Title: T1D-CATCH Protocol: Collaboration Around Technology Using Community Health Workers for Young Adults With Type 1 Diabetes

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A. STUDY TITLE

T1D-CATCH Protocol: Collaboration **A**round **T**echnology using **C**ommunity **H**ealth workers for young adults with type 1 diabetes

B. SIGNIFICANCE

Young adults (YA) of underrepresented racial minorities (URMs) are the largest growing population with type 1 diabetes (T1D) in the United States, and demonstrate wide racial-ethnic inequity in glycemic, hospitalization, and mortality outcomes. Many YA with T1D undergo a healthcare transition from pediatric to adult care. These changes, along with newfound independence, interfere with disease self-management, medical visit attendance, and attainment of optimal glycemic control. This population also face additional challenges from social determinants of health, low social support, structural racism, and inequities in healthcare delivery. Emerging evidence has demonstrated racial-ethnic inequity in use of diabetes technologies, such as insulin pump therapy and continuous glucose monitors (CGM), which may be contributing to poor outcomes and represents a potential intervention target.

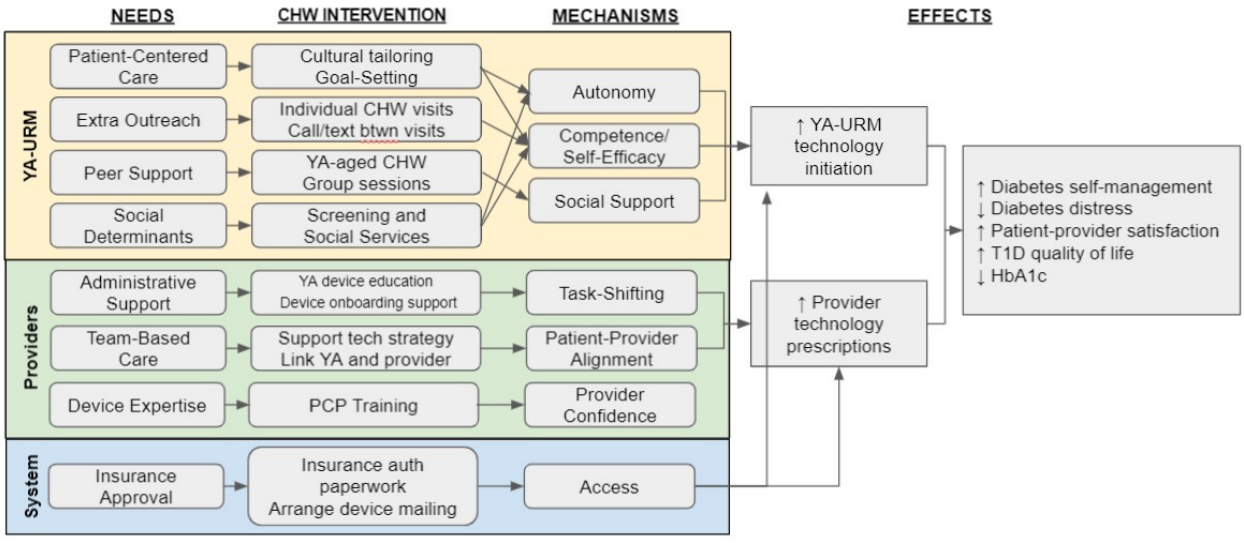
There also exists unique patient, provider, and system-level barriers to technology use that go beyond insurance coverage. Community health workers (CHWs) are an evidence-based, cost-effective, scalable work force that can address multi-level barriers to diabetes technology use in YA-URMs with T1D. CHWs engender trust with patients by having direct community and lived experience, offering specific support and empathy that may be difficult for other diabetes care professionals to provide. CHWs are unique in their ability to share lived experiences and advocate for patients from underserved communities, acting as links between community and health system.

