

Comparative Effectiveness of Clinic-Based Intensive Behavioral Therapy for Obese Adults With Type 2 Diabetes

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■ **IN BRIEF** In late 2011, the Centers for Medicare & Medicaid Services began reimbursing for intensive behavioral therapy (IBT) in primary care settings for obese, adult beneficiaries. The effectiveness of IBT is understudied, however, with no weight loss estimates available for adults with diabetes. This study compared weight change over 1 year between obese adults with type 2 diabetes who did receive IBT to those who did not. Findings indicated that IBT was modestly effective, resulting in ~3% weight loss over 1 year compared to 1% weight loss in the matched comparison group who did not receive IBT.

More than one-third of U.S. adults are obese (1,2). According to the Centers for Disease Control and Prevention, obesity rates in the United States have increased dramatically in the past 30 years, and obesity is epidemic in the United States (2). The proportion of adults with diabetes who are obese has increased considerably in recent years, from 35% in 1994 to 57% in 2010 (3). Obesity is a widely recognized risk factor for a litany of chronic health conditions, including type 2 diabetes (4).

The American Diabetes Association recommends weight loss for all overweight or obese individuals who have diabetes (5). A modest weight loss of 5% is generally recommended because it can improve or delay diabetes complications in those who are overweight or obese (6,7). Numerous studies conducted primarily in people without diabetes have demonstrated that lifestyle interventions focused on caloric restriction and increased physical activity can reduce body weight by 5–8% in 1 year (8). However, because typical weight loss among those with type 2 diabetes is 3% in 1

year (9), behavioral weight loss programs may be generally more difficult in this population.

Most published weight management programs for adults with diabetes are delivered in academic health settings, and it is well established that the delivery of clinic-based weight loss counseling for those with type 2 diabetes is infrequent (10). In response to recent trial evidence concluding that clinic-based weight management is effective at producing sustained, modest weight loss, the Centers for Medicare & Medicaid Services (CMS) in late 2011 began reimbursing for intensive behavioral therapy (IBT) for adult beneficiaries with a BMI ≥ 30 kg/m². IBT consists of a series of assessment and counseling visits delivered in a primary care center throughout 1 year and focused primarily on improving nutrition and physical activity behaviors toward a reasonable weight loss goal.

The coverage decision by CMS to reimburse for IBT was lauded as a new means to fill a major gap in preventive health care services (11), but estimates of the effectiveness of IBT remain scant and thus far are

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derived only from simulations or studies with uncontrolled designs (12,13). No studies to date have examined the effectiveness of IBT specifically in people with type 2 diabetes. The purpose of this analysis was to compare the 1-year weight change of obese adults with type 2 diabetes who did receive IBT to that of those who did not.

Methods

Design

This study utilized a retrospective cohort design with a matched comparison group. The target population was IBT-eligible obese adults with type 2 diabetes. All individuals were patients of the Marshfield Clinic Health System (MCHS), a large integrated care system serving the predominantly rural north-central Wisconsin region.

IBT

As described in more detail in the CMS coverage memorandum (10), IBT consists of assessment and counseling to promote sustained weight loss in adults with a BMI ≥ 30 kg/m². IBT visits last 15 minutes and are conducted in a clinical setting. The focus is on behavioral aspects of weight management, including nutrition and physical activity recommendations, along with counseling on behavioral self-management techniques such as goal-setting, self-monitoring, and problem-solving. Height and weight are to be assessed at each visit. CMS covers weekly visits for the first month, then biweekly visits for months 2–6. If a patient loses at least 3 kg during the first 6 months of IBT, monthly visits are covered for months 7–12, for a total of 22 possible visits in 1 year. For patients who do not achieve the ≥ 3 -kg weight loss threshold during the first 6 months of IBT, further IBT visits are no longer covered by CMS, and a reassessment of their readiness to change and BMI can be taken into consideration after an additional 6 months (at which time they can restart IBT). IBT is billed under Current Procedural

Terminology (CPT) code G0447 and, to be reimbursable by CMS, must be delivered by a primary care provider (PCP) or auxiliary primary care staff. Eligible providers include physicians, nurse practitioners, clinical nurse specialists, and physicians' assistants specializing in primary care, but IBT visits may also be led by auxiliary clinical personnel (e.g., registered dietitians [RDs] or registered nurses) under the direct supervision of an eligible PCP (i.e., "incident-to" billing scenarios, in which services are billed as being incident to a physician's services).

