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Intensive behavioral Therapy for weight loss in patients with, or At-Risk of, type 2 Diabetes: Results from the PaTH to health diabetes study

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ABSTRACT

Intensive behavioral therapy (IBT) is an important component of obesity treatment and can reduce the risk of type 2 diabetes (T2DM).

Objective was to compare the effectiveness of IBT to usual care in achieving weight loss in two study cohorts within PaTH Network: T2DM and At-Risk of T2DM.

The TD2M cohort was defined as age 18 years and older with an indication of T2DM in the EHR based on a validated algorithm and at least 2 outpatient primary care visits. The At-Risk of T2DM cohort was defined by a BMI $\geq$ 25 kg/m^2. The primary outcome was weight change within 1-year of index date. Mixed-effects models assessed the effectiveness of IBT by comparing the changes between study groups.

Between 2009 and 2020, a total of 567,908 patients were identified in the T2DM cohort and2,054,256 patients in the At-Risk of T2DM cohort. Both IBT patients and matched non-IBT patients in the T2DM cohort had decreased mean weight (primary outcome) (−1.56 lbs, 95 %CI: −1.88, −1.24 vs −1.70 lbs, 95 %CI: −1.95, −1.44) in 1-year after index date. In the At-Risk of T2DM cohort, both IBT and non-IBT patients experienced weight gain and resultant increased BMI. Patients with more than one IBT visit gained less weight than those with only one visit (1.22 lbs, 95 %CI: 0.82, 1.62 vs 6.72 lbs, 95 %CI: 6.48, 6.97; $p < 0.001$).

IBT was unlikely to result in clinically significant weight loss. Barriers to utilizing IBT require further research to ensure broader adoption of obesity management in primary care.

1. Background

The rising rate of obesity in the United States (US), surpassing 40 % in 2020, is a major public health concern. Obesity is associated with multiple co-morbidities, including type 2 diabetes mellitus (T2DM) which affects nearly 34 million US adults (Type 2 Diabetes, 2019). The Centers for Disease Control and Prevention (CDC) have identified diabetes as the 7th leading cause of death in the US (Diabetes Fast Facts, 2020). Diabetes costs the US approximately $327 billion annually, in terms of both health care expenses and missed work (Statistics, 2021). Further exacerbating this public health crisis is the growing percentage of individuals who are at-risk of T2DM, currently representing more than a third of US adults (New CDC Report, 2017; Albright, 2012). Effective interventions are needed to prevent individuals at-risk of T2DM from progressing to T2DM, and T2DM individuals from incurring serious complications, including cardiovascular disease, blindness, renal failure, and lower extremity amputation. The COVID-19 pandemic has exposed additional vulnerabilities of individuals with obesity and T2DM, including increased risk of severe disease or death after COVID-19 infection (Popkin et al., 2021; Barron et al., 2020), reflecting the

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urgency to develop interventions aimed at treating obesity and improving diabetes outcomes.

Health care providers play an integral role in the delivery of lifestyle interventions for obesity treatment. Counseling patients on nutrition, physical activity and behavior change at frequent clinic visits, as proposed by intensive behavioral therapy (IBT), is an effective approach to obesity treatment and can reduce the risk of T2DM (National Coverage Determination (NCD) for Intensive Behavioral Therapy for Obesity, 2021; Wadden et al., 2019; Wadden et al., 2019). To encourage uptake of IBT, the Centers for Medicare and Medicaid Services (CMS) implemented a Healthcare Common Procedure Coding System (HCPCS) code for IBT delivery within primary care settings to facilitate payment for screening and treatment of obesity (G0447 for individual counseling; G0473 for group counseling) by primary care physicians, nurse practitioners and physician assistants in 2011 (Centers for Medicare and Medicaid Services, 2012). This was followed by universal coverage without cost sharing among most private plans for adults of all ages, a key provision of the Affordable Care Act (Decision Memo for Intensive Behavioral Therapy for Obesity, 2015; Fitzpatrick et al., 2016; US Government Publishing Office., 2010; Batsis and Bynum, 2016). IBT provides up to 22 sessions of behavioral counseling for patients with obesity (body mass index [BMI] $\geq$ 30 kg/m^2) each year. Despite these obesity management initiatives, the rate of uptake of the Medicare IBT benefit in the first two years of implementation was small (0.10 % and 0.17 %, respectively) among beneficiaries (Batsis and Bynum, 2016). Furthermore, there are limited studies evaluating the uptake and effectiveness of IBT in real-world clinical settings (Lv et al., 2017).

In this paper, we examine post-policy impact of IBT in patients with, and at-risk of, T2DM. We leveraged the novel infrastructure of the Patient-Centered Outcomes Research Institute-funded PaTH Clinical Data Research Network (CDRN), a partnership of academic health systems with established governance to operate as an integrated research network. We compared changes in weight (primary outcome), hemoglobin A1c (HbA1c) and blood pressure (secondary outcomes) among patients who received IBT with those who did not, following implementation of preventive service coverage. We hypothesized that patients receiving IBT had greater weight loss than those who did not. Furthermore, we determined whether the impact from IBT differs by patient demographics (age, race/ethnicity, and rurality).

