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

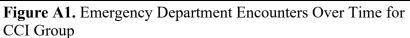
Zachary Wagner, Nasir H. Bhanpuri, James P. McCarter, Neeraj Sood

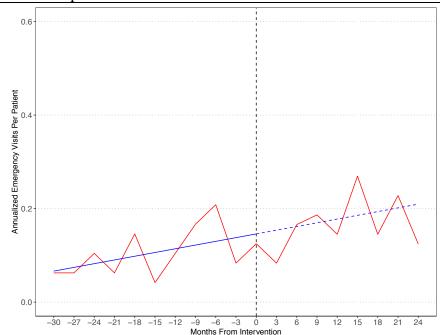
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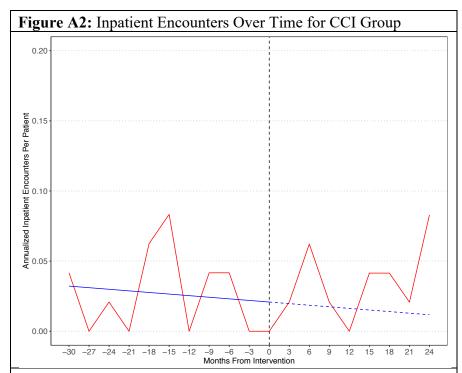
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Notes: Solid blue line represents the linear trend predicted using only the pre-intervention time period. The dashed blue line represent what would be expected if the pre-intervention trend continued into the post intervention period.



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.

Figure A3: CCI versus Matched Comparator Patient Time Series for Emergency Department

0.6

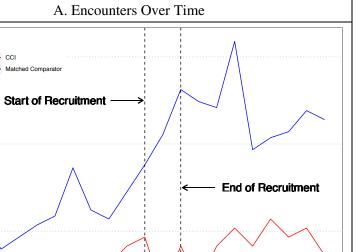
Annualized Emergency Visits Per Patient

0.0

13q3

14q1

14q3



B. Coefficients from Event Study

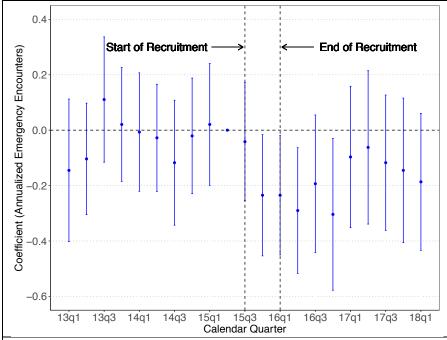
15q1 15q3 16q Calendar Quarter

16q1

16q3

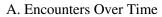
17q1

17q3



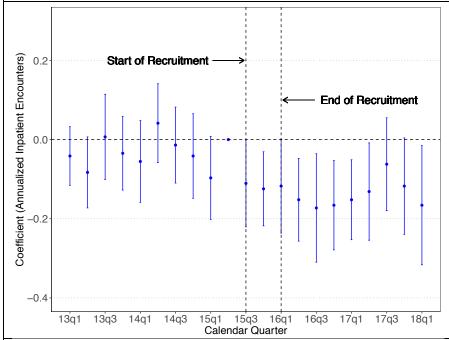
Each point in panel B is the coefficient estimate from the event study model. The points represent the differerence between the CCI and the mathched comparator group in each quarter relative to the difference in 15q1. Error bars represent 95% confidence intervals.

Figure A4: CCI versus Matched Comparator Patient Time Series for Hospitalizations





B. Coefficients from event study



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

Appendix Tables

Table A1. Interrupted Time Series (Regression Results, Emergency and Inpatient Encounters)

Lifeounters)	Annualized Nun	nher of Emergency		
	Annualized Number of Emergency Encounters		Annualized Number of Inpatient Encou	
_	95% Confidence			95% Confidence
	Coefficients	Interval	Coefficients	Interval
Pre-trend	0.007	(-0.002, 0.016)	-0.001	(-0.005, 0.004)
Month 6	-0.027	(-0.122, 0.069)	0.020	(-0.028, 0.068)
Month 12	0.0005	(-0.116, 0.117)	-0.010	(-0.051, 0.031)
Month 18	0.028	(-0.131, 0.187)	0.023	(-0.036, 0.082)
Month 24	-0.017	(-0.159, 0.125)	0.035	(-0.036, 0.105)
Constant	0.141***	(0.076, 0.206)	0.023**	(0.001, 0.044)
Observations	3,655		3,655	
R2	0.003		0.001	