C. APPROACH

Conceptual Design

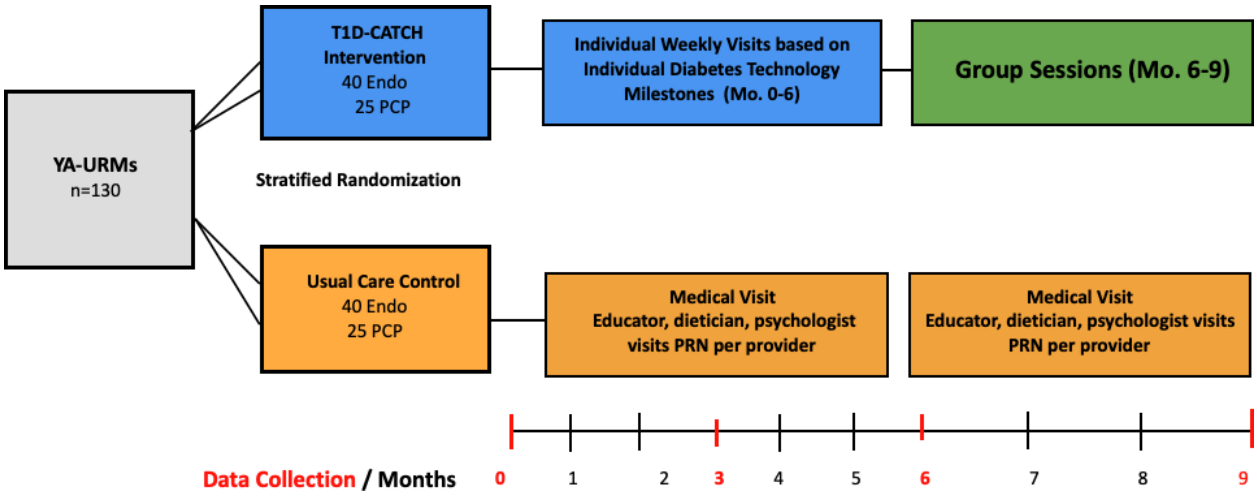
T1D-CATCH enhances the CHW model by utilizing its core roles of patient advocacy, outreach, coaching, education, care navigation, and social needs service linkage, with training to become part of team-based diabetes technology care for YA-URMs with T1D. YA-aged CHWs in T1D-CATCH will address commonly cited barriers by YA.

Figure 1. Conceptual Model of T1D-CATCH Effect in YA-URMs with T1D



Study Design

This program will be a 9-month randomized clinical trial of usual care versus T1D-CATCH, an intervention that enhances core CHW service roles to support increased use of T1D technology in YA-URMs. The study was designed to acquire preliminary data regarding the effects of the intervention, as well as feasibility data related to recruitment and retention, and study conduct. Thus, this design will combine the rigor of a RCT to evaluate early intervention effects and an implementation examination to inform future work.



Eligible YA-URMs will be randomized 1:1 to usual care vs. T1D-CATCH. Once YA-URMs are randomized to T1D-CATCH, the CHW will offer to have an introductory meeting with the participant to introduce technology, understand potential barriers to diabetes technology use, and assess for social needs. As described in Figure 2, CHWs will then conduct weekly individual sessions with YA-URMs determined by diabetes technology milestones, as well as social needs milestones for the first 6 months. An option for monthly CHW-led peer group sessions will be available for intervention arm participants from month 6-9 after individual CHW support has ended.

The *primary hypothesis* to be tested is:

- Compared with usual care, T1D-CATCH will significantly increase technology initiation and continued use at 6 months (Primary: % initiation; Secondary: % of initiated using at 6 months). We will measure potential mediators and distal health outcomes to inform preliminary efficacy and future effect sizes.

Primary Outcome: Technology use will be measured as a binary variable (yes/no). Technology will include any combination of CGM, pump, or CGM and pump. Technology initiation will be defined as at least 1 week of first use in the 6-month period and will be measured in several ways.

Secondary Outcome: Continued use by study end will be determined from device platform metrics detailing days/percent time use, in addition to self-report. Per standard diabetes technology clinical trial guidelines, CGM use is defined as ≥5/7 days wear and pump use defined as >90% time.

The *secondary aim* is to evaluate T1D-CATCH implementation by using Proctors Taxonomy of Implementation Outcomes. State of the art implementation science methods will guide the evaluation of acceptability, feasibility, adoption, fidelity, and cost to inform future larger pragmatic trials and overall sustainability.