2. Methods

2.1. Study design

The PaTH to Health: Diabetes study is a large-scale observational study with an overarching goal to understand the comparative effectiveness of IBT as covered by CMS and other insurers in improving weight loss for adults either with, or at-risk of, T2DM. The study leverages electronic health record (EHR) and claims data from six PaTH health systems comprising the PaTH CDRN (Penn State Health, UPMC, Temple Health System, Johns Hopkins Health System, University of Utah Health, and Geisinger Health System). All EHR data was extracted from the PaTH CDRN, which provides an infrastructure for pragmatic clinical trials and observational studies that require study populations beyond a single health system to answer important patient-centered clinical and health services questions (PaTH Investigators, 2019). The PCORnet common data model (CDM) transforms each health care system's dialect into a common language standardized on the meaningful use–recommended vocabularies (SNOMED, RxNORM, and LOINC). To ensure complete capture of longitudinal data, PaTH entered into agreements with local insurers (at UPMC) and Medicare (at all sites) to allow linking of claims data to EHR data. Our study included a comprehensive plan to engage patient partners and other stakeholders (e.g. clinicians, policymakers, community organization leaders) in all aspects of the research (Poger et al., 2020; Poger et al., 2020; Poger et al., 2021). The study protocol has been previously described (Kraschnewski et al., 2019) and was reviewed and approved by the centralized Institutional Review Board at Johns Hopkins School of Medicine.

2.2. Participants

For the current study, we constructed two patient cohorts: (1) T2DM and (2) At-Risk of T2DM. The T2DM cohort was defined as patients aged 18 years and older with an indication of T2DM from 2009 to 2019 using a clinically validated algorithm based on the SUrveillance, PREvention, and ManagEment of Diabetes Mellitus (SUPREME-DM) project criteria for identifying individuals with diabetes in the electronic health record: T2DM on the problem list, diabetes-specific medications, HbA1c results $>$ 7.0 %, or 1 inpatient diagnosis code or 2 out-patient diagnosis codes for T2DM (ICD-9 codes 250.xx and multiple ICD-10 codes, including E10.XX, E11.XX, E13.XX) (Hivert et al., 2009; Nichols et al., 2012). To ensure the inclusion of active patients in health systems, the T2DM cohort was restricted to patients who had at least 2 outpatient primary care visits over any 3 year period in 1 of the PaTH health systems starting January 1, 2012.

The At-Risk of T2DM cohort was defined as patients aged 18 years and older who had a BMI $\geq$ 25 kg/m^2 based on most recent recorded weight and at least one recorded height, and at least 2 outpatient primary care visits in one of the PaTH health systems in the past 3 years (since January 1, 2012). We recognized using BMI $\geq$ 25 kg/m2 as the threshold is a limited definition for patients at-risk of T2DM, particularly when used across all racial and ethnic groups. However, given that only patients with obesity (BMI $\geq$ 30 kg/m2) are eligible for IBT, this threshold allowed for appropriate inclusion of patients which could be further refined with our analyses (see Fig. 1 for outline of study cohorts).

The observational period for the outcome variables was from 2009 to 2020, tincluding 3 years of data prior to the first policy change (CMS instituting coverage for IBT for obesity) and 4 years after the last policy change (Pennsylvania Medicaid expansion) under study.

2.3. Intensive behavioral therapy

IBT and codes have been described previously (Kraschnewski et al., 2019; Kraschnewski et al., 2019). IBT consists of screening, assessment, and frequent face-to-face behavioral counseling for delivery of dietary and physical activity intervention to promote sustained weight loss in adults with a clinical diagnosis of obesity (BMI $\geq$ 30 kg/m^2). Each visit lasts 15 min and must be provided by a primary care physician, nurse practitioner, clinical nurse specialist, or physician assistant. IBT is billed under HCPCS code G0447 (individual counseling) or G0473 (group counseling) for Medicare beneficiaries. Comparable HCPCS codes for patients with Medicaid, self-pay, or private insurance for individual and group counseling are S9470 and S9449, respectively. Receipt of IBT was assessed through PaTH EHRs and supplemented by claims data when available, using G0447, G0473, S9470, and/or S9449 HCPCS codes in combination with a diagnosis of obesity (ICD-9 codes 278.00, 278.01, 278.03, and 278.91, respectively; V85.3-V85.4).

