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The impact of a continuous care intervention for treatment of type 2 diabetes on health care utilization

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Abstract

Introduction: Type 2 diabetes (T2D) is a major driver of health care costs, thus treatments enabling T2D reversal may reduce expenditures. We examined the impact of a T2D continuous care intervention (CCI) on health care utilization. Previous research documented that CCI, including individualized nutrition supported by remote care, simultaneously reduced hemoglobin A1c and medication use and improved cardiovascular status after two years; however, the impact on utilization is unknown.

Methods: This study used four years of data (two years pre-intervention, two years post-intervention) from the Indiana Network for Patient Care (INPC) health record. Two methods estimated the impact of CCI on utilization. First, an interrupted time series (ITS) including only CCI participants (n=193) compared post-intervention utilization to expected utilization had the pre-intervention trend persisted. Deviation from the trend was estimated non-parametrically for each 6-month interval after the implementation of CCI . Second, a 1:3 matched comparator group (n=579) was constructed and used for a difference-in-differences (DiD) analysis. The primary outcome was annualized outpatient encounters. Secondary outcomes included emergency encounters and hospitalizations.

Results: In two years prior to intervention, CCI participants had a mean of 5.77 annualized encounters (5.62 outpatient, 0.04 hospitalizations, 0.11 emergency). The CCI group showed a reduction in outpatient utilization after intervention. In ITS analysis, 1.6 to 1.9 fewer annualized outpatient encounters occurred in each 6-month interval post-intervention relative to expected utilization based on pre-intervention trends ($p<0.01$ each 6-month period; 28-33% reduction). The DiD analysis suggested a larger reduction; 5 fewer annualized outpatient encounters in the quarter after intervention, diminishing to 2.5 fewer after 2 years ($p<0.01$ each quarter). The study was underpowered to draw conclusions about hospitalization and emergency encounters due to the limited number of CCI patients and the rarity of encounters.

Conclusions: Outpatient encounters were significantly reduced for a T2D patient population up to 2 years after receiving an individualized intervention supporting nutrition and behavior change through remote care.

ClinicalTrials.gov Identifier: NCT02519309
Funding: Virta Health Corp.

Introduction

Annual costs associated with diabetes in the United States surpassed $327 billion in 2017 including $237 billion in direct medical costs, a steep increase from 2012 estimates [1]. Ninety-one percent of diagnosed diabetes cases are type two diabetes [2]. Average cost of care per patient with diabetes in the US is $16,752, 2.3 times the expenditure for patients without diabetes when adjusted for age. Expenditures are concentrated on patients with greater disease progression with just 10% of patients accounting for 57% of expenditures [3]. Diabetes care is expected to put substantial financial pressure on health system and payers in future years [4].

Treatments resulting in diabetes remission and restored metabolic health provide an opportunity to prevent the continued rapid rise of system expenditures for T2D. A clinical trial initiated in 2015 by Indiana University Health and Virta Health, tested a continuous care intervention (CCI) in a population with T2D in central Indiana providing telemedicine, health coaching, dietary and behavior change education including the use of nutritional ketosis, biometric feedback and an online peer community. After two years with 74% of participants retained, mean hemoglobin A1c (HbA1c) was reduced 12% while most diabetes medications were discontinued. 54% of patients completing two years of the treatment had a HbA1c below the diabetes threshold of 6.5% without medication use other than generic metformin [5,6]. Cardiovascular disease (CVD) risk factors also showed significant improvement [7]. Estimated annual mean expenditure for diabetes medications declined a significant 46% from $4,438 to $2,329 [8]. Nutritional ketosis and other low carbohydrate diets are now among the American Diabetes Association recommended eating patterns for T2D [9].

In this study, we examine how CCI impacted utilization of health services beyond medication reductions. To determine health care utilization by CCI trial participants, data from the Indiana Network for Patient Care (INPC) database capturing most outpatient, hospitalization and emergency department use was examined for two years prior to treatment and two years during treatment. Utilization was compared to anonymous INPC matched controls from central Indiana.