Sample

This study compared two groups: adults exposed to IBT and a matched comparison group of adults not exposed to IBT (who presumably received usual medical care). Per the MCHS electronic health record (EHR) system, all patients were ≥ 18 years of age, had type 2 diabetes as established by a previously validated EHR algorithm (14), and did not have an EHR-documented history of bariatric surgery at any point before the end of the study data collection period on 31 March 2016. Eligibility criteria for the IBT group were: 1) exposed to IBT, as evidenced by ≥ 1 G0447 CPT code observation between 31 March 2012 and 31 March 2015 (the first visit was their baseline index date) and 2) "homed" to an MCHS center on their baseline index date (defined as having an assigned PCP in an MCHS center or, if no assigned PCP, ≥ 1 preventive care visit in the past year or ≥ 2 evaluation and management visits in the past 3 years at an MCHS center). For each participant in the IBT group, up to three matched adults who were not exposed to IBT were randomly selected to construct the No IBT comparison group. Eligibility criteria for the No IBT group were: 1) no G0447 CPT code observations on or before 31 March 2016, 2) same sex as their matched IBT case, 3) date of birth within ± 3 years of their matched IBT case, 4) BMI measure collected

within ± 4 months of the baseline index date of their matched IBT case (this was their baseline index date), 5) BMI value within ± 2 kg/m² of their matched IBT case as of their respective baseline index dates, 6) same homed MCHS center as their matched IBT case, and 7) same CMS beneficiary status (i.e., on Medicare or Medicaid) as their matched IBT case as of their respective baseline index dates. All study procedures were approved by the Marshfield Clinic Research Foundation institutional review board, with a waiver of informed consent given the retrospective, analytical nature of this study.

Measures

The outcome was body weight, reported in kilograms, at baseline and in 3-month follow-up interval periods over the course of 1 year. The most recently known ambulatory body weight value within each 3-month follow-up interval was used for analyses. Weights were collected in clinical settings as part of usual patient care and were extracted from each patient's EHR. MCHS has standardized procedures for body weight collection (e.g., without shoes and wearing light street clothing), but adherence to these procedures is not apparent from medical records. Covariates included the baseline matching variables of age, sex, visit date, homed medical center, CMS benefit, and BMI. In addition, cardiovascular disease status was collected based on the presence of select diagnostic codes indicative of a prior ischemic vascular event (not reported, but available upon request).

Analysis

All analytical procedures were conducted with SAS Version 9.4 (Cary, N.C.). χ^2 tests and *t* tests were used to compare the IBT and No IBT groups on baseline demographic and clinical characteristics. Using a general linear mixed model, body weight was predicted between the two groups at the end of each 3-month follow-up period. An intention-to-treat approach was used, whereby all individuals in the

TABLE 1. Descriptive Characteristics of Obese Adults With Type 2 Diabetes Who Did or Did Not Participate in Clinic-Based IBT

	Exposed to IBT (n = 65)	Not exposed to IBT (n = 166)	P
Age (years; mean [SD])	62.2 ± 13.2	64.4 ± 11.5	0.210
Female (n [%])	50 (77)	121 (73)	0.530
BMI (kg/m ² ; mean [SD])	42.1 ± 8.6	41.1 ± 6.8	0.385
CMS beneficiary (n [%])	61 (94)	159 (96)	0.534
Cardiovascular disease (n [%])	28 (43)	62 (37)	0.422

analytical dataset were included, and no imputations were made for missing follow-up weights. Within each group, paired *t* tests were also used to compare weight changes between each 3-month follow-up period. To improve statistical precision, the baseline matching variables were included as covariates in statistical models.

Results

There were 231 study-eligible obese adults with type 2 diabetes included in the analytical dataset, including 65 who had received IBT and 166 who had not. The majority of participants were ≥65 years of age (61%), female (74%), white (97%), and CMS beneficiaries (95%). Mean ± SD BMI at baseline was 42.1 ± 8.6 kg/m² for the IBT group and 41.1 ± 6.8 kg/m² for the No IBT group. As expected given the matching procedures, the groups were similar at baseline and did not significantly differ on any covariates (Table 1).