2.4. Outcomes and covariates

Key T2DM prevention outcomes were assessed. The primary outcome for this study was weight change. Secondary outcomes included hemoglobin A1c, uncontrolled blood pressure (systolic blood pressure (SBP) $>$ 130 mmHg or diastolic blood pressure (DBP) $>$ 80 mmHg all the time), and uncontrolled diabetes (HbA1c $>$ 9 % any time in patients with T2DM). Key covariates included patient-level sociodemographics and medical comorbidities. Medical comorbidities were assessed using the Charlson Comorbidities Index (CCI) adapted for use with the HER (Glasheen et al., 2019). The CCI is based on age and 19 medical conditions that are each assigned an integer weight from one to six, with a weight of six representing the most severe morbidity. The

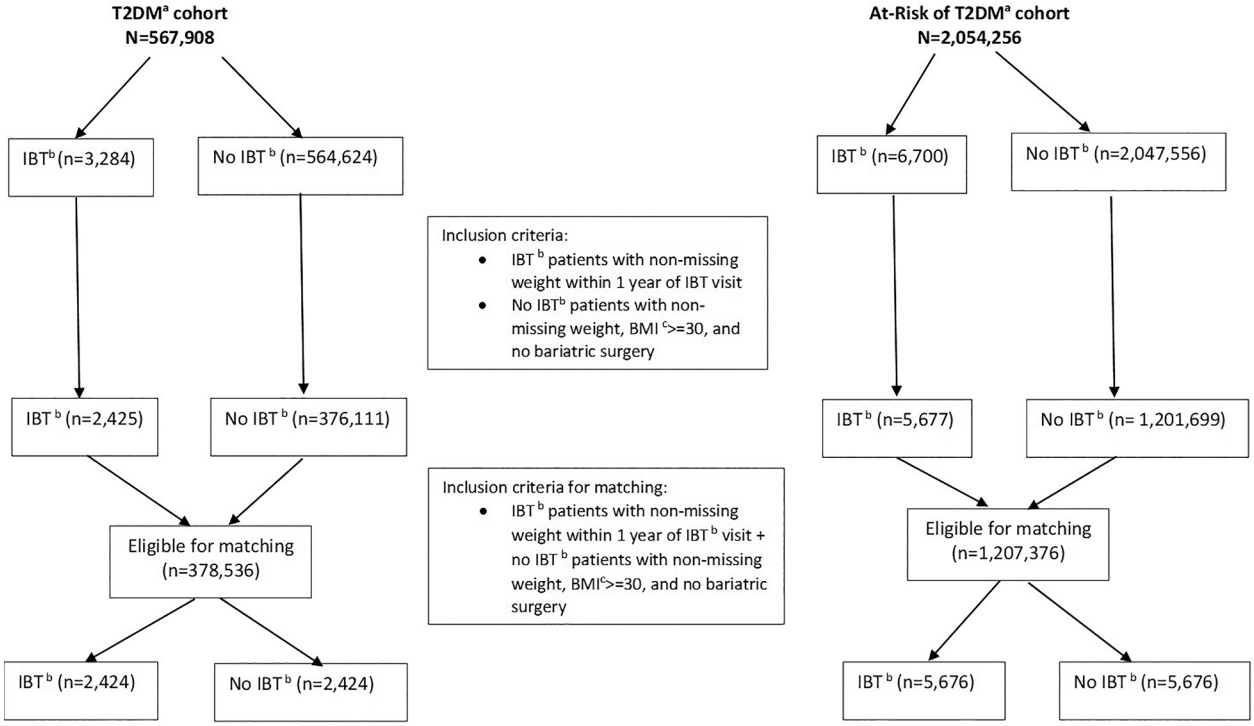

Fig. 1. Study flow diagram [a]Type 2 Diabetes Mellitus [b] Intensive Behavioral Therapy [c] Body Mass Index.

summation of the weighted comorbidity scores results in the CCI score.

2.5. Statistical analysis

To examine the effectiveness of IBT, we compared weight change and secondary outcomes (hemoglobin A1c, uncontrolled blood pressure, uncontrolled diabetes) among those who received IBT to those who did not based on a matched sample. Specifically, we matched each patient with IBT to one patient who never had IBT or bariatric surgery without replacement based on a greedy matching algorithm that used absolute difference as the distance measure. In order to have at least one match for each patient with IBT, we chose the matching variables to include sex, age, health care site, and index date, with a 1-year window used for age and index date matching, and exact matching for sex and site. The index date for a patient with IBT was the initial IBT visit date. For a patient without IBT, the potential index date corresponded to the visit when BMI was measured and had a value $\geq$ 30 kg/m^2, which meets the eligibility criteria to receive IBT. Other individual charateristics such as race and CCI were not used in matching procedure, but adjusted in the regression models.