Methods

Intervention and Treated Population

Virta Health and Indiana University Health (IUH) are conducting an ongoing clinical trial examining CCI for the treatment of type 2 diabetes (T2D). CCI involves telemedicine, health coaching, education in behavior change and nutrition (e.g. individualized carbohydrate restriction), biometric feedback (e.g. glucose, ketone bodies) and an online community. Trial design, methods, and clinical outcomes are described in [5-7,10,11]. The intervention is also described in more detail in the supplemental materials. In brief, the institutional review board (IRB) approved trial recruited participants between August 2015 and April 2016 and will follow participants for five years. Patients were primarily recruited from the greater Lafayette Indiana region (six counties) with a smaller number (~10%) residing in Indianapolis. The trial utilized a non-randomized design allowing patients to opt-in to the treatment. 262 individuals enrolled in CCI and another 87 consented to be followed as a usual care control group. CCI participants further self-selected their mode of educational delivery as all online (n=126) or additionally participating in periodic in person group classes (n=136). Intervention outcomes, including changes to glycemic control prescriptions, were communicated to each participant’s primary care provider.

Utilization Data and Comparator Population

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The Indiana Network for Patient Care (INPC) database captures electronic health records data including system encounters such as outpatient encounters, hospitalizations and emergency department use from hospitals and provider networks in the state of Indiana [12]. To determine system utilization over time by CCI trial participants, INPC data was accessed for eligible patients (n=193). CCI participants eligible for INPC data review (n=193) were mostly, though not entirely, those who completed two years of the intervention.

To assemble a pool from which to select a matched comparator group, records were obtained for 2,730 anonymous individuals with T2D in central Indiana. These patients in the comparator group were selected on the basis that they would have met the inclusion criteria for the Virta-IUH trial. Records were anonymized before sharing with study investigators. Patients were selected with a medical encounter (index date) occurring between August 1, 2015 and April 30, 2016 to match the clinical trial's enrollment period. To ensure anonymity of comparator group health records, the date of birth, index dates and days of other medical encounters for each patient were staggered forward or backwards a randomized number of days up to 30. (The intervals between encounters was unchanged.)

Like CCI patients, the comparator group individuals were between age 21 and 65 years at time of index date with a confirmed T2D diagnosis by fasting glucose > 125 mg/dL or HbA1c > 6.5%. Exclusion criteria for the INPC comparator group were the same as those applied to CCI participants: any diagnosis of type 1 diabetes; schizophrenia (ICD 295; ICD10 F20-F29); myocardial infarction (ICD9 410; ICD10 I21) or stroke (ICD9 430-434; ICD10 I60-I63) within six month prior to index; any stroke resulting in speech or language deficit (CD10 I69.328); any diabetic peripheral angiopathy with gangrene (E11.52). Transient ischemic attack (TIA) was not excluded. Exclusion by cancer requiring treatment within the last five years was determined by procedure codes rather than diagnosis codes since cancer diagnostic codes can be carried forward for many years. Patients with melanoma were excluded whereas those with non-melanoma skin cancers were not. Patients with chronic kidney disease (CKD) stages 4 and 5 were excluded whereas those with stages 1, 2, and 3 were not to match trial exclusion of serum creatinine >2 mg/dL. Patients with diabetic retinopathy requiring treatment were excluded whereas those with unspecified diabetic retinopathy (E11.319) were not. Patients with psychiatric conditions other than schizophrenia, including bipolar disorder and major depression, were not excluded. (Patients diagnosed as T2D with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC) (E11.00) were not excluded as this is usually a coding error as the first choice in the Epic (Epic Systems Corporation) electronic medical record diabetes drop down menu.)

The time interval for INPC record retrieval for both CCI participants and the comparator group was August 2013 to August 2018. This allowed for inclusion of medical records from at least two years prior to first trial enrollment in August of 2015 to more than two years after last trial enrollment in April 2016 so that encounters for two years of pre-treatment could be compared to two years during and after treatment. CCI participant retention in the trial was 83% at one year and 74% at two years [6]. The post-intervention period refers to any time after the initiation of the intervention whether the patient remained under care or not.