Table 1. Inclusion and Exclusion Criteria & Recruitment Sites

Inclusion	***Exclusion***
- T1D duration ≥6 months - 18-35 years old - Self-identified URM status: non-Hispanic Black or Hispanic - English- or Spanish-speaking - Not currently on a connected diabetes technology system (includes never offered, prescribed but not started **within 3 months of receiving the device**, discontinued, or previously refused technology)	- Developmental or sensory disability interfering with study participation - Current pregnancy - Participation in another behavioral or technology intervention study in the past 6 months.
Recruitment Sites • Montefiore Endocrinology Practices *(In-patient and out-patient sites: CHAM, Moses, Wakefield, & Weiler)* Montefiore Medical Center Primary Care Clinics	

Participants

A total of 130 YA-URMs will be enrolled for this study. Recruitment lists of eligible participants will be pulled from the EMR and sent to research staff weekly. An established algorithm for identifying patients with T1D will confirm inclusion criteria by chart review and self-reports. Study staff will call and confirm eligibility, and perform oral consent telephonically or in person, per participant preference and availability. They will then perform a brief baseline visit virtually to explain the study more in depth, data collection timepoints, and participant compensation schedules.

Overview of Intervention Arm

T1D-CATCH Intervention Overview

CHW Adaptation:

The Montefiore CHW role for T1D-CATCH will be enhanced in several ways (**Figure 3**). CHWs will adopt "YA-centered care promotion" by incorporating developmentally appropriate, non-coercive, non-judgmental communication strategies, and shared decision-making.

Figure 3. Planned *T1D-CATCH* Adaptations to Core CHW Services and Roles

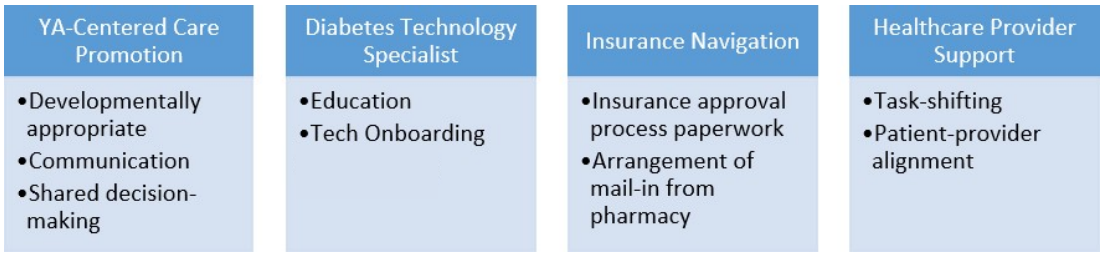
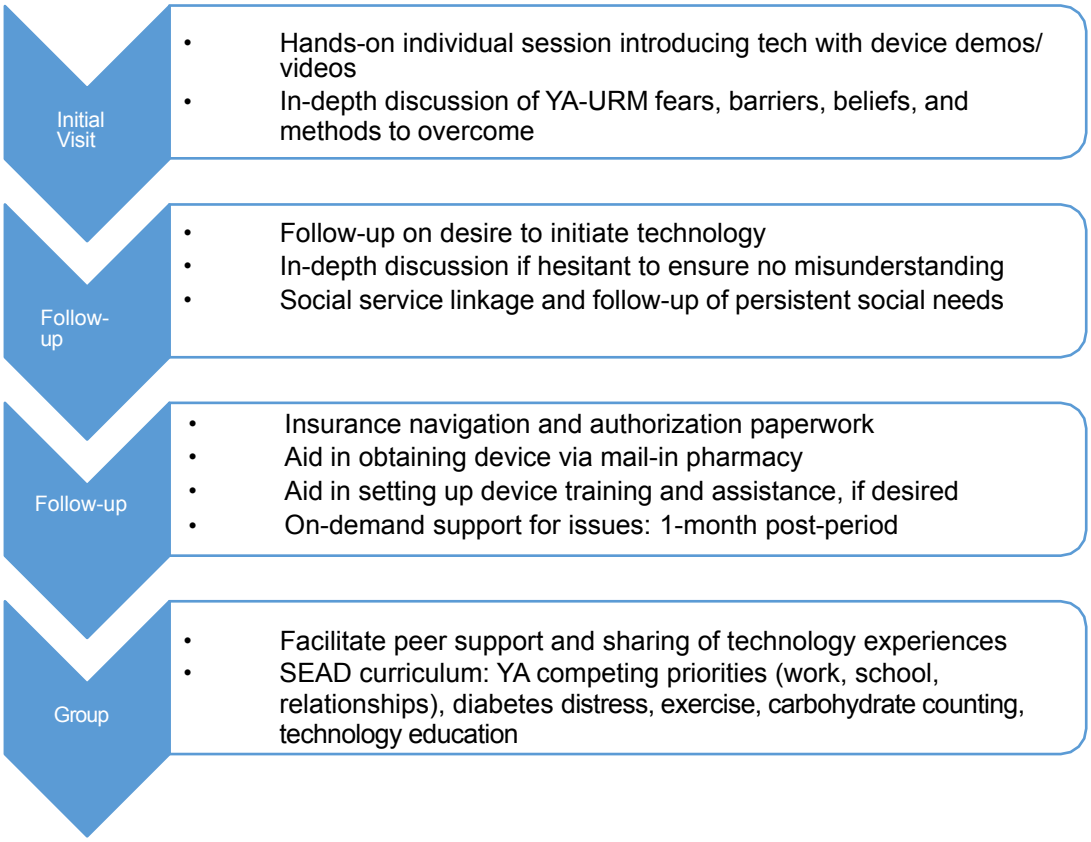