The outcome changes were compared between those with IBT and those without in a two-year window, from one year prior to index date (pre-period) to one year after (post-period). Linear or generalized linear mixed-effects models were used to accommodate within- and between-subjects variability and allow irregular time intervals between repeated measurements. All measures obtained in the 2-year window were included in the analysis. The outcome changes were first assessed as the 12-month average post index date comparing to 12-month average prior to index date. Thus, the main exposure variables in the models are indicator of IBT use, period indicator (post vs pre), and their interaction. The coefficient of the interaction term indicates the effect of IBT on mean change from pre-period to post-period. The other covariates adjusted in the models included age, sex, race, ethnicity, residence (rural/urban), site and CCI. Next, we conducted segmented regression analysis under mixed-effects models to compare the difference in slope change of continuous outcomes, such as weight and HbA1c from pre-period to post-period between those with IBT and those without in the T2DM cohort. We expanded the aforementioned model to include time (month) since index date, a three-way interaction term between time since index date, IBT indicator and period indicator, as well as lower-order two-way interactions. The coefficient associated with three-way interaction indicates whether there is a difference in slope changes between those with IBT and those without. Furthermore, we conducted subgroup analyses by age ($<$65, $\geq$65), gender, race/ethnicity and geographic location (i.e., rural vs urban).

3. Results

3.1. Overall patient characteristics

Between 2009 and 2020, a total of 567,908 patients with T2DM and 2,054,256 patients in the At-Risk of T2DM cohort were identified in PaTH. Summary statistics and distributions for demographic and clinical variables at baseline can be found in Appendix A.

IBT services during the study period have been reported elsewhere (Kraschnewski et al., 2019). Briefly, prior to CMS reimbursement, IBT services were rarely recorded in the EHR. Following the policy change, IBT prevalence ranged from 0.01 to 0.41 % of patients in the T2DM cohort and 0.01–0.58 % of patients in the At-Risk of T2DM cohort. The total number of IBT visits varied by patient from 1 to 55 during the study period. The mean number of IBT visits was 1.94 and the median was 1. Most patients (65.3 %) had only one visit, 15.5 % had two visits, 7.6 % had three visits, 4.1 % had four visits, 2.5 % had five visits, and 5 % had greater than five visits. Table 1 describes baseline characteristics of patients with IBT and matched patients without IBT for each cohort. All characteristics were similar between IBT and non-IBT groups. The distributions of two continuous variables, age and CCI, were also very similar between two groups as indicated by histograms (data not shown).

Table 2 shows outcome variables at baseline for IBT patients as compared to non-IBT matched patients for the T2DM cohort and At-Risk of T2DM cohort, respectively.

Table 3 show the effects of IBT for the T2DM cohort and At-Risk of T2DM cohort. In the T2DM cohort, both IBT patients and matched non-

Table 1
Baseline characteristics for matched samples.

Variable	T2DM[a] (N = 4848)		At-Risk of T2DM[a] (N = 11352)	
	IBT[b] (N = 2424)	Non-IBT[b] (N = 2424)	IBT[b] (N = 5676)	Non-IBT[b] (N = 5676)
Age, mean (SD)[c], years*	58.0 (15.1)	58.0 (15.1)	44.0 (18.7)	44.0 (18.7)
Gender, N (%)*				
Male	919 (37.9 %)	919 (37.9 %)	1152 (20.3 %)	1152 (20.3 %)
Female	1505 (62.1 %)	1505 (62.1 %)	4524 (79.7 %)	4524 (79.7 %)
Race/Ethnicity, N (%)				
Non-Hispanic White	1828 (75.4 %)	1973 (81.4 %)	4680 (82.5 %)	4849 (85.4 %)
Non-Hispanic Black	481 (19.8 %)	375 (15.5 %)	654 (11.5 %)	612 (10.8 %)
Hispanic	50 (2.1 %)	40 (1.7 %)	188 (3.3 %)	111 (2.0 %)
Non-Hispanic Other	34 (1.4 %)	15 (0.6 %)	75 (1.3 %)	41 (0.7 %)
Missing	31 (1.3 %)	21 (0.9 %)	79 (1.4 %)	63 (1.1 %)
Location				
Urban	2283 (94.2 %)	2227 (91.9 %)	5409 (95.3 %)	5219 (92.0 %)
Rural	99 (4.1 %)	143 (5.9 %)	220 (3.9 %)	396 (7.0 %)
Missing	42 (1.7 %)	54 (2.2 %)	47 (0.8 %)	61 (1.1 %)
Charlson Comorbidity Index, mean (SD)[c]	3.1 (2.2)	3.5 (2.3)	1.1 (1.5)	1.2 (1.7)

* Matching variable

[a] Type 2 Diabetes Mellitus.
[b] Intensive Behavioral Therapy.
[c] Standard Deviation.

Table 2
. Outcome variables at baseline for matched IBT and non-IBT patients.