Geographically, four counties in central Indiana were selected for comparator group inclusion; Delaware County (greater Muncie) and Monroe County (greater Bloomington) (n=950), and Marion and Hamilton County (greater Indianapolis) (n=1780). Muncie and Bloomington are mid-size industrial towns with universities demographically similar to Lafayette whereas Indianapolis is the nearest major metropolitan region. The greater Lafayette region itself was not included in comparator group formation as many individuals residing in the area were receiving the CCI treatment for T2D from Virta Health through local employers in 2017-18 whereas this is not the case for Muncie, Bloomington and Indianapolis.

INPC database inquiry was conducted by personnel of the Regenstrief Institute with IRB approval. CCI participants were identified by name, date of birth and medical record number and confirmed by cross-reference to the IUH-Arnett outpatient medical record system. Required institutional approvals allowed access for identified CCI patient records accounting for an estimated 96% of INPC recorded patient encounters. Approval was provided by major providers IUH, Franciscan Alliance and St. Vincent/Ascension. Approval was not obtainable from Community Health Network and several other minor providers accounting for <4% of encounters. No INPC recorded encounters were excluded from the comparator group as additional institutional approvals were not required for anonymized records. Insurance claims were not included in the captured data for either the CCI patients or comparator group. An unknown number of small and non-affiliated private medical practices do not participate in INPC.

We used an exact matching approach to construct a comparator group (n=579) from this pool that was similar to CCI participants on important observable characteristics [13]. Using a 3x1 ratio (three controls for each treated unit) we matched on sex of patient and four ICD9/10 recorded comorbidities that we found to be strong predictors of outpatient utilization: cardiac conditions (congestive heart failure, cardiac arrhythmias, or valvular disease), hypertension (complicated or uncomplicated), obesity, and respiratory conditions (chronic pulmonary disease or pulmonary circulation disorders).

Outcomes

The primary study outcome was annualized outpatient utilization. We included all CCI and matched control encounters that were classified as outpatient by Regenstrief Institute extracted INPC data for whom the provider was listed as a medical doctor or nurse practitioner. For CCI patients, visits that were part of trial data collection and CCI care delivery were excluded as we were interested in determining system utilization that was not part of the trial itself. Trial encounters were not designed to replace primary care provider visits nor were additional services provided beyond the intervention protocol during these encounters. Data collection visits occurred at baseline, 70 days, 1 year and 2 years for all patients. Patients who self-selected classroom educational delivery visited the clinic for 30 classes with their health coach over 2 years whereas patients who selected online education received the same instruction remotely. We summed outpatient encounters for each calendar quarter and analyzed data at the person-quarter level, multiplying quarterly encounters by four to create an annualized measure. We also evaluated CCI and matched comparator group hospitalizations and emergency department encounters by the same methods. However, these are relatively infrequent occurrences and, given our sample size, the study was not sufficiently powered for this analysis. Therefore, we focused primarily on outpatient utilization.

Statistical Analysis

We used two quasi-experimental analytical methods to assess the impact of CCI on healthcare utilization. First, we used an interrupted time-series (ITS) approach, which synchronizes all patients by intervention start date and compares post-intervention utilization to what would have been expected had the pre-intervention utilization trend continued into the post-intervention period [14]. For this analysis, we estimated the following equation including only the sample that received CCI.

$$(1) \quad Y_{it} = \beta_0 + \beta_1 Quarter_{it} + \beta_2 Month6 + \beta_3 Month12 + \beta_4 Month18 + \beta_5 Month24 + \epsilon_{it}$$