^{*}p<0.1;**p<0.05;***p<0.01

Table A2. Event Study Coefficients

14010 112. 11	Outpatient Encounters	Emergency	Inpatient
	(1)	Encounters (2)	Encounters (3)
CCI	2.197***	-0.031	0.00
	(0.715, 3.679)	(-0.076, 0.014)	(-0.018, 0.018)
13q1	-1.762***	-0.005	0.00
	(-2.360, -1.163)	(-0.061, 0.051)	(-0.012, 0.012)
13q2	-1.762***	-0.016	0.01
1342	(-2.328, -1.195)	(-0.055, 0.024)	(-0.007, 0.028)
13q3	-1.534***	-0.033*	-0.002
	(-2.141, -0.926)	(-0.068, 0.002)	(-0.012, 0.008)
	-1.389***	-0.026	0.002
13q4	(-1.992, -0.785)	(-0.057, 0.006)	0.003 (-0.012, 0.019)
	(-1.772, -0.763)	(-0.037, 0.000)	(-0.012, 0.017)
14q1	-1.554***	-0.019	0.009
1 141	(-2.122, -0.987)	(-0.054, 0.016)	(-0.010, 0.028)
14q2	-0.974***	-0.014	-0.005
	(-1.547, -0.402)	(-0.044, 0.016)	(-0.015, 0.005)
14.2	-0.428	0.014	0.003
14q3	(-1.052, 0.195)	(-0.027, 0.054)	(-0.009, 0.016)
		,	,
14q4	-0.394	-0.01	0.01
	(-0.976, 0.188)	(-0.045, 0.024)	(-0.007, 0.028)
		0.01.5	
15q1	-0.297	-0.016	0.019*
	(-0.781, 0.187)	(-0.053, 0.021)	(-0.0004, 0.038)
15q3	0.974***	0.016	0.017
	(0.404, 1.544)	(-0.023, 0.054)	(-0.006, 0.041)
15q4	1.575***	0.033	0.021**
	(0.871, 2.279)	(-0.008, 0.074)	(0.002, 0.039)

16q1	2.432***	0.059***	0.029***
-	(1.758, 3.106)	(0.023, 0.094)	(0.008, 0.051)
16q2	4.477***	0.052**	0.033***
•	(3.666, 5.288)	(0.012, 0.091)	(0.014, 0.052)
16q3	3.489***	0.048*	0.043***
•	(2.669, 4.308)	(-0.001, 0.097)	(0.016, 0.071)
16q4	3.206***	0.086***	0.036***
- 1	(2.368, 4.043)	(0.033, 0.140)	(0.014, 0.058)
17q1	3.648***	0.024	0.028***
1	(2.829, 4.466)	(-0.018, 0.066)	(0.007, 0.048)
17q2	3.820***	0.031	0.038***
	(2.982, 4.659)	(-0.011, 0.073)	(0.017, 0.059)
17q3	3.095***	0.035	0.021**
	(2.228, 3.962)	(-0.012, 0.081)	(0.002, 0.039)
17q4	3.040***	0.047*	0.029**
1	(2.263, 3.817)	(-0.004, 0.098)	(0.007, 0.052)
18q1	3.033***	0.041*	0.041**
- 1	(2.215, 3.851)	(-0.002, 0.084)	(0.010, 0.073)
13q1 X CCI	-0.269	-0.036	-0.01
•	(-1.702, 1.163)	(-0.101, 0.028)	(-0.029, 0.008)
13q2 X CCI	0.187	-0.026	-0.021*
•	(-1.322, 1.695)	(-0.076, 0.024)	(-0.043, 0.002)
13q3 X CCI	0.58	0.028	0.002
•	(-0.861, 2.022)	(-0.029, 0.084)	(-0.025, 0.029)
13q4 X CCI	0.435	0.005	-0.009
-	(-1.078, 1.949)	(-0.046, 0.057)	(-0.032, 0.015)