Outcome	T2DM[a] (n = 4848)		At-Risk of T2DM[a] (n = 11352)	
	IBT[d] (N = 2424)	Non-IBT[d] (N = 2424)	IBT[d] (N = 5676)	Non-IBT[d] (N = 5676)
Weight, mean (SD), lbs	231.3 (58.9)	233.1 (46.9)	212.1 (54.6)	221.8 (42.5)
BMI[b], mean (SD), kg/m^2	37.3 (8.5)	37.7 (6.5)	35.0 (8.0)	36.5 (5.9)
HbA1c, mean (SD), %	7.5 (1.8)	7.34 (1.7)	5.6 (0.4)	5.6 (0.5)
Systolic BP[c], mean (SD), mmHg	130.1 (16.2)	130.3 (16.3)	122.8 (15.8)	125.1 (15.0)
Diastolic BP[c], mean (SD), mmHg	76.9 (10.3)	76.9 (10.5)	74.4 (11.0)	76.9 (10.2)
Uncontrolled BP[c], N (%)	1114 (53.2 %)	1285 (53.1 %)	1920 (37.7 %)	2481 (44.0 %)
Uncontrolled T2DM[a], N (%)	255 (16.9 %)	237 (13.1 %)	N/A	N/A

[a] Type 2 Diabetes Mellitus.
[b] Body Mass Index.
[c] Blood Pressure.
[d] Intensive Behavioral Therapy[e]Outcomes variables at baseline were defined as the closest non-missing measurement to the index date within 1 year.

IBT patients had decreased weight and BMI, with no statistically significant difference between groups. Both groups also experienced improved systolic and diastolic blood pressure over time, with no significant difference between groups. IBT patients showed a greater decrease in hemoglobin A1c compared to non-IBT patients (difference of change: 0.21 %; $p < 0.001$). Moreover, the proportions of T2DM patients with uncontrolled diabetes decreased significantly in both IBT (OR 0.64, 95 % CI: 0.55, 0.75I) and non-IBT (OR 0.83, 95 % CI: 0.73, 0.95) groups, with additional reduction in the IBT group (Ratio of ORs: 1.3, 95 % CI: 1.06, 1.59; $p = 0.012$). In the At-Risk of T2DM cohort, both IBT and non-IBT patients experienced weight gain and resultant increased BMI, with IBT patients experiencing more weight gain. IBT patients also had a non-clinically significant improvement in diastolic blood pressure measures compared to the non-IBT patients.

We used segmented regression to compare the changes in slope of weight and hemoglobin A1c between IBT and non-IBT patients in the T2DM cohort (Table 4 above). Briefly, there was a statistically significant change in the pre-post change in slope of weight loss between the IBT and Non-IBT patients (0.49, 95 %CI: 0.37,0.60). There were no statistically significant differences in changes in slopes between groups for hemoglobin A1c.

Further, we conducted subgroup analyses by age, gender, race/ethnicity and geographic location (i.e., rural vs urban). Fig. 2 demonstrates change in HbA1c from pre- to post- period index date in patients with T2DM. Patients in the At-Risk of T2DM cohort who were younger than 65 years and who were female had significantly more weight gain with IBT than in the non-IBT group. There were no clinically significant differences in outcomes by location in the T2DM cohort. Patients in the At-Risk of T2DM cohort who were White, Black and Hispanic and in the IBT group gained weight as compared to the non-IBT group. In the At-Risk for T2DM cohort, IBT patients gained statistically significant more weight in both the rural and urban locations.

4. Discussion

Obesity screening, assessment and management are key components to achieve and maintain meaningful weight loss and improve T2DM outcomes. Unfortunately, analysis of IBT impact did not demonstrate clinically significant weight loss when compared to matched controls in either the T2DM or At-Risk of T2DM cohorts, which is consistent with data indicating that most patients only had one IBT visit. In terms of secondary outcomes, we did find a significant reduction in HbA1c in the IBT group, suggesting that more contact with care providers, as intended by IBT, may promote better glycemic control independent of weight loss. Additionally, patients who participate in IBT may be more engaged in their diabetes control, and providers who provide IBT services may monitor patients' glycemia more closely. More research is needed to explore possible mechanisms.

At the outset of this study, our hypotheses and study design were based on the premise that the ACA's provision to reimburse IBT services addressed a key barrier to IBT utilization and would incentivize more frequent use of this service and improvements in patient-centered outcomes. We did not find widespread evidence of this; instead, the data demonstrates that reimbursement for IBT services is a necessary but not sufficient step for examining the usefulness and effectiveness of IBT in the treatment of obesity and prevention of diabetes. There remain additional barriers related largely to implementation that preclude widespread use of IBT and impede patient adherence. For example, because it is now reimbursable, we can expect IBT services to be more consistently and reliably coded, yet we found little uptake of IBT services, and most patients who initiated treatment appeared to discontinue the treatment after only a few visits. Comparing our data results with the official CMS policy/protocol/requirements for reimbursement, the stipulations and conditions for both initial and continued eligibility of IBT services are stringent (perhaps aspirational) and set a very high bar. Although these stipulations might represent "best practice," the gap between this protocol (as currently defined) and the status quo (i.e., nothing) is significant. Further, CMS required visits to be face-to-face until 2020 when IBT services were approved for telemedicine visits during the pandemic (Telehealth Services, 2021). If allowed to continue post-pandemic, telemedicine options could overcome transportation and access barriers for many patients.