As outlined in Figure 1, IBT session attendance waned over time. Only about one-third of those in the IBT group attended half of their allowable IBT visits, and <10% completed all 22 possible visits within 1 year. Ninety-eight percent of IBT visits were delivered by RDs. In terms of available weight data over time, 94% of the IBT group and 84% of the No IBT group had at least one available follow-up body weight after baseline.

After covariate adjustment, there was only a significant overall effect for time ($F = 10.3$, $P < 0.001$), but not for group ($F = 0.0$, $P = 0.989$). The overall group-by-time interaction

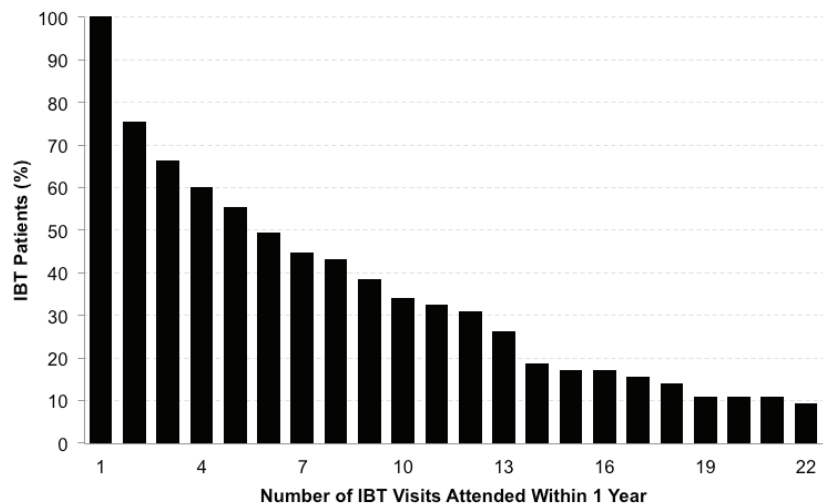


FIGURE 1. IBT visit attendance among obese adults with type 2 diabetes.

was borderline significant ($F = 2.3$, $P = 0.058$), suggesting somewhat different, although statistically indistinguishable, overall rates of weight change between the two groups throughout the study. Group-by-time interactions at the end of each quarter indicated that patients in the IBT group lost significantly more weight than those in the No IBT group between baseline and both 3- ($P = 0.004$) and 6-month ($P = 0.014$) follow-ups, but not between baseline and the 9- ($P = 0.057$) or 12-month ($P = 0.172$) follow-ups. More specifically, as outlined in Figure 2, the IBT group lost 4.0 ± 0.8 kg between baseline and 6 months ($P < 0.001$), but regained 0.4 ± 0.8 kg between the 6- and 12-month follow-ups ($P = 0.606$). In contrast, the No IBT group steadily lost a modest 1.4 ±

0.7 kg total between baseline and 12 months ($P = 0.014$).

Discussion

In this sample of obese adults with type 2 diabetes from north-central Wisconsin, IBT was found to be modestly effective. It resulted in ~3% weight loss over 1 year as compared to 1% weight loss in a matched comparison group of patients who did not receive IBT. Although weight loss for adults who received IBT was about three times greater than for those receiving usual medical care, it was only half as much as previously projected/intimated by the CMS memorandum (10) determining coverage for IBT (as informed by the most recent U.S. Preventive Services Task Force scientific review on behavioral obesity treatments [15]). This is actually consistent with previous research, however, because individuals with

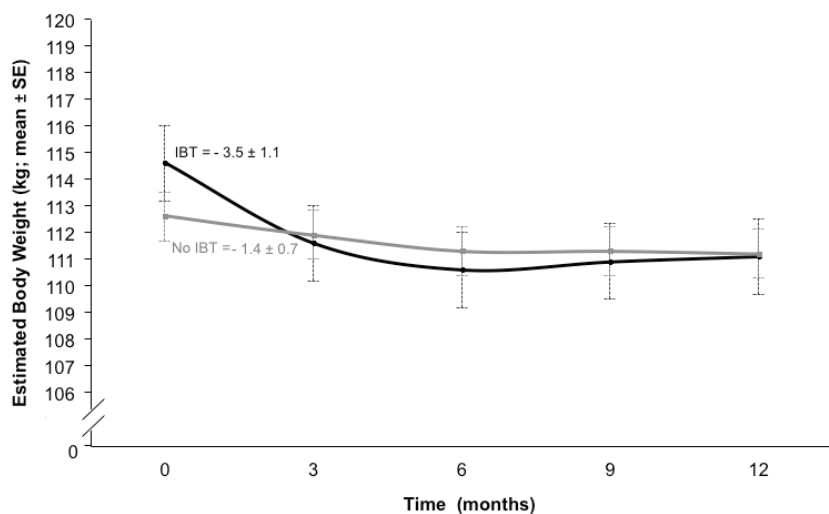


FIGURE 2. Model-estimated body weight change within 1 year among obese adults with type 2 diabetes who did or did not participate in clinic-based IBT.

diabetes tend to lose less weight in a given behavioral weight management program relative to those without diabetes (9) and usually <5% within 1 year (16).