Figure 4. CHW Workflow with YA-URMs

CHW Workflow with Providers:



CHWs will have been introduced to providers at practice meetings in the months leading up to trial start, to facilitate integration of this new member on the care team. CHWs will communicate with providers through the EMR at several other key touch points during the study: 1) when participant communicates desire to start technology, 2) when participant receives and gets trained on a device, and 4) when technology, social, or clinical issues arise.[4] The CHW's will continue to remind participants and providers that they cannot perform clinical management or insurance authorization tasks. However, they can triage participant needs and will direct participants to their providers for further aid.

CHW Training:
CHWs will have rigorous 100-hour training that was developed by our YA-URM advisory board, team of experienced CHW and T1D investigators, and T1D clinicians. **Table 2** outlines the CHW training curriculum.

Table 2. Month 1 *T1D-CATCH* Training Schedule

Training Activity	Hours per session	Total Hours (100)	Topics covered
Formalized Lectures (SEAD Education Series [36], ECHO- T1D [83])	1	16	Differences in T1D/T2D, Basic T1D self-management, In-depth discussion of clinical utility of each diabetes technology (pump, CGM), YA T1D care strategies, ECHO-T1D sessions on insurance navigation, provider workflows, peer support
Provider Shadowing (SEAD and PCPs)	4	60	Real-world T1D management and provider workflows, patient-provider relationships/ communication styles, MD/NP/RD/psych/SW shadowing
YA-URM T1D Sessions	1	4	Sessions with YA-URM stakeholder board and ECHO- T1D peer support coaches to learn about living with T1D and YA tailoring
Device Rep Education	1	5	In-depth didactic teaching on each technology's logistical aspects, opportunity to wear device demo (5 companies)
Role-playing	1	10	Practice CHW initial visit and group visit with stakeholder boards and study staff
Practice Meetings	1	5	Familiarity with primary/endocrine providers, better integration in clinic

Overview of Usual Care Control Arm

Control arm participants will receive usual primary or endocrine care at Montefiore, consisting of a physician (MD), nurse practitioner (NP), or certified diabetes care and education specialist (CDCES) visit with review of blood sugars and treatment decisions based on provider experience. In all practices, patients are recommended to see their healthcare provider every 3 months and attend individual or group sessions with allied diabetes health professionals as needed, per ADA standards of care. Since no real-world standardized decision-support tool is used to prescribe diabetes technology, practices will vary by provider, representing the real world. All diabetes technology devices are fully covered in the state of NY under Medicaid and Medicaid-managed insurance plans, which will remove low prescription rates due to cost.

Assessments

Table 3 outlines the data that will be collected at 0, 3, 6, and 9 months of the study. Study self-report questionnaires, validated surveys, EMR-generated, and device platform-generated data are included, and will be input by participant for self-report and the study coordinator for EMR or device platform data.