While results from clinical trials have demonstrated promising

Table 3
Post to Pre Comparison of Outcome Variables for matched IBT and non-IBT patients.

	T2DM[c] (N = 4848)				At-Risk of T2DM[c] (N = 11352)			
Outcome	**IBT[d] (N = 2424)**	**Non-IBT[d] (N = 2424)**	**Difference (Non-IBT - IBT)**	**P-value**	**IBT[d] (N = 5676)**	**Non-IBT[d] (N = 5676)**	**Difference (Non-IBT - IBT)**	**P-value**
Weight, lbs[a]	−1.56 (−1.88, −1.24)	−1.70 (−1.95, −1.44)	−0.14 (−0.55, 0.27)	0.513	5.24 (5.04, 5.44)	1.75 (1.56, 1.94)	−3.49 (−3.76, −3.22)	<0.001
Body Mass Index (BMI, kg/m^2)[a]	−0.22 (−0.28, −0.17)	−0.22 (−0.27, −0.18)	0.0 (−0.27, −0.18)	0.964	0.78 (0.75, 0.82)	0.28 (0.24, 0.31)	−0.51 (−0.56, −0.46)	<0.001
Hemoglobin A1c, %[a]	−0.32 (−0.38, −0.27)	−0.11 (−0.16, −0.06)	0.21 (0.14, 0.29)	<0.001	−0.03 (−0.06, 0.0)	−0.01 (−0.04, 0.02)	0.02 (−0.02, 0.07)	0.299
Systolic Blood Pressure, mmHg [a]	−0.56 (−0.93, −0.20)	−0.65 (−0.94, −0.35)	−0.08 (−0.56, 0.39)	0.726	0.12 (−0.07, 0.32)	0.05 (−0.13, 0.24)	−0.07 (−0.34, 0.20)	0.610
Diastolic Blood Pressure, mmHg [a]	−0.78 (−1.01, −0.55)	−0.49 (−0.68, −0.30)	0.29 (0.0, 0.59)	0.051	0.0 (−0.14, 0.14)	0.24 (0.11, 0.37)	0.24 (0.0.5, 0.43)	0.013
Uncontrolled Blood Pressure, %[b]	0.92 (0.87, 0.98)	0.91 (0.86, 0.95)	0.98 (0.91, 1.06)	0.646	0.98 (0.94, 1.03)	1.03 (0.99, 1.07)	1.05 (0.99, 1.11)	0.118
Uncontrolled T2DM, %[a,c]	0.64 (0.55, 0.75)	0.83 (0.73, 0.95)	1.30 (1.06, 1.59)	0.012	N/A	N/A	N/A	N/A

[a] Mean (95 % CI): difference of means between post-period and pre-period.
[b] Odds Ratio (95 % CI): ratio of odds of uncontrolled Blood Pressure (>130/>80)/T2DM[c] in post-period against that in pre-period.
[c] Type 2 Diabetes Mellitus.
[d] Intensive Behavioral Therapy.

Table 4
Pre to Post Comparison of Slope for Outcome Variables within T2DM[a] Cohort.

	IBT[b] (N = 2424)			Non-IBT[b] (N = 2424)			IBT[c] vs Non-IBT[b] (N = 4848)	
Outcome	**Pre**	**Post**	**P-value**	**Pre**	**Post**	**P-value**	**Difference**	**P-value**
Weight[c]	0.20 (0.14, 0.27)	−0.64 (−0.70, −0.57)	<0.001	0.06 (0.01, 0.11)	−0.29 (−0.34, −0.24)	<0.001	−0.49 (−0.60, −0.37)	<0.001
Body Mass Index[c]	0.03 (0.02, 0.04)	−0.11 (−0.12, −0.10)	<0.001	0.02 (0.01, 0.03)	−0.04 (−0.05, −0.04)	<0.001	−0.08 (−0.10, −0.06)	<0.001
Hemoglobin A1c[c]	0.03 (0.02, 0.04)	0.02 (0.01, 0.03)	0.196	0.0 (−0.0, 0.01)	−0.01 (−0.01, 0.01)	0.673	−0.01 (−0.03, 0.01)	0.495
Systolic BP[c, d]	−0.06 (−0.13, 0.01)	0.04 (−0.03, 0.11)	0.048	0.0 (−0.06, 0.05)	−0.02 (−0.08, 0.04)	0.629	0.12 (−0.01, 0.25)	0.066
Diastolic BP[c,d]	−0.08 (−0.12, −0.03)	0.06 (0.02, 0.11)	<0.001	−0.03 (−0.07, 0.0)	−0.03 (−0.07, 0.01)	0.944	0.14 (0.05, 0.22)	0.001