Similar to other behavioral weight loss programs in adults with type 2 diabetes (16) (and those without diabetes [8]), weight loss in the IBT group seemed to reach a nadir after about 6 months and began to erode thereafter, becoming statistically indistinguishable from the No IBT group by the end of 1 year. Although more beneficial in the early months, the impact of IBT was particularly hampered by low completion of allowable study visits. Studies with more professional contact tend to produce greater weight loss and more sustained weight loss maintenance (15), but the reasons for low IBT visit attendance are unknown. Many IBT participants did not meet the ≥3-kg weight loss threshold by the end of 6 months (and therefore were excluded from further covered IBT visits), but visit attendance dropped most precipitously before that point. This may be related to differences between research trials, for which the evidence base justifying IBT largely exists, and real-world programs that attempt to emulate those trials. Trial participants are usually

healthier, younger, and more apt to adhere to a prescribed treatment regimen (11,17), but there are also differences in treatment delivery. For example, many of the larger and more successful randomized controlled trials of behavioral weight loss therapy for adults with type 2 diabetes, such as Look AHEAD (18), utilize vigilant adherence promotion practices whereby study staff routinely monitor, prompt, encourage, and reward continued participant engagement in program activities. Such efforts toward optimizing program fidelity are impractical in most nonresearch health care settings and, to the extent they do occur, are likely less intense.

Utilization challenges with IBT have been raised by others (11,19), particularly in older age-groups where it appears IBT is more likely to occur. Given the limited reimbursement for IBT at ~\$27 per visit, it will be important for future research to examine the reach of this service among IBT-eligible type 2 diabetes patients. It appears that <1% of those in the general CMS population have taken advantage of it (20). Also of note, nearly all IBT sessions in our study were led by RDs; thus, the degree to which PCPs are aware of (or feel able to deliver) IBT seems quite low. This finding supports the notion

that the medical infrastructure is not currently suited to delivering IBT on a wider scale, which is why Batsis et al. (19) have advocated for broader use of telemedicine to deliver IBT, particularly in rural areas with more transportation barriers and proportionately larger geriatric populations. There may also be low awareness of or confusion about the ability of auxiliary primary care staff such as RDs to bill for IBT under incident-to billing scenarios (19,21).

This study reflected the real-world IBT experience of obese adults with type 2 diabetes. A strength of our analysis was the ability to use existing EHR data from a defined population of health care system patients. This permitted construction of a matched parallel comparison group and passive surveillance of clinic-measured body weight over time. This source population was limited, however, to a homogenous, predominantly rural region of the United States, which restricts widespread generalizability. Also, body weights collected in the clinical setting do not follow strict research procedures, and the EHR does not contain query-able data on lifestyle factors that can better contextualize weight loss (e.g., nutrition and physical activity). Future research may consider more detailed examinations of medical chart notes to understand what documented lifestyle changes IBT patients are making.

Our analysis indicates that IBT is modestly effective for obese adults with type 2 diabetes, but as is common with other behavioral weight management therapies, weight loss was limited after 6 months. Despite this, the CMS decision to cover IBT for its beneficiaries presents an important opportunity to directly confront the obesity epidemic in medical settings, particularly if IBT methods can be refined. Mitigating early IBT disengagement seems to be an important priority for future research; practical methods (e.g., telemedicine) are needed for health

care systems and providers to help maintain the interest of obese adults with type 2 diabetes in ongoing, clinic-based weight management counseling.

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Author Contributions

T.L.H. drafted the manuscript and analyzed the data. J.J.V. designed the study and reviewed/edited the manuscript. J.J.V. is the guarantor of this work and takes responsibility for the integrity of the data, analyses, and conclusions.

Duality of Interest

No potential conflicts of interest relevant to this article were reported.

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