05/01/2019

Title: Cost-effectiveness of Shared Telemedicine Appointments in Young Adults with T1D: CoYoT1 Trial

Authors: Wen Wan, PhD[1], Aviva G. Nathan, MPH[1], Parmida Zarei, BS[1], M. Reza Skandari, PhD[1], Mark W. Reid, PhD[2], Jennifer K. Raymond, MD, MCR[2], Elbert S. Huang, MD, MPH[1]

Affiliations:

[1]Section of General Internal Medicine, University of Chicago, Chicago, IL

[2]Children's Hospital Los Angeles, University of Southern California, Los Angeles, CA

Corresponding Author:
Wen Wan, PhD
Statistician
Section of General Internal Medicine
University of Chicago
5841 S. Maryland Ave., MC 2007
Chicago, IL 60637
773-702-3108
773-834-2238 (fax)
wwan1@medicine.bsd.uchicago.edu

Running Title: CEA of Shared Telemedicine vs Usual Care in Young Adults with T1D [<47 characters with spaces]
Abstract: 150 [≤150 words]
Word Count: 1,158 [≤1,200 excluding abstract]
Tables+Figures: 1
Supplemental eTables: 14
Supplemental eFigure: 0
References: 14 [≤15]

OBJECTIVE: Young adults (YAs) with type 1 diabetes (T1D) often struggle to achieve glycemic control and maintain routine clinic visits. We aimed to evaluate the societal cost-effectiveness of the Colorado YAs with T1D (CoYoT1) Clinic, an innovative care model of shared medical appointments through home telehealth.

RESEARCH DESIGN AND METHODS: Patients self-selected into the CoYoT1 (N=42) or usual care (N=39) groups.

RESULTS: Within the trial, we found no significant differences in 9-month quality-adjusted life; however, the control group had a larger decline from baseline in utility than the CoYoT1 group, indicating a quality of life (QoL) benefit of the intervention(difference in difference mean ± SD: +0.04 ± 0.09, *P*=0.03). There was no significant difference in total costs. The CoYoT1 group had more study-related visits but fewer non-study office visits and hospitalizations.

CONCLUSIONS: The CoYoT1 care model may help YAs with T1D maintain a higher QoL with no increase in costs.

INTRODUCTION

The absolute numbers of young adults with type 1 diabetes (T1D) is on the rise.[1] The transition period from pediatric to adult care is challenging and frequently accompanied by missed clinic visits and suboptimal glycemic control.[2-6] An innovative care model - shared medical appointments delivered through home telehealth - was evaluated by the recent Colorado Young adults with T1D (CoYoT1) trial. The trial demonstrated that the care model improved patient attendance and diabetes care engagement.[3,7] We aimed to evaluate the societal cost-effectiveness of the CoYoT1 model versus usual care (control).

RESEARCH DESIGN AND METHODS

In this prospective pragmatic trial, patients with T1D aged 18-25 years self-selected into either the CoYoT1 or control groups at the Barbara Davis Center for Diabetes (BDC). During the trial, we collected patients' quality of life (QoL) assessed by the EuroQol 5-level 5-dimension questionnaire, self-reported healthcare utilization , and clinical staff time related to group and/or individual visits at baseline, 3, 6, and 9 months. Main outcomes included health-related utility, quality-adjusted life years (QALYs), and total costs. Details on the intervention and the clinical findings have been previously published.[3,7] We have provided an impact inventory table[8] and reporting checklist[9] in eTables 1 and 2 in the Supplement.

The 9-month total costs included 1) all direct costs associated with trial staff time as part of the study, healthcare utilization that occurred outside of the study, device use (CGM and/or pump), and test strip use; and 2) all indirect costs associated with reduced work productivity and commute time for an in-person clinic visit, if employed. We calculated costs by multiplying the U.S. Bureau of Labor Statistics median hourly wages (or prices per service) by hours spent (or number of services used) in the 9-month time period. All cost assumptions are provided in eTable 3. All costs are expressed in 2015 U.S. dollars.

We applied the intent-to-treat principle to all analyses. The Wilcoxon's test and the Fisher's exact test were used for group comparison as appropriate. We used the analysis of covariance method to compare QALYs, adjusting for baseline utility.[10] We used linear mixed models to model repeated-measures outcomes and to test effects of treatment, time, and their interaction, respectively. To account for baseline imbalanced costs,[11] we used the bootstrap method to calculate mean difference in difference (DID) and its 95% confidence interval (CI). We also conducted subgroup analyses per baseline HbA1c level above and below 8.0%.

RESULTS

Eighty-one patients participated in the study, 42 in the CoYoT1 group and 39 in the control group. The CoYoT1 group had a shorter duration of diabetes than the control group but all other major baseline characteristics were balanced (eTable 6).