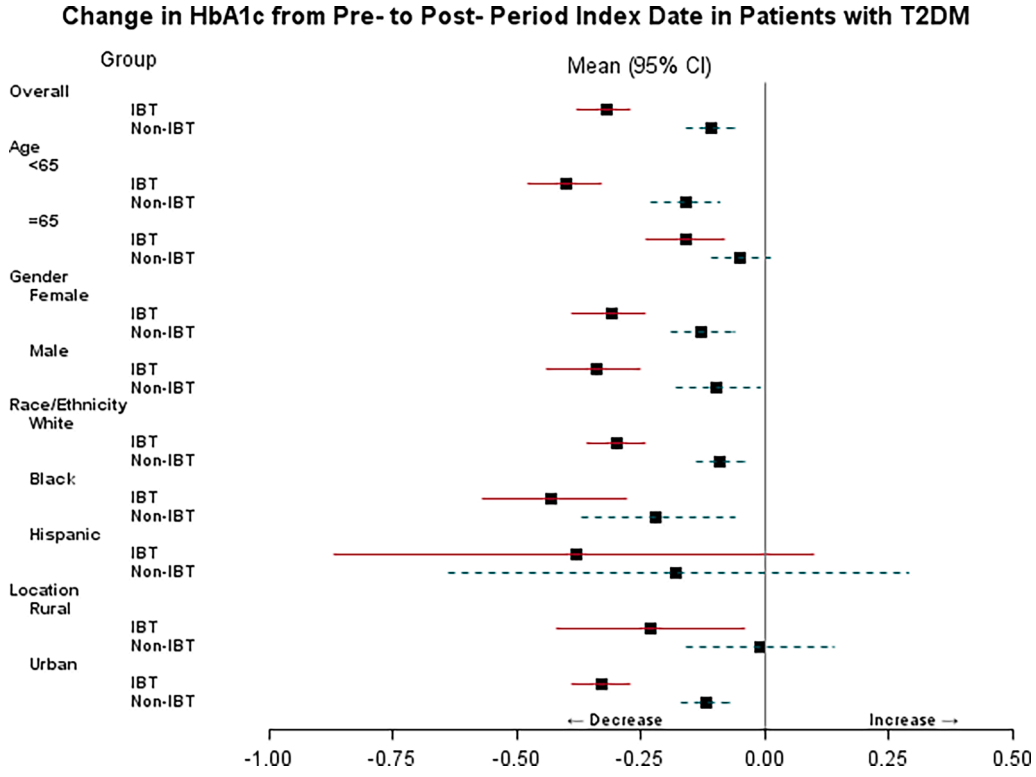

Fig. 2. Change in HbA1c from Pre- to Post- period index date in patients with T2DM.

results in clinically meaningful weight loss (8 % to 10 % of initial weight) (Wadden et al., 2012) and in diabetes incidence (Knowler et al., 2002) with lifestyle interventions, few studies have studied the real-world impact of IBT. A recent systematic review of obesity counseling programs within primary care revealed that studies did not follow the intense CMS visit protocol and resulted in lower mean weight loss at 6 months (Wadden et al., 2014). Additional limitations of IBT's effectiveness in the real-world setting is that obesity is a chronic, relapsing, and progressive disease. Similar to other chronic diseases like diabetes and hypertension, pharmacotherapy combined with lifestyle intervention is necessary for optimal treatment outcome. IBT alone may not be sufficient on its own to deliver meaningful weight loss and the weight loss target set by CMS guidelines. Wadden et al. (Wadden et al., 2020) (Wadden et al., 2019; Wadden et al., 2020) have been the only researchers to date to evaluate the IBT protocol by CMS in a randomized-controlled trial and their results are promising; IBT produced clinically meaningful weight loss at 56 weeks (a loss of 6.1 % from baseline body weight), but this was enhanced by the addition of liraglutide 3.0 mg, warranting further understanding of the multi-faceted approach to address obesity. Unfortunately, the majority of Medicare and Medicaid patients do not have coverage for anti-obesity medication, placing them at a high risk of treatment failure by IBT alone and disqualification from continuing eligibility.

