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Strengths and limitations of this study

- This intervention will focus on Medicaid-insured individuals with type 2 diabetes (T2D) and poor glycemic control who are at high risk of adverse pregnancy outcomes.
- ACHIEVE is a novel multi-component intervention using a Mobile health (mHealth) application (app), provider dashboard, continuous glucose monitoring (CGM), referral for social needs, and team-based care to address glycemic control.
- Challenges of this trial will include engaging a high-risk population of pregnant individuals with poor glycemic control and unmet social needs using a mHealth intervention.

ABSTRACT

Introduction: Type 2 diabetes (T2D) is one of the most frequent comorbid medical conditions in pregnancy. Glycemic control decreases the risk of adverse pregnancy outcomes for the pregnant individual and infant. Achieving glycemic control can be challenging for Medicaid-insured pregnant individuals who experience a high burden of unmet social needs. Multi-faceted provider-patient based approaches are needed to improve glycemic control in this high-risk pregnant population. Mobile health (mHealth) applications (app), provider dashboards, continuous glucose monitoring (CGM), and addressing social needs have been independently associated with improved glycemic control in non-pregnant individuals living with diabetes. The combined effect of these interventions on glycemic control among pregnant individuals with T2D remains to be evaluated.

Methods and analysis: In a two-arm randomized controlled trial (RCT), we will examine the combined effects of a multi-component provider-patient intervention, including a patient mHealth app, provider dashboard, CGM, a community health worker (CHW) to address non-medical health-related social needs, and team-based care versus the current standard of diabetes and prenatal care. We will recruit 124 Medicaid-insured pregnant individuals living with T2D, who are ≤20 weeks of gestation with poor glycemic control measured as a hemoglobin A1c (A1c) ≥ 6.5% assessed within 12 weeks of trial randomization or within 12 weeks of enrolling in prenatal care from an integrated diabetes and prenatal care program at a tertiary care academic health system located in the Midwestern U.S. We will measure how many individuals achieve the primary outcome of glycemic control measured as an A1c <6.5% by the time of delivery, and secondarily, adverse pregnancy outcomes; patient-reported outcomes (e.g., health and technology engagement, literacy, and comprehension; provider-patient communication; diabetes

self-efficacy; distress, knowledge, and beliefs; social needs referrals and utilization; medication adherence); and CGM measures of glycemic control (in the intervention group).

Ethics and dissemination: The Institutional Review Board at The Ohio State University approved this study (IRB: 2022H0399; date: 03/06/23). We plan to submit manuscripts describing the user-designed methods and will submit the results of the trial for publication in peer-reviewed journals and presentations at international scientific meetings.

Trial registration number: NCT05662462; pre-results.

INTRODUCTION

Background

Type 2 diabetes (T2D) is one of the most frequent chronic comorbid conditions in pregnancy.[1-3] Every year in the U.S. more than 100,000 pregnancies are complicated by T2D, which is anticipated to double in the next 10 years, affecting 1 in 20 pregnancies.[4-6] T2D increases the risk of adverse pregnancy outcomes for the pregnant individual, including severe maternal morbidity, cesarean delivery, preeclampsia, and severe maternal morbidity; and infant, including large for gestational age at birth, preterm birth, and neonatal hypoglycemia.[7-9] Inadequate glycemic control further increases the risk of these adverse outcomes by at least two-fold.[10-12]

Improving glycemic control as measured by hemoglobin A1c (A1c) decreases the risk of adverse pregnancy outcomes.[7 12] Guidelines recommend achieving an A1c target in pregnancy of at least <6.5% to optimize outcomes.[13 14] Glycemic control for pregnant individuals with T2D can be achieved with insulin pharmacotherapy, consistent glucose monitoring, lifestyle modifications including diet and exercise, and interdisciplinary, team-based diabetes and prenatal care.[11] Pregnant individuals living with T2D who experience a higher burden of adverse social determinants of health (SDoH) and unmet non-medical health-related social needs (social needs),[10] including food insecurity[15] and inadequate physical activity,[16] are less likely to achieve glycemic control.

More than half of pregnant individuals with T2D are insured by Medicaid.[17] Medicaid-insured pregnant individuals experience a higher burden of T2D, adverse pregnancy outcomes, and adverse SDoH.[18-20] Addressing modifiable social needs that affect glycemic control in this population could improve pregnancy outcomes by addressing maternal health inequity.[10 21-25] A

model that addresses unmet social needs for individuals with chronic comorbidities is the Agency for Healthcare Research and Quality (AHRQ) Pathways Community Hub model.[26] The Hub model leverages care coordination with community health workers (CHWs) to facilitate social needs-related screening and referrals through the use of social needs pathways.[27]

Mobile health (mHealth) applications (app) can address health disparities in prenatal access and care due to adverse SDoH.[28 29] mHealth apps are pervasive among reproductive-age female individuals, and >90% actively engage in their use.[30] mHealth apps include access to digital information, reminders, and convenient communication modes with healthcare providers. Electronic data linked to patients' mHealth apps can allow the care team to actively engage with patients in their care and help them to achieve treatment goals.[31 32] In addition, continuous glucose monitoring (CGM) is a personal mobile technology that allows identification of precise, individualized patterns of dysglycemia.[33] CGM has been shown to improve glycemic control and decrease the risk of adverse pregnancy outcomes for individuals with type 1 diabetes,[34] but its impact among pregnant individuals with T2D remains largely unstudied.[33]

Current mHealth apps for diabetes management typically lack user-centered design features and are not holistically focused on the combination of addressing unmet pregnancy and social needs, CGM integration, and team-based care supported with provider dashboards. Whether an integrated, theory-driven, and user-centered intervention can result in improved glycemic control and patient-reported outcomes among Medicaid-insured pregnant individuals with T2D remains to be answered.

The proposed ACHIEVE intervention integrates new and existing technologies to develop an innovative ecosystem, including a mHealth patient app, provider dashboard, CGM device, social needs referrals, and team-based care.

Aim and hypotheses

The objective of ACHIEVE is to test whether a multi-component intervention (mHealth app, provider dashboard, CGM device, social needs referrals, and team-based care) versus the current standard of care for prenatal and diabetes care results in improved glycemic control by the time of delivery (A1c <6.5%) for Medicaid-insured pregnant individuals with T2D (Figure 1).

Primary hypothesis

We hypothesize a 25% absolute increase in the proportion of individuals in the intervention group who will meet the target A1c <6.5% by the time of delivery compared with the standard care group.