Compared with controls, the CoYoT1 group had a smaller decline in utility from baseline (mean ± SD: -0.03 ± 0.06 vs -0.07 ± 0.10, $P = 0.03$) and less diabetes-related distress ($P < 0.01$) (Table 1). Nine-month QALYs were similar: 0.70 ± 0.05 years (CoYoT1) vs 0.68 ± 0.08 years (control) ($P = 0.86$).

The per-person 9-month mean total costs were $4,257 ± 2,590 for the CoYoT1 group and $8,929 ± 18,348 for controls ($P < 0.79$) (Table 1). The DID for total costs was -$2,965 (95% CI = (-$12,199, +$2,777)) (eTable 7-8) and not statistically significant. The CoYoT1 group had more study-related visits but fewer non-study office visits (means: 1.27 vs 3.0, $P = 0.01$) and hospitalizations (mean frequencies: 0.0 vs 0.23, two-sided $P = 0.15$) than controls (eTable 9). For key clinical outcomes including HbA1c, BMI, number of severe hyperglycemia (and hypoglycemia) events, we found no significant differences. No within-trial incremental cost-effectiveness ratio was calculated due to the lack of significant difference in 9-month total costs or QALYs.

In the subgroup analyses, among patients with high baseline HbA1c (≥8.0%), the CoYoT1 group experienced a small reduction in utility from baseline and maintained diabetes distress scores over time, while controls had a greater reduction in utility ($P = 0.016$) and an increase in diabetes distress ($P = 0.046$). Among patients with low baseline HbA1c (<8.0%), the CoYoT1 had a reduction in their diabetes distress score by 0.5, while controls had an increase in their distress score by 0.4 ($P < 0.01$). In both subgroup analyses, HbA1c were not different for intervention and control ($P = 0.41$ and 0.37).

DISCUSSION

Young adults with T1D suffer from poor health outcomes with only 14% of this population meeting the American Diabetes Association's (ADA) HbA1c goal < 7.0%.[6] Efforts to improve health outcomes in this population have focused on developing new systems of care that may improve the transition between pediatric and adult medicine.[5] Our study is the first to evaluate the societal cost-effectiveness of the CoYoT1 care model, a combination of telemedicine and shared medical appointments, compared to usual care in transition-age young adults with T1D.

During the trial, the CoYoT1 group maintained a higher QoL over time than the control group. In addition, the CoYoT1 group tended to have lower (non-significant) healthcare costs with fewer non-study office visits (i.e., urgent care visits) and hospitalizations (non-significant). To forecast the long-term implications of the quality of life findings, we used the Sheffield model[12] to simulate the patient-level natural history of T1D over the projected life-time of patients. We found that if the QoL benefits were to persist over a lifetime, there would be a gain of 0.95 QALYs. The life-time base-case, subgroup, and sensitivity CEAs were all consistent with each other (eTables 11-14).

The clinical findings from our trial suggest that the combination of home telemedicine and shared medical appointments is a safe and efficient method for delivering care to young adults with T1D. The model improved clinic follow-up and patient appointment satisfaction resulting in increased young adult engagement in care.[3,7] These features of CoYoT1 likely reduced patients' diabetes-related distress and helped maintain higher QoL.[13] While CoYoT1 enhanced patients' QoL and increased CGM use,[7] we did not find significant improvements in glucose control. This is consistent with a recent meta-analysis and systematic review of telemedicine use among patients with T1D which concluded that there was insufficient evidence to support telemedicine use for glucose control with a mild reduction in HbA1c (0.18%) and found that studies with longer duration were associated with larger effects.[14]

Our study has limitations. First, a sample selection bias might still exist because patients self-selected for participation in CoYoT1. However, the major demographic characteristics of the study groups were balanced. Second, our study may be underpowered because of missing data. We used the multiple imputation method to address the problem of missing data and its results (eTable 10) were consistent with our main findings.

Based on this single-center trial, the CoYoT1 care model may help transition-age young adults with T1D maintain a higher QoL with no increase in costs, with an accompanying shift to more routine diabetes care while decreasing acute care visits (e.g. urgent care, ED, and hospitalizations). Additional trials with larger patient numbers, longer term follow-up, and more structured training for shared telemedicine visits are needed.

ACKNOWLEDGMENTS

Funding: This study was supported by grants from Helmsley Charitable Trust (2015PG-T1D059) and the National Institute of Diabetes and Digestive and Kidney Diseases (P30 DK092949, K24 DK105340 (Dr. Huang)).

Author Affiliations: Section of General Internal Medicine, University of Chicago, Chicago (Wan, Skandari, Nathan, Zarei, Huang); Center for Translational and Policy Research of Chronic Diseases, University of Chicago, Chicago (Wan, Skandari, Nathan, Zarei, Huang); Center for Endocrinology, Diabetes and Metabolism, Children's Hospital of Los Angeles, Los Angeles, CA (Raymond and Reid).