There are also significant implementation barriers to IBT on the provider side. First, it has been well described that physicians are not knowledgeable or confident enough to deliver lifestyle intervention that includes counseling for nutrition, physical activity, and behavior change. According to a survey of family physicians, 73 % viewed weight management as important but 72 % reported not being well prepared by medical school to treat overweight and obesity. The majority of physicians (60 %) reported insufficient knowledge of nutritional issues related to weight management (Fogelman et al., 2002). An online survey of 81 program directors of Internal Medicine residency program in US showed only 2.5 % rated their residents as "very prepared" to manage obesity and 63 % are "somewhat prepared" to treat obesity. Major gaps in obesity medicine education were identified including weight stigma, pharmacological treatment of obesity and etiological aspects of obesity among others (Butsch et al., 2020). It is important to note that potential models for provider education have been found to be effective, however, have not been widely disseminated at this time (Wadden et al., 2019). Second, CMS restricts the delivery of IBT services to primary care providers (PCPs) that include General Internal Medicine, Family Practice, Obstetrics/Gynecology, Pediatric Medicine, and Geriatric Medicine. This excludes other specialties that also deliver obesity care such as Endocrinology, Gastroenterology, and Cardiology among others (Statistics and Data, 2021). Third, there is wide variation in IBT utilization by health systems, suggesting differences in the effort and commitment by hospital systems to provide the necessary support to providers so that IBT services are more widely available to patients (Kraschnewski et al., 2019). Fourth, the low reimbursement rate for IBT is a potential barrier to its utilization. Fifth, CMS restricts IBT services to only those who have reached obesity, BMI $\geq$ 30 kg/m^2. This BMI cutoff does not account for the ethnicity of the individual, such as Asians who reach obesity at the BMI of 27.5 kg/m^2 and are at a greater risk for developing diabetes at a lower BMI. It also excludes individuals with BMI in overweight category who have metabolic complications related to their excess weight such as diabetes. These individuals would have to gain weight in order to qualify for the benefit which will likely worsen their comorbid condition. Consideration should be given to individuals who are in weight reduced state, post weight loss, with BMI in normal or overweight category. These individuals are at risk for weight regain as obesity is a chronic and relapsing disease. They would greatly benefit from continued/IBT services to maintain lost weight. Lastly, the duration of face-to-face behavioral counseling for obesity is limited to 15 min which may not be sufficient to counsel a patient on diet, physical activity, and behavior change considering her/his unique challenges and/or barriers. This limited time to counsel patient could also be a potential barrier to HCP's utilizing IBT codes. Consideration should be give to providing extended duration of counseling time such as 30 min and 45 min with appropriate compensation.

This study has several limitations which should be considered. First, our study represents a limited geography of the country, restricted to the mid-Atlantic and Utah; the generalizability to the entire US is unknown. Second, most patients received only a single IBT visit, which limited the ability to investigate impact of full implementation. It is possible that PCPs provided "IBT-like" consultations but chose not to code or bill for the IBT service because the reimbursement rates for other codes (e.g. obesity complications) during the visit are higher than IBT. Such coding practices lead to underestimation of IBT services utility and would result in misclassification of exposure and underestimation of the effect from IBT. Further, results may be limited by patient self-selection for IBT, that is, asking their physician for this care. We cannot determine how IBT was initiated within the EHR. Given this is an observational study and the data are retrospective, we cannot explore the potential reasons for low use, such as lack of knowledge/education about coverage of IBT services or patient refusal of IBT services.

Additionally, use of the EHR ignores confounding variables critically important to weight loss efforts, such as individual behaviors (nutritional intake, physical activity) and clinical factors (such as physician characteristics and clinical practices). The significant associations between demographic variables and IBT service may be overestimated because of residual confounding. It also limits the precision of key variables, such as body mass index and blood pressure, which were measured based on clinical practice as opposed to research protocol and, therefore, subject to misclassification/measurement errors. Finally, EHR data is subject to significant missingness, which may bias the associations. However, BMI was only missing in 3 % of our study cohort, limiting the potential impact of missingness on our study results. HbA_{1c} data were missing in 17 % of patients. The amount of missing data in our study are comparable with previous studies using EHRs.[62] Missing data could cause misclassification. For example, if IBT was not consistently documented, it would not be captured in the EHR, potentially resulting in an underestimation of the overall uptake of IBT use. The subgroup differences in IBT use are probably not biased by missing data, given that rates of data missing from the EHR are likely to be similar across patient subpopulations. The evaluation of IBT's effect on clinical outcomes, however, may be affected by the missing data in outcomes (eg, weight, HbA_{1c}). Patients with more missing data may be those who had poor weight loss outcomes. If this scenario is more prevalent in those who received IBT than in those who did not receive IBT, the IBT effect may have been overestimated. Unobserved confounders, such as behavior factors and insurance status, may also bias the results in either direction.

Our study database did not have duration of T2DM and primary payer information for patients, which could have been key matching variables. Study strengths include the diverse patient population, reflected in Table 1, given that >80 % of Americans see a PCP regularly (Schoen et al., 2004).

5. Conclusion

This study examined the real world implementation of IBT for obesity using EHR and claims data from the PaTH network. We found that there was low uptake of IBT even after it became a covered service. For the minority of patients who did receive counseling with this code, the majority received only one visit. Surprisingly, and in contrast to data from clinical trials, receipt of IBT did not demonstrate a protective effect for those at risk to develop T2DM. It does not appear that IBT for weight loss, as currently practiced, is successful in helping patients achieve weight loss or prevent developing T2DM. Whether changes in the implementation of obesity IBT can improve outcomes with or without improved coverage of anti-obesity medication remains an open question.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

The authors do not have permission to share data.

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Data Sharing Agreement

The datasets generated during and/or analyzed during the current study are not publicly available due to data sharing agreements with electronic health record data. However, opportunities exist for collaborations with the PaTH Network.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pmedr.2022.102099.

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