Secondary hypotheses

We hypothesize that individuals in the intervention group will have fewer adverse pregnancy outcomes, and superior patient-reported outcomes (i.e., health and technology engagement, literacy, and comprehension, provider-patient communication, diabetes self-management, self-efficacy, distress, knowledge, and beliefs, social needs referrals and utilization, and medication adherence) compared with the standard care group.

METHODS AND ANALYSIS

Design

ACHIEVE is a randomized, controlled, single-center superiority trial to determine whether Medicaid-insured pregnant individuals with T2D enrolled in a multi-component intervention (mHealth app, provider dashboard, CGM device, social needs referrals, and team-based care) will improve glycemic control compared with those receiving standard prenatal and

diabetes care. Each sub-component of the proposed intervention is grounded in Social Cognitive Theory (SCT), and aims to address an individual's skills, knowledge and beliefs, and self-efficacy to achieve glycemic control.[35] Randomization will be performed with a 1:1 non-blinded allocation between intervention:standard care groups.

Population

Individuals will be recruited as part of The Ohio State University Diabetes during Pregnancy program, which provides integrated diabetes and prenatal care at a tertiary academic medical center located in the Midwestern United States.[12 36] Some individuals continue to receive routine prenatal care in their local community, and then receive high-risk prenatal and diabetes care from the program. These individuals will also be eligible for study participation.

Inclusion criteria

Individuals with an ultrasound-confirmed intrauterine pregnancy, aged ≥18 years, with a diagnosis of T2D, with poor glycemic control measured as an A1c ≥6.5% assessed within 12 weeks of trial randomization or within 12 weeks of enrolling in prenatal care, who are ≤20 weeks of gestation at trial randomization, English or Spanish speaking, who are Medicaid-insured or -eligible, and available to participate in a longitudinal study across pregnancy will be eligible. Because this intervention includes a mHealth app, individuals will need to use a smartphone (either iPhone or Android) with internet access. For those without a smartphone, a device and access to the internet will be provided for the duration of the trial.

Exclusion criteria

We will exclude individuals who cannot cognitively complete the study requirements, consent to all study activities through the time of delivery, be accessible for participation in study activities or cannot read and write in either English or Spanish.

Recruitment

Individuals will be recruited over a three-year time period. Potentially eligible individuals will be identified via the electronic health record (EHR). In addition, individuals will be recruited using flyers placed in clinic and direct provider referrals from the community.

Baseline visit

A research assistant or healthcare provider will ask patients if they are interested in joining the study and they will be referred for an orientation visit. Informed consent will be obtained in person in English or Spanish. Baseline data, including demographics, diabetes history, and information about current technology familiarity and utilization will be collected using electronic data capture. Participants will complete a blood draw for measurement of A1c using a standardized assay. Enrolled individuals will be randomized in a 1:1 ratio to the intervention: standard care. Participants randomized to the intervention group will: 1) receive assistance in downloading and using the mHealth app via their smartphone and using the CGM device for glucose monitoring; and 2) be trained with placing DEXCOM G7® CGM sensors and transmitters including instruction about frequent troubleshooting with new CGM initiation.

Partial patient and public involvement

Medicaid-insured pregnant individuals with T2D and their healthcare providers, including both physicians and nurses, clinical social workers, and community health workers, have collaboratively worked with the study team in designing the mHealth app and dashboard interface by providing feedback about the intervention prototype via structured interviews over multiple iterations.[31] Additional testing of the integrated system and tools (i.e., patient mHealth app and provider dashboard) to address usability and patient/provider-centeredness will be conducted prior to the RCT.

Measures

The primary clinical outcome is the proportion of individuals with an A1c <6.5% by the time of delivery. For those individuals with more than one A1c assessment in late pregnancy, the value most proximate to delivery will be used as a measure of the risk of adverse pregnancy outcomes at birth associated with dysglycemia.[12] For most participants without a preterm delivery, this A1c assessment will be in the late third trimester. A1c will be assessed once per trimester, consistent with U.S. guidelines for diabetes management in pregnancy.[13 14] Of note, we selected an A1c threshold of <6.5% as opposed to ≤6.0% as an aggressive target <6.0% may result in more frequent episodes of hypoglycemia, and the risk of adverse neonatal outcomes are similar at both thresholds.[7 12] A1c will be measured using automated high pressure liquid chromatography (VARIANT II TURBO HgbA1c Kit, Bio-Rad laboratories, Hercules, CA).

Secondary adverse pregnancy outcomes at birth related to pregnancy dysglycemia include large-for-gestational-age at birth (standardized birthweight ≥90% for gestational age) using a recent U.S. infant sex-specific standard,[37] neonatal hypoglycemia (defined as any blood glucose <30 mg/dL during the delivery admission), hypertensive disorder of pregnancy,[38] NICU admission for any indication, preterm birth <37 weeks per the best obstetric estimate for any indication,[39] and respiratory distress syndrome.[40]

Secondary measures of glycemic control for the standard care group will include: weekly self-monitored blood glucose values, including both fasting and 2-hour postprandial values, at guideline recommended target values; and for the intervention group using CGM will include: the percentage of time in range (TIR) between 63 to 140 mg/dL, consistent with emerging data for diabetes in pregnancy,[34] as well as both continuous and dichotomous measures (≥85%). We will also assess CGM summary statistical indices including mean CGM glucose levels during the

day and night, area under the curve, time spent above and below target range, and low and high blood glucose indices.[34]

Patient-reported outcomes (PROs) will be collected at pre-specified intervals at randomization, during pregnancy, and at delivery, including patient knowledge, skills, and confidence to manage health using the Patient Activation Measure (PAM),[41] social needs using the Accountable Health Communities Health-Related Social Needs Screening Tool,[42] provider-patient communication using the Doctor-Patient Communication Scale,[43] and health literacy using the Short Assessment of Health Literacy-Spanish and English (SAHL-S&E) and eHealth Literacy Scale (eHEALS).[44 45] In addition, we will assess diabetes management related PROs including Diabetes Knowledge Questionnaire (DKQ),[46] Diabetes Distress Scale,[47] Diabetes Management Self-Efficacy Scale,[48] and the Morisky Medication Adherence Scale (MMAS-4).[49]

Health care utilization will be abstracted from the EHR and patient surveys and will include prenatal visits, antepartum hospitalizations, emergency department visits, obstetric triage visits, and unscheduled clinic visits.

Within the intervention group, engagement data will be collected through log files and will be measured as the number of times a participant uses the mHealth app (total and average use of the app and specific functions), as well as the number of social needs referrals made and completed.