Table 3. Data Collection (Self-report questions in REDCap English and Spanish)

		Domain	Data Source	Description	Month
	Baseline	**Demographic**	Study self-report questionnaire	Age, gender, race-ethnicity, education, employment, country of origin, language	0
		Clinical/ Psychosocial	Study self-report questionnaire	Age at diagnosis, treatment regimen, medical history	0
		Social Determinants	EMR/REDCap	Epic-integrated scale	0
AIM 1	**Main**	**Technology Use** **Primary: Initiation** **Second: Cont. use**	EMR prescriptions, self-report, CHW dashboard, device platforms [159–163]	Technology yes/no, Days of wear, % use	3, 6, 9
	Mediators	**YA-URM Autonomy, Competence, Social Support**	Validated survey	Healthcare self-determination survey	0,3, 6, 9
	Distal Health	**HbA1c**	POC or laboratory	In Clinic; DCA Vantage	0,3, 6, 9
		Quality of life, Diabetes Distress, Self-management, Satisfaction in Care	Validated surveys	T1DAL-YA, PAID, DSMQ, HCCQ	0,3, 6, 9
AIM 2	**Implementation**	**Feasibility**	Post-intervention interviews	Intervention content, complexity, comfort, delivery, credibility	9
		Adoption	Recruitment logs, EMR	YA consent rates, % provider opt-in, CHW communications	9
		Fidelity	CHW dashboard, session recordings, EMR	Session attendance, content delivery, insurance tasks	0,3, 6, 9

		Cost	Time sheets, receipts, budget	CHW salary/ benefits, equip., consumables	9

D. STATISTICAL ANALYSIS

Sample Size Determination

Participants will be allocated equally to intervention and control arms using stratified randomization by endocrine vs. primary care setting, oversampling from endocrinology to increase recruitment feasibility (n=80 endocrine, 50 primary care). With a sample size of 130 participants, and using a 2 tailed Wald test of the logistic regression coefficient at a 0.05 significance level, we will have 80% power to detect a between group difference of 19 percentage points (% pts) if the control technology initiation rate is 1%; a difference of 25 %pts if the control initiation rate is 10%; and a difference of 29 %pts if the control initiation rate is 25%.

Randomization

Participants will be randomized after enrollment into the study. REDCap will generate randomization algorithms to assign participants to arm using permutated block randomization procedures with random block sizes unknown to study staff, stratified by primary versus endocrine care. The study statistician will be blinded to arm; however, it will be impossible to blind providers, lead investigators, interventionists, and study staff to trial arm assignment.

Analysis of Outcomes

Variables will be described using summary statistics with counts/percents for categorical variables and mean/standard deviation or median/interquartile range for continuous variables.

The primary analysis for the Aim 1 will be a pair of logistic regression models. The outcome variables will be indicators for technology use at the midpoint and end of the study, respectively. The key predictor variable will be the randomized treatment assignment. Covariates will be included to adjust for differences between treatment groups on any baseline characteristics which were not adequately balanced by randomization.

For Aim 2, post-intervention interviews (n=24) will be audio-record and transcribed, and use two independent coders for analysis via NVivo software using a standardized codebook for analysis based on the Proctor feasibility framework. For quantitative data on adoption and fidelity, we will use descriptive statistics to summarize measures, showing counts and percent for categorical variables, and means and standard deviations or medians and interquartile ranges for continuous variables. For cost-effective analyses total labor, durable equipment, and consumables, costs in the CHW arm will be calculated.

E. STUDY TIMELINE

F. PARTICIPANT COMPENSATION

Study Timepoint	Study procedures completed	Participant compensation
Baseline, 0 months	Completes baseline surveys, and first baseline visit with Study Coordinator	$50
3 Month Assessment	Completes month 3 follow-up assessments via REDCap	$75
6 Month Assessment	Completes month 6 follow-up assessments via REDCap	$100
9 Month Assessment	Completes month 9 follow-up assessments via REDCap	$125
Total Compensation	End of Study	**$350**

	YR 1		**YR 2**		**YR 3**	
Month	1-6	7-12	13-18	19-24	25-30	31-36
T1D-CATCH Adaptation, CHW training, Stakeholder board input						
Recruitment and Enrollment		**n=30**	**n=35**	**n=35**	**n=30**	
Data Collection, Cleaning, Management						
Statistical Analysis						
Dissemination of results						
Future definitive *T1D-CATCH* trial grant app						