Where Y_{it} represents the number of outpatient encounters for person i in quarter t. The term $Quarter_{it}$ is a continuous variable indicating the study quarter. Quarters for this analysis were standardized to be the number of quarters from the start of the intervention at time zero (ranging from -10 to +9). The $Month$ variables are binary variables indicating whether the observation is from 0-6, 7-12, 13-18, or 19-24 months after the beginning of the intervention. Therefore, the term β_1 represents the linear time trend in

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outpatient encounters prior to the start of the intervention. The terms β_2-β_5 represent the deviation from what is predicted by the pre-intervention time-trend during each of the respective post-intervention periods. Assuming that the pre-intervention time trend is linear and would have continued into the post-intervention periods, β_2-β_5 represent the impact of CCI at each time point. As CCI is ongoing, 'post-intervention' refers to the time after the initiation of CCI treatment whether the patient remained under care or not.

Second, a limitation of the ITS analysis is that some unobserved factor in the post-intervention period could have impacted health care utilization. In such a case, the pre-intervention time trend would not be a good counterfactual for what would have occurred in absence of the intervention. To account for this, we conducted a difference-in-differences (DiD) analysis using the matched comparator group. Assuming that trends in utilization are parallel and shocks to utilization in the post periods are common between the matched comparator group and the CCI group, the matched comparator should serve as a good counterfactual. In other words, the comparator group should reflect how utilization in the CCI group would have looked without the intervention. We used an event study empirical approach, which compares the difference between the CCI group and the matched comparator group in each study period relative to the difference in a reference study period (the period directly before CCI begins). For this analysis, we preserve the calendar date as comparators cannot be synchronized by intervention start date. We estimate the following equation.

$$(2)\ \ Y_{it} = \beta_0 + \beta_1 CCI_i + \sum_t \beta_q Quarter_t + \sum_t \alpha_t Quarter \times CCI_{it} + \epsilon_{it}$$

In this equation, CCI is an indicator for whether the person was part of CCI and $Quarter$ is an indicator for the calendar quarter (Q2 of 2013 to Q1 of 2018 with Q1 of 2013 as the reference). The interaction term, $Quarter \times CCI$, models the difference between the CCI group and the matched control group in each quarter relative to the difference in the quarter just prior to the start of the intervention recruitment (Q2 of 2015). Thus, the set of α terms represent the difference-in-differences estimate for CCI in each quarter relative to the difference in Q1 2013. A key assumption in this type of DiD analysis is that the trends are parallel between the treatment and control group. If this assumption holds, we would expect the α_t terms to be statistically indistinguishable from zero for each quarter prior to the intervention. Moreover, if CCI reduces utilization, we would expect the α_t terms to be negative in the quarters after the intervention begins.

We clustered standard errors by individual for all analyses to account for autocorrelation in the error term. Analysis was conducted in R statistical software.

Results

The average age for the 193 participants in the CCI population was 54 years (Table 1). In the two years prior to the intervention, CCI participants had a mean of 5.77 annualized health system encounters (5.62 outpatient encounters, 0.04 hospitalizations, and 0.11 emergency encounters). By ICD9/10 codes, comorbidities were common in this population; 5% had a cardiac condition, 22% had hypertension, 46% were obese, and 4% had a respiratory condition. Actual incidences of disease were substantially higher based on medical examination and history [5].

Figure 1 presents the trend in outpatient utilization over the study period where patients are synchronized by their personal intervention start date. The linear trend line demonstrates that utilization appears to increase linearly in the pre-intervention period (left of the vertical dashed line) and that there is a reduction in outpatient encounters after the intervention begins (right of the vertical dashed line). The diagonal dashed line indicates predicted utilization based on the pre-intervention trend estimated in equation 1 (β_1). Table 2 presents the coefficients from the interrupted time series analysis. These coefficients show that CCI was associated with 1.5 fewer annualized encounters (28% reduction from baseline) in the first 6 months after the intervention began (95% CI -2.4, -0.6; p<0.01), and this reduction persisted for 24 months after the intervention; 2.1 fewer encounters 7-12 months post (95% CI -3.3, -1.0; p<0.01), 1.9 fewer encounters 13-18 months post (95% CI -3.2, -0.6; p<0.01), and 1.9 fewer encounters 19-24 months post (95% CI -3.5, -0.4; p<0.01).