Procedures

User-centered design testing

A User-Centered Design Work Group (UCDWG) comprised of 10 individuals and representing key stakeholder groups including physicians (maternal-fetal medicine and endocrinology), certified diabetes care and education specialists, nurses, Medicaid-insured

pregnant individuals living with T2D, CHWs, and licensed clinical social workers will guide the adaptation and refinement of the intervention prior to participant enrollment through multiple iterations of testing. The UCDWG will provide input on the mHealth app and provider dashboard functions.

Interventions

The ACHIEVE intervention is supported by a robust digital electronic platform. This platform is integrated with REDCap (Research Electronic Data Capture) and other electronic systems, including the ACHIEVE mHealth app and provider dashboard, HUB Care Coordination System portal, and EHR data. REDCap is a secure, web-based application designed to support data capture for research studies, including data entry, audit trails for tracking data manipulation, automated export procedures, and procedures for importing data from external sources.[50] The ACHIEVE intervention can tailor care in real-time based on changing medical and social needs. It uses rule-based algorithms to synthesize data reported by participants and providers, and adjusts the collection of PROs based on defined parameters and providing personalized educational content to patients via the mHealth app.

Participants will receive training with regards to using the mHealth app and CGM from certified diabetes care and education specialists. Participants will be further supported to engage in care pathways to resolve unmet social needs with the assistance of CHWs. Secure messaging will allow for electronic communication between participants and the certified diabetes care and education specialists and CHWs.

We describe each of the key elements of the ACHIEVE intervention below, namely the patient mHealth app, provider dashboard, CGM device, social needs referrals, and team-based care.

mHealth application.

The mHealth app provides education, reminders, care goals, care pathway recommendations, summaries of CGM data and PROs, messaging, and a calendar function for goal tracking. Content is based on current U.S. clinical guidelines for T2D in pregnancy.[13 14] The mHealth app directs participants to online diabetes and pregnancy resources and learning. Assessment of patient reported outcomes will be embedded in the mHealth app, and rule-based algorithms will provide tailored goals for medical and social needs and information on how to achieve them (i.e., care pathways), and establish the frequency of assessment for PROs including social needs screening. Data are transferred to the digital health platform, which post processing displays data on the provider dashboard.

Provider dashboard.

The ACHIEVE intervention will include a bi-directional dashboard that displays information about participants, including priority goals and care pathways, and recommendations generated via the digital platform. The dashboard will present recommendations for participant goals and care pathways provided by the digital platform algorithms. Providers can access the dashboard embedded within an online portal to monitor participant progress and close the loop on participant tasks. Both certified diabetes care and education specialists and CHWs can assess social needs pathway selections and assess recurring needs through the dashboard. Providers can use auto-generated recommendations or manually select recommendations from a clinically validated data repository.

Continuous glucose monitoring.

Participants in the intervention group will use DEXCOM® G7 CGM sensors and transmitters for glucose monitoring. The Dexcom CGM system is accurate and safe in pregnant

individuals with diabetes.[51] The DEXCOM G7 CGM system was recently approved by the FDA for use in pregnancy.[52] Participants will be taught how to place and remove CGM sensors, and will then replace sensors themselves every 10 days. DEXCOM sensors can be applied on the abdomen, arm, or upper buttocks, is well-tolerated in pregnancy, and do not require calibration.[51] The mHealth app will allow for wireless synchronization with the CGM transmitter so that data are reported back to the healthcare team, which will be reviewed by the certified diabetes care and education specialist at least twice weekly.

Social needs referrals.

We will partner with Health Impact Ohio's Central Ohio Pathways Hub, which consists of three features: (1) the Hub, a regional coordination entity, which employs CHWs to assess the social needs of patients and connect them to community resources; (2) the CHWs initiate a "social need care pathway," a defined action plan to address each patient's unique needs, which is recorded and tracked in an electronic database; and (3) completion of each pathway is linked to payment from insurance companies (e.g., Medicaid-managed care plans) based on specific performance benchmarks.[27 53] The CHWs are embedded within the local communities in which participants live in. Participants will be screened at enrollment and throughout the intervention for social needs using a survey adapted from the Accountable Health Communities Health-Related Social Needs Screening Tool and prior studies.[54 55] Once an unmet social need is identified, participants will be referred to the Health Impact Ohio Hub through the provider dashboard to address unmet social needs (e.g., food insecurity, unstable housing, unemployment). Health Impact Ohio CHWs will perform a comprehensive social needs assessment and connect the participant to community resources through Hub pathways.

Team based care.

Team-based care will be provided by physicians, nurses, certified diabetes care and education specialist, and clinical social workers, as well as CHWs. Team-based care will be facilitated by the provider dashboard and patient mHealth app. The clinical care pathways will address lifestyle factors, including diabetes nutrition therapy, physical activity, smoking cessation, psychosocial stress reduction, and pharmacologic management (pharmacotherapy adherence and modifications) to improve glycemic control.

Standard care arm.

Participants randomized to the standard care group will receive the current standard of diabetes and prenatal care at our center as part of the integrated diabetes and prenatal care program.[11 12] Participants will complete weekly self-monitored blood glucose logs on paper, which will be electronically sent to the EHR for provider review. Communication with the certified diabetes care and education specialists and CHWs will be via Epic's MyChart instance (Epic MyChart). A1c will be assessed, and PROs will be collected at pre-specified intervals similar to the intervention arm (i.e., approximately monthly).

Statistical analysis plan

Baseline characteristics

We will provide descriptive summaries and examine any potential differences in socio-demographic and clinical characteristics between the intervention and standard care groups using $\chi 2$- tests for categorical variables and independent 2 sample t-tests for continuous variables.

Primary and secondary hypothesis

Primary analyses will follow the intention-to-treat principle in which pregnant individuals will be analyzed in the group to which they were randomized, regardless of whether they receive

the assigned intervention or discontinue prior to delivery. As this is a randomized trial, we will not adjust for baseline participant characteristics or participant engagement measures in the primary intention-to-treat analysis unless we identify statistically significant differences between the intervention and standard care groups.

Preplanned posthoc analyses

We will conduct subgroup analyses to determine the effect of the intervention among subgroups if there is a significant interaction effect between the subgroup of interest and the treatment effect, including self-reported race and ethnicity, body mass index at randomization, gestational age at randomization, and baseline A1c at randomization. Exploratory analyses will also be conducted to assess the effect of the intervention on intermediate outcomes (e.g., social needs, T2D self-management, provider-patient communication), and the mediating and moderating roles of the intermediate outcomes.