14q1 X CCI	0.083 (-1.332, 1.498)	-0.002 (-0.055, 0.052)	-0.014 (-0.040, 0.012)	
14q2 X CCI	0.228 (-1.318, 1.774)	-0.007 (-0.055, 0.041)	0.01 (-0.015, 0.035)	
14q3 X CCI	-0.131 (-1.635, 1.373)	-0.029 (-0.086, 0.027)	-0.003 (-0.027, 0.021)	
14q4 X CCI	0.332 (-1.116, 1.779)	-0.005 (-0.057, 0.047)	-0.01 (-0.037, 0.016)	
15q1 X CCI	0.028 (-1.353, 1.409)	0.005 (-0.050, 0.060)	-0.024* (-0.050, 0.002)	
15q3 X CCI	-0.477 (-1.894, 0.941)	-0.01 (-0.064, 0.043)	-0.028** (-0.055, -0.0002)	
15q4 X CCI	-2.218*** (-3.702, -0.734)	-0.059** (-0.113, -0.004)	-0.031*** (-0.054, -0.008)	
16q1 X CCI	-3.613*** (-5.206, -2.020)	-0.059** (-0.113, -0.005)	-0.029* (-0.059, 0.0003)	
16q2 X CCI	-5.016*** (-6.686, -3.345)	-0.073** (-0.129, -0.016)	-0.038*** (-0.064, -0.012)	
16q3 X CCI	-4.463*** (-6.138, -2.788)	-0.048 (-0.110, 0.014)	-0.043** (-0.077, -0.009)	
16q4 X CCI	-3.910*** (-5.585, -2.236)	-0.076** (-0.144, -0.008)	-0.041*** (-0.070, -0.013)	
17q1 X CCI	-4.373*** (-5.977, -2.769)	-0.024 (-0.088, 0.040)	-0.038*** (-0.063, -0.013)	
17q2 X CCI	-4.256*** (-5.999, -2.512)	-0.016 (-0.085, 0.054)	-0.033** (-0.064, -0.002)	

17q3 X CCI	-3.095***	-0.029	-0.016
•	(-5.075, -1.115)	(-0.090, 0.032)	(-0.045, 0.014)
17q4 X CCI	-2.542**	-0.036	-0.029*
	(-4.544, -0.540)	(-0.101, 0.029)	(-0.060, 0.001)
18q1 X CCI	-2.494**	-0.047	-0.041**
•	(-4.428, -0.560)	(-0.108, 0.015)	(-0.079, -0.004)
Constant	3.896***	0.073***	0.010*
	(3.362, 4.431)	(0.041, 0.104)	(-0.001, 0.022)
Observations	16212	16212	16212
\mathbb{R}^2	0.057	0.01	0.007

^{*}p<0.1;**p<0.05;***p<0.01

Additional Description of the Intervention

Virta Health and Indiana University Health (IUH) are conducting an ongoing clinical trial examining a CCI for the treatment of type 2 diabetes (T2D). The 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. CCI participants underwent history, physical exam and laboratory testing for inclusion and exclusion criteria. Upon qualifying, participants received a cell-connected scale, a blood glucose and ketone meter, and a blood pressure cuff if needed for monitoring hypertension. A web app was provided for biomarker reporting, remote care team communication, nutrition and behavior change education, and access to an optional online peer community for information sharing and emotional support. The remote care team included a health coach and medical provider for advice and medication management. CCI participants retained their primary care provider (PCP). Coordination of care between the PCP and CCI provider occurred as needed Biomarker tracking frequency varied from multiple times daily to weekly based on care needs; initial instructions were to weigh and measure blood betahydroxybutyrate (BHB) concentration daily, and to measure blood glucose 1-3 times a day. BHB levels allowed a direct measure of dietary adherence. The remote care team monitored this information and the care provider recommended medication reductions as glycemic control improved.

Participants reported daily energy, mood, hunger, and cravings a four-point scale. Side-effects were also reported from a list of possible symptoms. Ratings and BHB concentrations were used to adjust guidance on nutrition. Individualized nutrition advice provided to CCI participants allowed sustained nutritional ketosis with a BHB goal of >0.5 mmol/L. The usual initial daily recommendation called for < 30 grams of total dietary carbohydrates and 1.5 grams of protein per kilogram of reference body weight. Participants were coached to incorporate dietary fats to satiety including sources of saturated, monounsaturated and polyunsaturated fats. Other dietary aspects were individualized to ensure safety and satisfaction including 3–5 servings of non-starchy vegetables and adequate intake of minerals and fluid. Patients were advised daily consumption of a multivitamin, 1000–2000 IU vitamin D3, and 1000 mg omega-3. Daily magnesium supplementation was also advised (500 mg magnesium oxide or 200 mg magnesium chloride). Adequate sodium and fluid was recommended upon symptoms of headaches, lightheadedness, or constipation. The remote care team utilized behavior change strategies tailored to the needs of each participant to help achieve glucose control and sustained ketosis.