Column 2 of Table 1 presents the matched comparator group for reference to the CCI group. Patient age and medical record derived BMI, which were not used for matching, appear similar between groups. In the two years prior to the intervention, comparator group patients had a mean of 3.6 annualized health system encounters (3.2 outpatient encounters, 0.07 inpatient encounters, and 0.25 emergency encounters). While the matched comparator group had fewer encounters than the CCI group prior to the intervention, Figure 2 demonstrates that pre-intervention trends were very similar (panel A of figure 2), which is essential for the DiD analysis to be valid. Moreover, coefficients from the event study (panel B of figure 2) were statistically indistinguishable from zero in every pre-intervention period. In Q4 of 2015, the first full quarter after recruitment for the intervention began, but while many participants had yet to start CCI, the coefficient becomes negative (estimate of -2.2; 95% CI -3.7, -0.7; p<0.01) and continues to get more pronounced as recruitment continues. Once all participants had started the intervention, Q2 of 2016, the estimate reflects a reduction in outpatient encounters of 5.0 encounters per year (95% CI -6.7, -3.3; p<0.01). This effect diminished over time but remained statistically significant two years after the intervention (estimate of -2.5; 95% CI -4.4, -0.6; p<0.01). Appendix table A2 presents full regression results.

Appendix figures A1-A4 and tables A1 and A2 demonstrate that we cannot draw conclusions about the impact of CCI on hospitalization and emergency department encounters. Our sample size combined with the rarity of hospitalization and emergency department encounters does not allow us to produce estimates with precision.

Discussion

Prior evidence demonstrates that the CCI treatment, including technology-provided nutrition education, health coaching and telemedicine improves diabetes status and reduces medication use over two years [6]. However, its impact on health system utilization over the same time was previously unknown. In this study, we find that in the two years following initiation of CCI, outpatient encounters are reduced relative to both the two-year pre-intervention trend-line and encounters observed in an INPC-assembled T2D comparator population. Consistency across these distinct analytical strategies helps to provide confidence that our results are valid. The study was insufficiently powered to determine whether hospitalization and emergency department utilization was reduced as these are rarer events, the intervention population was small (n=193) and the observation window for the intervention only two years.

In 2017, outpatient encounters accounted for roughly 21% of all health care expenditures for patients with diabetes, resulting in $87 billion annually [1]. Therefore, the savings associated with the reduction in outpatient utilization we document are not trivial. Our ITS estimates, which are more conservative than the DiD estimates (28% reduction in outpatient visits), suggest that if CCI were implemented for all patients with diabetes, this would save over $24 billion annually. Moreover, this does not include potential savings from reduced utilization of other services not addressed in this paper (e.g., medication use).

Patient costs for T2D rise with disease progression, initially for treatment [15,16] and eventually disease sequela [9,17]. Expenditures rise in populations with higher HbA1c and greater obesity [18,19]. Bariatric surgery to reverse diabetes [20] may result in cost-effective health gains including reductions in expenditure for diabetes care post-surgery [21,22]. A direct measure of savings in T2D surgical patients with BMI >35 kg/m^2 versus matched controls determined that the surgical cost of $25,317 was recovered in savings over 30 months [23].

There are several possible interpretations of the reduction in outpatient encounters. First, the patients' improved health (e.g. reduced hyperglycemia, weight loss, reduced blood pressure, reduced medication use, etc.) may have necessitated fewer visits with primary care and specialty providers. Second, the remote physician and health coach interactions provided by CCI may be substituting for regular in person care provider interactions as diabetes-related and other health-related questions and concerns are being addressed by the remote care team. Third, the patients may be utilizing the study-related provider interactions (e.g. clinical data collection at baseline, 70 days, 1 and 2 years) and group classes (for those choosing classroom education) to substitute for other outpatient care. All three interpretations are consistent with the reduction of the difference between CCI and the comparator group outpatient encounters from the first to the second year. By design, patient-health coach and patient-physician interactions in the trial intervention are lower in frequency in the second year of the treatment as are classes. Retention in the trial is also lower at the end of 2 years (74%) versus baseline (100%), 70 days (91%) and 1 year (83%) so that not all health gains may be retained or patients may return to their prior outpatient utilization as CCI support and trial follow-up is no longer available as a source of care. It is possible that trends would further converge beyond two years.