Power calculations and sample size

Recent pharmacological intervention trials in pregnancies complicated by T2D have assessed medium effect sizes approximating absolute changes of 15 to 30%.[56 57] We target to detect a 25% absolute increase in the proportion of participants in the intervention versus standard care group with an A1c <6.5% by delivery (64% intervention vs. 39% control). A total sample size of 124 participants (62 per study arm) will provide at least 80% power to detect such a difference between the two groups after accounting for up to 10% loss-to-follow-up based on a one-sided Fisher's Exact test. The loss-to-follow-up rate of 10% is based on prior diabetes in pregnancy trials at our center.[32,33]

Compensation

Participants in both study arms will receive compensation of US$100 per month for participation in the trial from randomization to delivery for completion of study activities, including study surveys, attending study sessions, and reporting PROs, including clinical and social needs outcomes.

Data statement

We will follow CONSORT (i.e., Consolidated Standards of Reporting Trials) guidelines. We will submit study results for publication in peer-reviewed journals and presentation at international meetings. We will attempt to publish all findings in open-access journals when possible, or in other journals with a concurrent uploading of the manuscript content into PubMed central for public access. Curated technical appendices and statistical code will be made available from the corresponding authors on request.

Ethics and dissemination

The OSU Institutional Review Board (IRB) has approved this protocol. All protocol amendments will be communicated for approval to the OSU IRB.

DISCUSSION

In this randomized controlled trial, we will examine the effect of a multi-component intervention (mHealth app, provider dashboard, CGM device, social needs referral, and team-based care) versus current standard of care for prenatal and diabetes care on glycemic control among Medicaid-insured pregnant individuals with T2D. The ACHIEVE trial brings together multiple technologies in an integrated and theory-driven framework to facilitate comprehensive, tailored, patient-centered, and team-based T2D management in pregnancy.

Decreasing disparities in glycemic control and adverse pregnancy outcomes through addressing social needs

ACHIEVE is an intervention to address glycemic control and consequently adverse pregnancy outcomes and to improve the patient experience among Medicaid-insured pregnant individuals living with T2D. This is an at risk population that experiences a high burden of adverse pregnancy outcomes and inadequate glycemic control that are related to unmet social needs.[10] While clinical care is critical, it is insufficient as social needs, such as food security, adequate housing, safe environment, and access to health care, also impact diabetes and pregnancy outcomes.[22] The ACHIEVE intervention aims to provide an integrated care ecosystem that incorporates digital communication, education, and remote care management to address the structural challenges faced by Medicaid-insured pregnant individuals living with diabetes and poor glycemic control.[58]

A multi-component intervention for proactive health transformation

ACHIEVE is an integrated multi-component intervention (mHealth app, provider dashboard, CGM, social needs referrals and team-based care), employs a Social Cognitive Theory paradigm, and is informed by prior informatics- and behavioral-based interventions to promote glycemic control among non-pregnant individuals with diabetes.[59-61] Few existing apps for prenatal care provide comprehensive evidence-based educational content, tracking tools, user-centered design (UCD), and the potential for integration with the EHR.[62 63] And for T2D in pregnancy, studies using a tailored mHealth app with CGM remain to be conducted.[33 64] ACHIEVE integrates health information technology (HIT) tools and a dynamic, closed-loop system so that patients and providers can track treatment goals and care pathways.

A sustainable and scalable intervention

The patient mHealth app and provider dashboard of the intervention are embedded within an existing electronic health platform and REDCap.[50] In addition, the intervention enhances existing delivery systems, including the established Central Ohio Pathways HUB model to address social needs. Should efficacy of the ACHIEVE intervention be demonstrated, this program could be deployed across healthcare systems. To assist with future transferability of the intervention across clinical sites, we plan to provide technical and implementation documentation of the ACHIEVE intervention via GitHub.

Limitations and strengths

Limitations

First, this study is non-blinded to providers and patients as they need to be aware of intervention allocation. However, study arm will be blinded to those assessing and analyzing the association between the intervention and primary outcome (A1c), including both the laboratory staff and biostatistician. Second, this study is powered for a primary clinical outcome of glycemic control that is associated with adverse pregnancy outcomes, but is not specifically powered for adverse pregnancy outcomes. Should this intervention demonstrate efficacy for glycemic control, the next step would be larger clinical trial powered to detect whether adverse pregnancy outcomes can be prevented. Third, this intervention is focused on glycemic control during pregnancy, and periconception and postpartum glycemic control are not primarily addressed by this intervention. In the future, this intervention could be expanded to include these critical time periods. Finally, this single-site study is restricted to Medicaid-insured pregnant individuals with T2D and poor glycemic control. Hence, these findings may not necessarily be generalizable to all pregnant individuals with T2D.

Strengths

T2D is one of the most frequent chronic comorbid conditions in pregnancy. Medicaid-insured pregnant individuals experience a higher burden of T2D, associated adverse pregnancy outcomes, and unmet social needs.[18-20] We aim to develop a scalable model of care that addresses modifiable social needs that directly affect glycemic control. If this intervention proves to be efficacious, it may have major public health impact.

Conclusions

In conclusion, this study will address whether a multi-component provider-patient based intervention for Medicaid-insured pregnant individuals with T2D and poor glycemic control that includes a mHealth app, provider dashboard, CGM device, social needs referrals, and team-based care results in improved glycemic control, patient reported outcomes, and pregnancy outcomes. These results will provide key information on the effectiveness of an mHealth intervention for diabetes management in pregnancy for individuals with unmet social needs compared with the current standard of care. If effective, ACHIEVE will advance health equity by addressing the pregnancy and diabetes care needs of a high-risk and underserved patient population.

Contributors: KKV, JJJ, and NF designed the study. ASM and TH provided oversight for study design and implementation. NF with support from CS and RS led the design and implementation of the user-centered design phase. NF, KKV, and JJ with support from TS, AB, and LB led the RCT. XP provided statistical support and oversight. JH and CB led the assessment and implementation of social needs pathways. KKV, JJJ, and NF wrote the methods manuscript. All authors revised the manuscript for relevant scientific content and approved the final version of the manuscript.

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Competing interests: None declared.

Patient and public involvement: Patients were involved in the design of this study. Refer to the Methods section for further details.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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TABLES AND FIGURES

Figure 1. ACHIEVE conceptual framework.