Author Contributions: Dr. Wan, Dr. Skandari, Dr. Reid, Dr. Raymond, and Dr. Huang had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: All authors.

Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: Wan, Huang.

Critical revision of the manuscript for important intellectual content: All authors.

Statistical analysis: Wan, Skandari

Obtained funding: Raymond and Huang.

Administrative, technical, or material support: All authors.

Study supervision: All authors.

Conflict of Interest Disclosures: All authors have no financial/commercial conflicts of interests.

REFERENCES

1. Peters A, Laffel L, American Diabetes Association Transitions Working G. Diabetes care for emerging adults: recommendations for transition from pediatric to adult diabetes care systems: a position statement of the American Diabetes Association, with representation by the American College of Osteopathic Family Physicians, the American Academy of Pediatrics, the American Association of Clinical Endocrinologists, the American Osteopathic Association, the Centers for Disease Control and Prevention, Children with Diabetes, The Endocrine Society, the International Society for Pediatric and Adolescent Diabetes, Juvenile Diabetes Research Foundation International, the National Diabetes Education Program, and the Pediatric Endocrine Society (formerly Lawson Wilkins Pediatric Endocrine Society). *Diabetes Care.* 2011;34(11):2477-2485.
2. Weigensberg MJ, Vigen C, Sequeira P, et al. Diabetes Empowerment Council: Integrative Pilot Intervention for Transitioning Young Adults With Type 1 Diabetes. *Glob Adv Health Med.* 2018;7:2164956118761808.
3. Raymond JK, Berget CL, Driscoll KA, Ketchum K, Cain C, Fred Thomas JF. CoYoT1 Clinic: Innovative Telemedicine Care Model for Young Adults with Type 1 Diabetes. *Diabetes Technol Ther.* 2016;18(6):385-390.
4. Viiginia A L. The Challenges of Diabetes Management for Emerging Young Adults. *Diabetes Spectrum.* 2011;24(1):4-5.
5. Los E, Ulrich J, Guttmann-Bauman I. Technology Use in Transition-Age Patients With Type 1 Diabetes: Reality and Promises. *J Diabetes Sci Technol.* 2016;10(3):662-668.
6. Miller KM, Foster NC, Beck RW, et al. Current state of type 1 diabetes treatment in the U.S.: updated data from the T1D Exchange clinic registry. *Diabetes Care.* 2015;38(6):971-978.
7. Reid MW, Krishnan S, Berget C, et al. CoYoT1 Clinic: Home Telemedicine Increases Young Adult Engagement in Diabetes Care. *Diabetes Technol Ther.* 2018;20(5):370-379.
8. Sanders GD, Neumann PJ, Basu A, et al. Recommendations for Conduct, Methodological Practices, and Reporting of Cost-effectiveness Analyses: Second Panel on Cost-Effectiveness in Health and Medicine. *JAMA.* 2016;316(10):1093-1103.
9. Husereau D, Drummond M, Petrou S, et al. Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement. *Value Health.* 2013;16(2):e1-5.
10. Manca A, Hawkins N, Sculpher MJ. Estimating mean QALYs in trial-based cost-effectiveness analysis: the importance of controlling for baseline utility. *Health Econ.* 2005;14(5):487-496.
11. van Asselt AD, van Mastrigt GA, Dirksen CD, Arntz A, Severens JL, Kessels AG. How to deal with cost differences at baseline. *Pharmacoeconomics.* 2009;27(6):519-528.
12. Henriksson M, Jindal R, Sternhufvud C, Bergenheim K, Sorstadius E, Willis M. A Systematic Review of Cost-Effectiveness Models in Type 1 Diabetes Mellitus. *Pharmacoeconomics.* 2016;34(6):569-585.
13. Chew BH, Mohd-Sidik S, Shariff-Ghazali S. Negative effects of diabetes-related distress on health-related quality of life: an evaluation among the adult patients with type 2 diabetes mellitus in three primary healthcare clinics in Malaysia. *Health Qual Life Outcomes.* 2015;13:187.
14. Lee SWH, Ooi L, Lai YK. Telemedicine for the Management of Glycemic Control and Clinical Outcomes of Type 1 Diabetes Mellitus: A Systematic Review and Meta-Analysis of Randomized Controlled Studies. *Front Pharmacol.* 2017;8:330.

