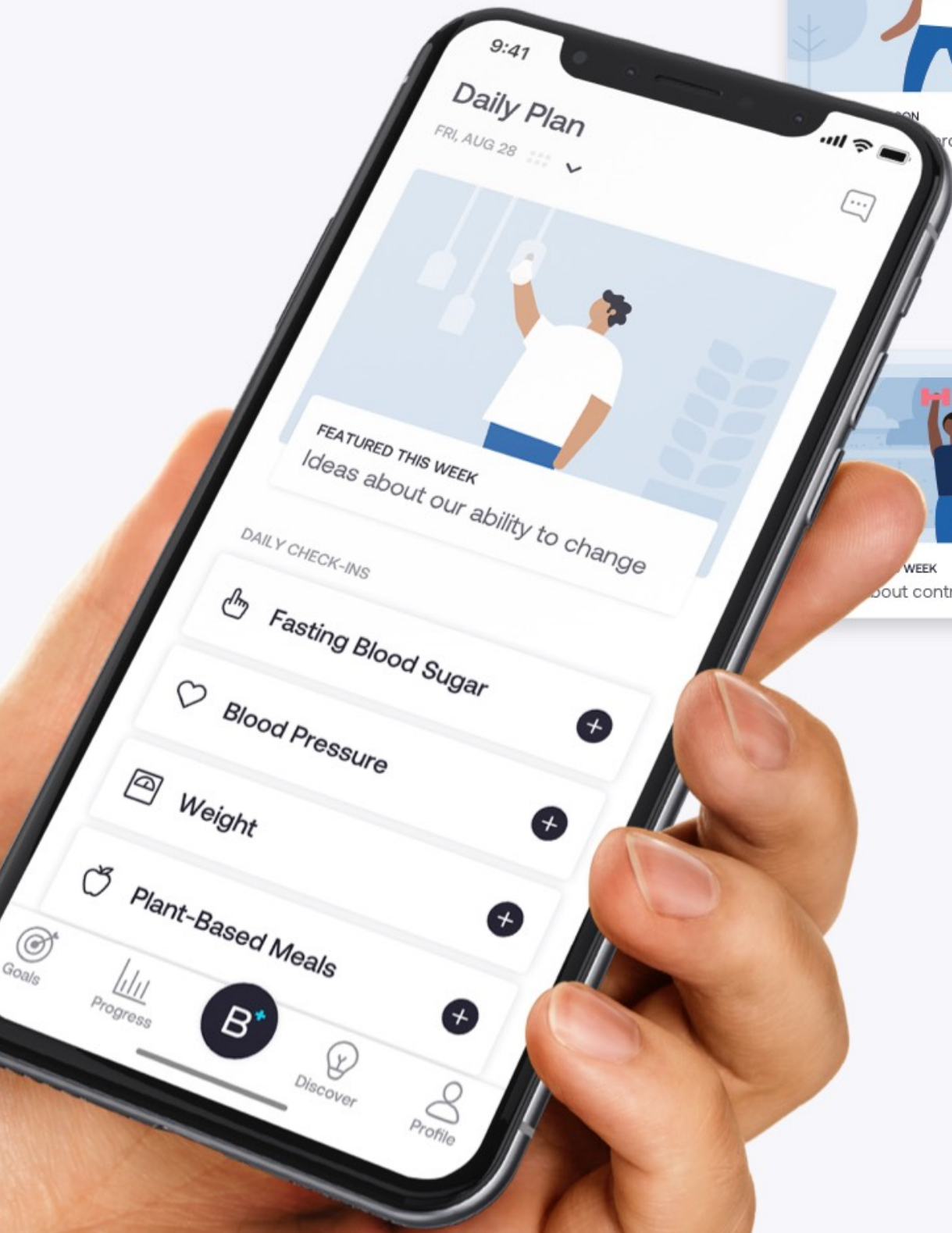
Percent of Patients
Using BT-001 as
Intended

Average Lessons
Completed

Percent of Patients Using
the App at Week 10

Net Promoter
Score

Better⁺



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