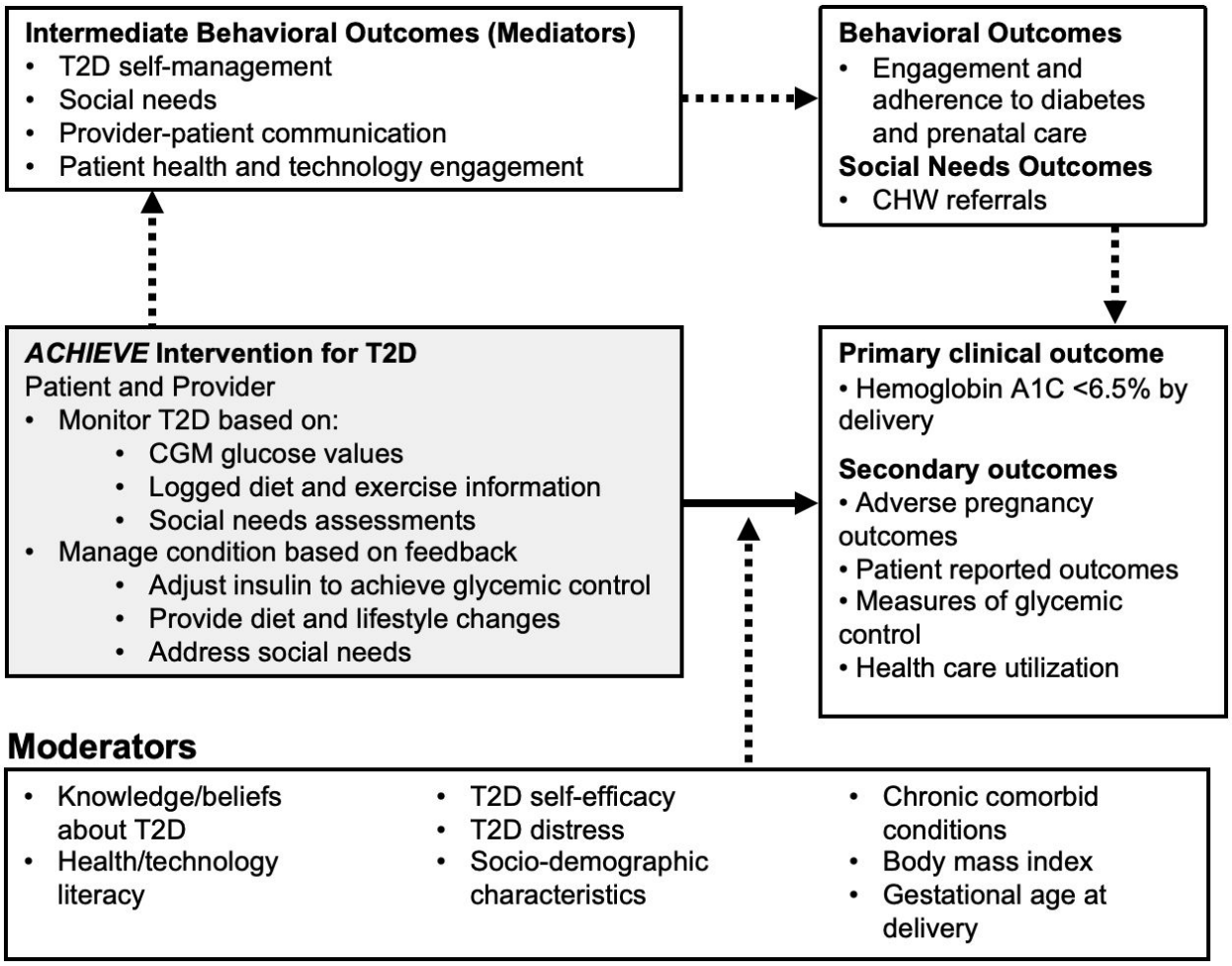
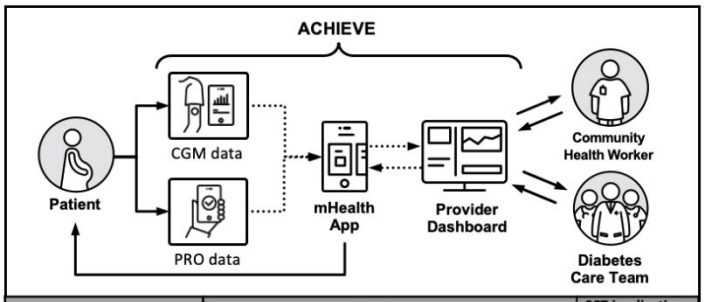


Figure 2. ACHIEVE intervention components.



Component	Proposed sub-component	SCT implications for patient
mHealth App	Report and monitor PROs (e.g., social needs, diet/exercise activity, and self-care) and CGM glucose data	Skills
	Manage T2D and pregnancy with data sharing	Skills
	Track care goals with educational information about care pathways on how to achieve goals	Knowledge & Beliefs
	Reminder function with calendar	Skills
	Video conferencing and messaging with provider	Skills
DEXCOM G7 PRO	Monitoring of glucose using a continuous glucose monitor and digital data transfer of measurements to provider via mHealth app	Skills
Rule-based algorithms / **Digital Health Platform**	Integrate patient and provider data between mhealth app, portal, and EHR	Self-efficacy
	Use rule-based algorithms to prioritize care goals, care pathways, and identify "out of range" values	Self-efficacy
	Automate PRO collection schedule	Skills
Provider Dashboard	Monitor patient PROs, CGM data, goals, and care or social need pathways	Skills
	Prioritize goals and care pathways based on recommendations	Knowledge & Beliefs
	Dashboard drill-downs about patient CGM and PRO data	Knowledge & Beliefs
	Communicate with diabetes care team and patient	Skills
	Document, track, and make social need referrals related to patient	Knowledge & Beliefs
Team-based Care	Manage patient focusing on active problem solving and motivational language (concordant with ADA and clinical guidelines for T2D in pregnancy): **Diabetes care team (physician, nurse, certified diabetes care and education specialist)** a. Glycemic control b. Diet and lifestyle modification c. Insulin pharmacotherapy **Community health worker** a. Social needs assessment and referrals	Self-efficacy
	Prioritize care goals and care/social need pathways (over-ride system recommendations if required)	Self-efficacy
	Increase awareness of patient challenges and motivate adherence to care pathways	Knowledge & Beliefs
	Engage patient	Self-efficacy

Abbreviations: CGM: continuous glucose monitoring; EHR: electronic health record; PRO: patient reported outcome; SCT: Social Cognitive theory; T2D: type 2 diabetes.