Table 1. Within-trial CEA results

	CoYoT1 (n=42)		Control (n=39)		P[a]
Utility and QALYs	**mean (SD)**	**median (Range)**	**mean (SD)**	**median (Range)**	
Utility at 9 months	0.87 (0.11)	0.90 (0.55, 1.0)	0.82 (0.17)	0.84 (0.39, 1.0)	**0.03**[b]
QALYs	0.70 (0.05)	0.70 (0.56, 0.75)	0.68 (0.08)	0.69 (0.46, 0.75)	0.86[c]
Diabetes distress scale at 9 months	1.78 (0.72)	1.65 (1.0, 3.65)	2.18 (0.69)	2.15 (1.12, 3.65)	**<0.01**[b]
Per-Patient Costs ($)	**mean (SD)**	**median (IQR)**	**mean (SD)**	**median (IQR)**	
Total direct costs	4,024 (2471)	3930 (1973, 5545)	8,625 (18442)	3996 (1072, 4903)	0.68
Trial staff for intervention/control	198 (55)	220 (161, 238)	54 (69)	52 (0, 77)	**<0.01**
Other medical care	201 (394)	58 (0, 199)	3,488 (14185)	241 (0, 498)	**0.02**
Strip test use	1,033 (958)	680 (472, 1070)	975 (529)	816 (544, 1361)	0.38
Pump use	1,365 (1269)	1063 (0, 2127)	741 (1264)	0 (0, 1595)	**0.03**
CGM use	1,018 (1391)	0 (0, 1277)	1,111 (1695)	0 (0, 3830)	0.80
Total indirect costs	248 (419)	22 (10, 326)	694 (2303)	19 (0, 325)	0.43
Missed work	119 (301)	0 (0, 0)	278 (767)	0 (0, 242)	0.58
Poor performance	91 (219)	0 (0, 121)	406 (1559)	0 (0, 182)	0.30
Total commute time for in-person clinic visits	17 (11)	15 (9, 20)	11 (16)	5 (0, 15)	**0.01**
Total costs	4,257 (2590)	4228 (2139, 6061)	8,929 (18348)	4271 (2035, 5497)	0.79
Clinical variables at 9 months	**mean (SD)**	**median (range)**	**mean (SD)**	**median (range)**	
HbA1c	8.40 (1.54)	8.10 (5.8, 11.4)	8.08 (0.95)	7.8 (6.9, 10.3)	0.63[b]
BMI	25.16 (4.54)	25.2 (18.4, 39.0)	25.37 (4.62)	23.7 (19.5, 33.6)	0.18[b]
# of patients having severe hyper events (%)	0		3 (9)		0.11[d]
# of patients having severe hypo events (%)	1 (3)		2 (6)		0.61[d]
# of study visits	3.45 (1.04)	4 (1, 4)	0.64 (0.71)	1 (0, 2)	**<0.01**
daily strip tests	5.11 (6.89)	3.65 (0.9, 32.7)	3.35 (1.81)	3.2 (0.9, 6.0)	0.61[b]
Pump use - Yes (%)	14 (47)		4 (36)		0.73[d]
CGM use - Yes (%)	11 (37)		3 (30)		1.00[d]
Subgroup analyses	**mean (SD)**	**median (range)**	**mean (SD)**	**median (range)**	
In the subgroup with high baseline HbA1c (≥8.0%) (n=43)					
Utility at 9 months	0.88 (0.12)	0.90 (0.59, 1.0)	0.82 (0.15)	0.84 (0.45, 1.0)	**0.016**[b]
HbA1c at 9 months	9.3 (1.41)	9.25 (7.4, 11.4)	8.5 (1.09)	8.25 (7.5, 10.3)	0.41[b]
# of clinical visits	3.38 (1.10)	4 (1, 4)	0.53 (0.61)	0 (0, 2)	**<0.01**
Diabetes distress scale at 9 months	1.96 (0.83)	1.76 (1.06, 3.65)	2.07 (0.57)	1.94 (1.23, 3.18)	**0.046**[b]
In the subgroup with low baseline HbA1c (<8.0%) (n=34)					
Utility at 9 months	0.87 (0.12)	0.87 (0.55, 1.0)	0.81 (0.20)	0.86 (0.39, 1.0)	0.71[b]
HbA1c at 9 months	7.41 (0.99)	7.6 (5.8, 9.0)	7.58 (0.44)	7.6 (6.9, 8.1)	0.37[b]
# of clinical visits	4 (0)	4 (4, 4)	0.75 (0.79)	1 (0, 2)	**<0.01**
Diabetes distress scale at 9 months	1.47 (0.33)	1.47 (1.0, 2.0)	2.29 (0.81)	2.21 (1.12, 3.65)	**<0.01**[b]

a. The default statistical method was Wilcoxon's test.
b. A linear mixed model was used to compare the groups, adjusting its baseline outcome. The p-value is for group comparison across all visits.
c. An analysis of covariance was used to test the treatment effect, adjusting its baseline utility.
d. A Fisher's exact test was used to compare the groups.