The CCI was not designed to replace primary care provider (PCP) visits nor were additional diabetes-related services provided including screening for diabetic retinopathy and diabetic foot exams [24,25]. The CCI could be improved by further integrating PCP communications and comprehensively tracking aspects of diabetes care that cannot yet be accomplished by technology-supported remote care.

The results of this study should be viewed in light of its limitations. First, even though we have longitudinal data on study participants and from a matched comparator group; our quasi experimental analysis cannot address all potential sources of bias in study findings. The ITS analysis relies on the assumption that the linear trend in utilization would have continued in absence of the intervention. If this assumption does not hold (as is the case in the comparator group), our results could be biased in an unpredictable way. For the DiD analysis, the comparator group was assembled retrospectively from individuals with similar baseline characteristics in their medical record rather than a prospective randomized control. Our results rely on the assumption that the comparator group serves as a good counterfactual for what utilization trends would have looked like in the CCI group had participants not enrolled in intervention. The larger estimates in the first quarters after recruitment finished are partly driven by the fact that the comparator group experience a spike in utilization during this time. If the CCI group would not have experienced this same spike, our results would be overstated. However, consistency across these two distinct analytical strategies provides some confidence that our results are not driven by random chance.

Second, the sample size of intervention participants was insufficient for examination of rarer events like hospitalization and emergency care, which are the biggest drivers of health care expenditures. Future work should further examine the impact of CCI on hospitalization and emergency care using a larger sample size. Third, utilization was assessed from a statewide medical records exchange, which does not include medical expenditures. Thus, we are unable to directly estimate the cost implications of the utilization reductions we identify. Fourth, the data did not capture utilization by individuals moving out of the state. Finally, the timeframe of two years does not capture long-term sequelae of diabetes that manifest over decades.

Ideally, future studies of the impact of CCI on medical costs would allow for intent-to-treat analysis of large populations (many thousands) randomized to eligibility or ineligibility to CCI and measured by insurance claims [26]. Claims tracking would capture expenditures on nearly all categories of care in addition to system encounters including pharmaceuticals, procedures (e.g. radiology, outpatient surgery), laboratory tests, durable medical equipment and supplies, which together are a substantial portion of overall expenditures in T2D patients [15,16]. As CCI is now commercially available, it's cost of delivery could be included in the study to provide payer return on investment (ROI) or cost effectiveness calculations [23].

Conclusions

In this study, outpatient encounters were significantly reduced over two years for a T2D patient population receiving an individualized remote-supported intervention. Future studies with more comprehensive design and larger populations will be required to determine the overall ROI of CCI diabetes treatment.

Acknowledgments
The authors thank the trial participants for their commitment to health and advancing scientific knowledge. Special thanks to Virta-IUH trial principal investigator Dr. Sarah Hallberg and clinic staff and Regenstrief Institute staff Cristian Guandique (data science), Dr. Sui L. Hui (biostatistics) and Cynthia Lim Louis and Jennifer Gatz (project coordination).

The study was supported by Virta Health. Wagner and Sood are paid scientific advisors for Virta Health. Bhanpuri and McCarter are employees of Virta Health.