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A multi-component provider-patient intervention to improve glycemic control in Medicaid-insured pregnant individuals with type 2 diabetes: clinical trial protocol for the ACHIEVE Study

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TITLE: A multi-component provider-patient intervention to improve glycemic control in Medicaid-insured pregnant individuals with type 2 diabetes: clinical trial protocol for the ACHIEVE Study

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ABSTRACT

Introduction: Type 2 diabetes (T2D) is one of the most frequent comorbid medical conditions in pregnancy. Glycemic control decreases the risk of adverse pregnancy outcomes for the pregnant individual and infant. Achieving glycemic control can be challenging for Medicaid-insured pregnant individuals who experience a high burden of unmet social needs. Multi-faceted provider-patient based approaches are needed to improve glycemic control in this high-risk pregnant population. Mobile health (mHealth) applications (app), provider dashboards, continuous glucose monitoring (CGM), and addressing social needs have been independently associated with improved glycemic control in non-pregnant individuals living with diabetes. The combined effect of these interventions on glycemic control among pregnant individuals with T2D remains to be evaluated.

Methods and analysis: In a two-arm randomized controlled trial (RCT), we will examine the combined effects of a multi-component provider-patient intervention, including a patient mHealth app, provider dashboard, CGM, a community health worker (CHW) to address non-medical health-related social needs, and team-based care versus the current standard of diabetes and prenatal care. We will recruit 124 Medicaid-insured pregnant individuals living with T2D, who are ≤20 weeks of gestation with poor glycemic control measured as a hemoglobin A1c (A1c) ≥ 6.5% assessed within 12 weeks of trial randomization or within 12 weeks of enrolling in prenatal care from an integrated diabetes and prenatal care program at a tertiary care academic health system located in the Midwestern U.S. We will measure how many individuals achieve the primary outcome of glycemic control measured as an A1c <6.5% by the time of delivery, and secondarily, adverse pregnancy outcomes; patient-reported outcomes (e.g., health and technology engagement, literacy, and comprehension; provider-patient communication; diabetes

self-efficacy; distress, knowledge, and beliefs; social needs referrals and utilization; medication adherence); and CGM measures of glycemic control (in the intervention group).

Ethics and dissemination: The Institutional Review Board at The Ohio State University approved this study (IRB: 2022H0399; date: 03/06/23). We plan to submit manuscripts describing the user-designed methods and will submit the results of the trial for publication in peer-reviewed journals and presentations at international scientific meetings.

Trial registration number: NCT05662462; pre-results.

Strengths and limitations of this study

- ACHIEVE is a multi-component intervention using a Mobile health (mHealth) application (app), provider dashboard, continuous glucose monitoring (CGM), referral for social needs, and team-based care to address glycemic control.
- Strengths of the ACHIEVE trial include an intervention focused on Medicaid-insured individuals with type 2 diabetes (T2D) and poor glycemic control who are at high risk of adverse pregnancy outcomes.
- Limitations of the ACHIEVE trial include that it that it is powered for pregnancy glycemic control and not adverse pregnancy outcomes and periconception or postpartum outcomes.
- Challenges of this trial will include engaging a high-risk population of pregnant individuals with poor glycemic control and unmet social needs using a mHealth intervention.

INTRODUCTION

Background

Type 2 diabetes (T2D) is one of the most frequent chronic comorbid conditions in pregnancy.[1-3] Every year in the U.S. more than 100,000 pregnancies are complicated by T2D, which is anticipated to double in the next 10 years, affecting 1 in 20 pregnancies.[4-6] T2D increases the risk of adverse pregnancy outcomes for the pregnant individual, including severe maternal morbidity, cesarean delivery, preeclampsia, and severe maternal morbidity; and infant, including large for gestational age at birth, preterm birth, and neonatal hypoglycemia.[7-9] Inadequate glycemic control further increases the risk of these adverse outcomes by at least two-fold.[10-12]

Improving glycemic control as measured by hemoglobin A1c (A1c) decreases the risk of adverse pregnancy outcomes.[7 12] Guidelines recommend achieving an A1c target in pregnancy of at least <6.5% to optimize outcomes.[13 14] Glycemic control for pregnant individuals with T2D can be achieved with insulin pharmacotherapy, consistent glucose monitoring, lifestyle modifications including diet and exercise, and interdisciplinary, team-based diabetes and prenatal care.[11] Pregnant individuals living with T2D who experience a higher burden of adverse social determinants of health (SDoH) and unmet non-medical health-related social needs (social needs),[10] including food insecurity[15] and inadequate physical activity,[16] are less likely to achieve glycemic control.

More than half of pregnant individuals with T2D are insured by Medicaid.[17] Medicaid-insured pregnant individuals experience a higher burden of T2D, adverse pregnancy outcomes, and adverse SDoH.[18-20] Addressing modifiable social needs that affect glycemic control in this population could improve pregnancy outcomes by addressing maternal health inequity.[10 21-25] A

model that addresses unmet social needs for individuals with chronic comorbidities is the Agency for Healthcare Research and Quality (AHRQ) Pathways Community Hub model.[26] The Hub model leverages care coordination with community health workers (CHWs) to facilitate social needs-related screening and referrals through the use of social needs pathways.[27]

Mobile health (mHealth) applications (app) can address health disparities in prenatal access and care due to adverse SDoH.[28 29] mHealth apps are pervasive among reproductive-age female individuals, and >90% actively engage in their use.[30] mHealth apps include access to digital information, reminders, and convenient communication modes with healthcare providers. Electronic data linked to patients' mHealth apps can allow the care team to actively engage with patients in their care and help them to achieve treatment goals.[31 32] In addition, continuous glucose monitoring (CGM) is a personal mobile technology that allows identification of precise, individualized patterns of dysglycemia.[33] CGM has been shown to improve glycemic control and decrease the risk of adverse pregnancy outcomes for individuals with type 1 diabetes,[34] but its impact among pregnant individuals with T2D remains largely unstudied.[33]

Current mHealth apps for diabetes management typically lack user-centered design features and are not holistically focused on the combination of addressing unmet pregnancy and social needs, CGM integration, and team-based care supported with provider dashboards. Whether an integrated, theory-driven, and user-centered intervention can result in improved glycemic control and patient-reported outcomes among Medicaid-insured pregnant individuals with T2D remains to be answered.

The proposed ACHIEVE intervention integrates new and existing technologies to develop an innovative ecosystem, including a mHealth patient app, provider dashboard, CGM device, social needs referrals, and team-based care.

Aim and hypotheses

The objective of ACHIEVE is to test whether a multi-component intervention (mHealth app, provider dashboard, CGM device, social needs referrals, and team-based care) versus the current standard of care for prenatal and diabetes care results in improved glycemic control by the time of delivery (A1c <6.5%) for Medicaid-insured pregnant individuals with T2D (Figure 1).

Primary hypothesis

We hypothesize a 25% absolute increase in the proportion of individuals in the intervention group who will meet the target A1c <6.5% by the time of delivery compared with the standard care group.

Secondary hypotheses

We hypothesize that individuals in the intervention group will have fewer adverse pregnancy outcomes, and superior patient-reported outcomes (i.e., health and technology engagement, literacy, and comprehension, provider-patient communication, diabetes self-management, self-efficacy, distress, knowledge, and beliefs, social needs referrals and utilization, and medication adherence) compared with the standard care group.

METHODS AND ANALYSIS

Design

ACHIEVE is a randomized, controlled, single-center superiority trial to determine whether Medicaid-insured pregnant individuals with T2D enrolled in a multi-component intervention (mHealth app, provider dashboard, CGM device, social needs referrals, and team-based care) will improve glycemic control compared with those receiving standard prenatal and

diabetes care (Figure 2). Each sub-component of the proposed intervention is grounded in Social Cognitive Theory (SCT), and aims to address an individual's skills, knowledge and beliefs, and self-efficacy to achieve glycemic control.[35] Data management and coordination will occur by an independent team at the clinical site of the ACHIEVE trial and will be led by the study statistician (XP). Participant data will be collected, stored, and maintained REDCap (Research Electronic Data Capture), a secure and confidential data management system. Randomization by computer-generated random numbers by the study statistician will be performed with a 1:1 non-blinded allocation between intervention:standard care groups. The allocation will be kept in a sealed envelope until the research staff enrolls and assigns a participant to a study group. An independent data safety monitoring board (DSMB) will monitor and audit trial conduct, including review of any adverse events, annually during the clinical trial.

Population

Individuals will be recruited as part of The Ohio State University Diabetes during Pregnancy program, which provides integrated diabetes and prenatal care at a tertiary academic medical center located in the Midwestern United States.[12 36] Some individuals continue to receive routine prenatal care in their local community, and then receive high-risk prenatal and diabetes care from the program. These individuals will also be eligible for study participation. The ACHIEVE trial will end at delivery, and postpartum individuals in both the intervention and standard care group will be provided with a referral to an endocrinologist and primary care provider for postpartum diabetes and reproductive health care.

Inclusion criteria

Individuals with an ultrasound-confirmed intrauterine pregnancy, aged ≥18 years, with a diagnosis of T2D, with poor glycemic control measured as an A1c ≥6.5% assessed within 12 weeks of trial randomization or within 12 weeks of enrolling in prenatal care, who are ≤20 weeks of gestation at trial randomization, English or Spanish speaking, who are Medicaid-insured or -eligible, and available to participate in a longitudinal study across pregnancy will be eligible. Because this intervention includes a mHealth app, individuals will need to use a smartphone (either iPhone or Android) with internet access. For those without a smartphone, a device and access to the internet will be provided for the duration of the trial.

Exclusion criteria

We will exclude individuals who cannot cognitively complete the study requirements, consent to all study activities through the time of delivery, be accessible for participation in study activities or cannot read and write in either English or Spanish. Individuals enrolled in a concurrent clinical trial focused on improving glycemic control will not be eligible for enrollment.

Recruitment

Individuals will be recruited over a three-year time period. Potentially eligible individuals will be identified via the electronic health record (EHR). In addition, individuals will be recruited using flyers placed in clinic and direct provider referrals from the community.

Baseline visit

A research assistant or healthcare provider will ask patients if they are interested in joining the study and they will be referred for an orientation visit. Informed consent will be obtained in person in English or Spanish. Baseline data, including demographics, diabetes history, and information about current technology familiarity and utilization will be collected

using electronic data capture. Participants will complete a blood draw for measurement of A1c using a standardized assay. Enrolled individuals will be randomized in a 1:1 ratio to the intervention: standard care. Participants randomized to the intervention group will: 1) receive assistance in downloading and using the mHealth app via their smartphone and using the CGM device for glucose monitoring; and 2) be trained with placing DEXCOM G7® CGM sensors and transmitters including instruction about frequent troubleshooting with new CGM initiation.

Partial patient and public involvement

Medicaid-insured pregnant individuals with T2D and their healthcare providers, including both physicians and nurses, clinical social workers, and community health workers, have collaboratively worked with the study team in designing the mHealth app and dashboard interface by providing feedback about the intervention prototype via structured interviews over multiple iterations.[31] Additional testing of the integrated system and tools (i.e., patient mHealth app and provider dashboard) to address usability and patient/provider-centeredness will be conducted prior to the RCT.

Measures

The primary clinical outcome is the proportion of individuals with an A1c <6.5% by the time of delivery. For those individuals with more than one A1c assessment in late pregnancy, the value most proximate to delivery will be used as a measure of the risk of adverse pregnancy outcomes at birth associated with dysglycemia.[12] For most participants without a preterm delivery, this A1c assessment will be in the late third trimester. A1c will be assessed once per trimester, consistent with U.S. guidelines for diabetes management in pregnancy.[13 14] Of note, we selected an A1c threshold of <6.5% as opposed to <6.0% as an aggressive target <6.0% may result in more frequent episodes of hypoglycemia, and the risk of adverse neonatal outcomes are

similar at both thresholds.[7 12] A1c will be measured using automated high pressure liquid chromatography (VARIANT II TURBO HgbA1c Kit, Bio-Rad laboratories, Hercules, CA).