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Tables

Table 1. Patient Characteristics

Attributes	CCI Group	Comparator Group
Number of patients (N)	193	579
Total Annualized Encounters at Baseline (mean (sd))	5.77 (6.71)	3.55 (4.98)
Outpatient Encounters (mean (sd))	5.62 (6.54)	3.23 (4.49)
Hospitalization Encounters (mean (sd))	0.04 (0.15)	0.07 (0.30)
Emergency Encounters (mean (sd))	0.11 (0.28)	0.25 (0.76)
Age (mean (sd)) (years)	54.3 (8.5)	51.7 (10.1)
BMI (mean (sd)) (kg/m^2)	40.1 (8.1)	36.2 (8.3)
Caucasian (%)	90%	75%
Female (%)[1]	65%	65%
Cardiac Condition (%)[1]	5%	5%
Hypertension (%)[1]	22%	22%
Obesity (%)[1]	46%	46%
Respiratory Condition (%)[1]	4%	4%

sd = standard deviation
1 = Attributes used for matching based on ICD-9/10 codes in medical record

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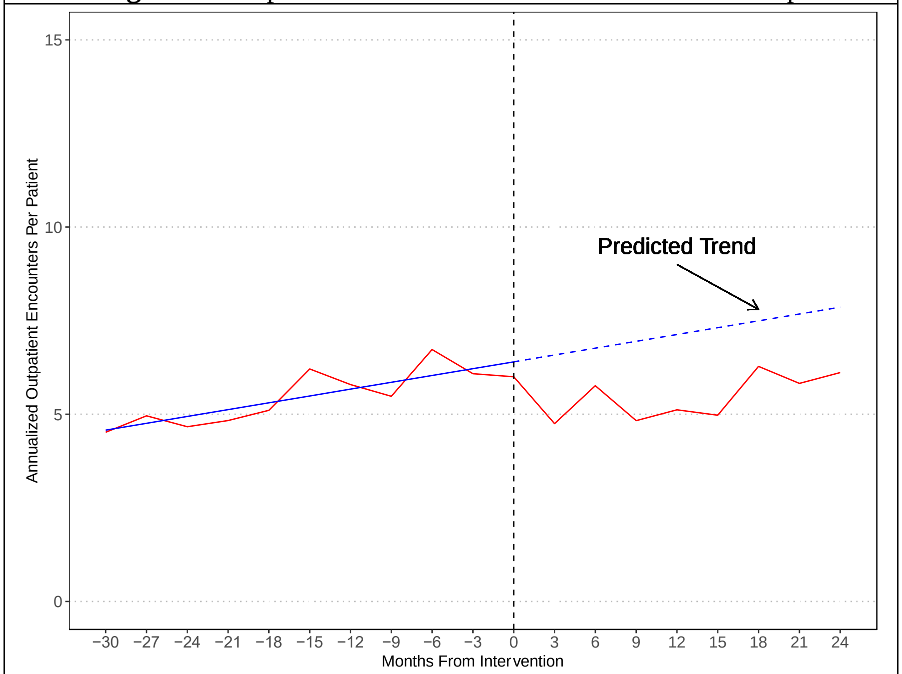
Table 2. Interrupted Time Series (Regression Results)

	Annualized Number of Outpatient Encounters	
	Coefficients	95% Confidence Interval
Pre-trend	0.192***	(0.103, 0.281)
Month 6	-1.467***	(-2.377, -0.584)
Month 12	-2.123***	(-3.258, -1.037)
Month 18	-1.851***	(-3.159, -0.599)
Month 24	-1.892**	(-3.489, -0.353)
Constant	6.450***	(5.429, 7.469)
Observations	3,648	
R2	0.004	

Note: *p<0.1;**p<0.05;***p<0.01

Figures

Figure 1: Outpatient Encounters Over Time for CCI Group



Notes: Solid blue line represents the linear trend predicted using only the pre-intervention time period. The dashed blue line represent what would be expected if the pre-intervention trend continued into the post intervention period.

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Figure 2: CCI versus Matched Comparator Patient Time Series

A. Outpatient Encounters Over Time

B. Coefficients from event study

Each point in panel B is the coefficient estimate from the event study model. The points represent the differerence between the CCI and the mathched comparator group in each quarter relative to the difference in 15q1. Error bars represent 95% confidence intervals.