Secondary adverse pregnancy outcomes at birth related to pregnancy dysglycemia include large-for-gestational-age at birth (standardized birthweight ≥90% for gestational age) using a recent U.S. infant sex-specific standard,[37] neonatal hypoglycemia (defined as any blood glucose <30 mg/dL during the delivery admission), hypertensive disorder of pregnancy,[38] NICU admission for any indication, preterm birth <37 weeks per the best obstetric estimate for any indication,[39] and respiratory distress syndrome.[40]

Secondary measures of glycemic control for the standard care group will include: weekly self-monitored blood glucose values, including both fasting and 2-hour postprandial values, at guideline recommended target values; and for the intervention group using CGM will include: the percentage of time in range (TIR) between 63 to 140 mg/dL, consistent with emerging data for diabetes in pregnancy,[34] as well as both continuous and dichotomous measures (≥85%). We will also assess CGM summary statistical indices including mean CGM glucose levels during the day and night, area under the curve, time spent above and below target range, and low and high blood glucose indices.[34]

Patient-reported outcomes (PROs) will be collected at pre-specified intervals at randomization, during pregnancy, and at delivery, including patient knowledge, skills, and confidence to manage health using the Patient Activation Measure (PAM),[41] social needs using the Accountable Health Communities Health-Related Social Needs Screening Tool,[42] provider-patient communication using the Doctor-Patient Communication Scale,[43] and health literacy using the Short Assessment of Health Literacy-Spanish and English (SAHL-S&E) and eHealth Literacy Scale (eHEALS).[44 45] In addition, we will assess diabetes management related PROs

including Diabetes Knowledge Questionnaire (DKQ),[46] Diabetes Distress Scale,[47] Diabetes Management Self-Efficacy Scale,[48] and the Morisky Medication Adherence Scale (MMAS-4).[49]

Health care utilization will be abstracted from the EHR and patient surveys and will include prenatal visits, antepartum hospitalizations, emergency department visits, obstetric triage visits, and unscheduled clinic visits.

Within the intervention group, engagement data will be collected through log files and will be measured as the number of times a participant uses the mHealth app (total and average use of the app and specific functions), as well as the number of social needs referrals made and completed. For participants who are lost to follow-up or discontinue participation, clinical outcomes will be abstracted from the EHR and PROs will be assessed until trial discontinuation.

Procedures

User-centered design testing

A User-Centered Design Work Group (UCDWG) comprised of 10 individuals and representing key stakeholder groups including physicians (maternal-fetal medicine and endocrinology), certified diabetes care and education specialists, nurses, Medicaid-insured pregnant individuals living with T2D, CHWs, and licensed clinical social workers will guide the adaptation and refinement of the intervention prior to participant enrollment through multiple iterations of testing. The UCDWG will provide input on the mHealth app and provider dashboard functions.

Interventions

The ACHIEVE intervention is supported by a robust digital electronic platform. This platform is integrated with REDCap (Research Electronic Data Capture) and other electronic

systems, including the ACHIEVE mHealth app and provider dashboard, HUB Care Coordination System portal, and EHR data. REDCap is a secure, web-based application designed to support data capture for research studies, including data entry, audit trails for tracking data manipulation, automated export procedures, and procedures for importing data from external sources.[50] The ACHIEVE intervention can tailor care in real-time based on changing medical and social needs. It uses rule-based algorithms to synthesize data reported by participants and providers, and adjusts the collection of PROs based on defined parameters and providing personalized educational content to patients via the mHealth app.

Participants will receive training with regards to using the mHealth app and CGM from certified diabetes care and education specialists. Participants will be further supported to engage in care pathways to resolve unmet social needs with the assistance of CHWs. Secure messaging will allow for electronic communication between participants and the certified diabetes care and education specialists and CHWs.

We describe each of the key elements of the ACHIEVE intervention below, namely the patient mHealth app, provider dashboard, CGM device, social needs referrals, and team-based care (Figure 2).

mHealth application.

The mHealth app provides education, reminders, care goals, care pathway recommendations, summaries of CGM data and PROs, messaging, and a calendar function for goal tracking. Content is based on current U.S. clinical guidelines for T2D in pregnancy.[13 14] The mHealth app directs participants to online diabetes and pregnancy resources and learning. Assessment of patient reported outcomes will be embedded in the mHealth app, and rule-based algorithms will provide tailored goals for medical and social needs and information on how to

achieve them (i.e., care pathways), and establish the frequency of assessment for PROs including social needs screening. Data are transferred to the digital health platform, which post processing displays data on the provider dashboard.

Provider dashboard.

The ACHIEVE intervention will include a bi-directional dashboard that displays information about participants, including priority goals and care pathways, and recommendations generated via the digital platform. The dashboard will present recommendations for participant goals and care pathways provided by the digital platform algorithms. Providers can access the dashboard embedded within an online portal to monitor participant progress and close the loop on participant tasks. Both certified diabetes care and education specialists and CHWs can assess social needs pathway selections and assess recurring needs through the dashboard. Providers can use auto-generated recommendations or manually select recommendations from a clinically validated data repository.

Continuous glucose monitoring.

Participants in the intervention group will use DEXCOM® G7 CGM sensors and transmitters for glucose monitoring. The Dexcom CGM system is accurate and safe in pregnant individuals with diabetes.[51] The DEXCOM G7 CGM system was recently approved by the FDA for use in pregnancy.[52] Participants will be taught how to place and remove CGM sensors, and will then replace sensors themselves every 10 days. DEXCOM sensors can be applied on the abdomen, arm, or upper buttocks, is well-tolerated in pregnancy, and do not require calibration.[51] The mHealth app will allow for wireless synchronization with the CGM transmitter so that data are reported back to the healthcare team, which will be reviewed by the certified diabetes care and education specialist at least twice weekly.

Social needs referrals.

We will partner with Health Impact Ohio's Central Ohio Pathways Hub, which consists of three features: (1) the Hub, a regional coordination entity, which employs CHWs to assess the social needs of patients and connect them to community resources; (2) the CHWs initiate a "social need care pathway," a defined action plan to address each patient's unique needs, which is recorded and tracked in an electronic database; and (3) completion of each pathway is linked to payment from insurance companies (e.g., Medicaid-managed care plans) based on specific performance benchmarks.[27 53] The CHWs are embedded within the local communities in which participants live in. Participants will be screened at enrollment and throughout the intervention for social needs using a survey adapted from the Accountable Health Communities Health-Related Social Needs Screening Tool and prior studies.[54 55] Once an unmet social need is identified, participants will be referred to the Health Impact Ohio Hub through the provider dashboard to address unmet social needs (e.g., food insecurity, unstable housing, unemployment). Health Impact Ohio CHWs will perform a comprehensive social needs assessment and connect the participant to community resources through Hub pathways.

Team based care.

Team-based care will be provided by physicians, nurses, certified diabetes care and education specialist, and clinical social workers, as well as CHWs. Team-based care will be facilitated by the provider dashboard and patient mHealth app. The clinical care pathways will address lifestyle factors, including diabetes nutrition therapy, physical activity, smoking cessation, psychosocial stress reduction, and pharmacologic management (pharmacotherapy adherence and modifications) to improve glycemic control.

Standard care arm.

Participants randomized to the standard care group will receive the current standard of diabetes and prenatal care at our center as part of the integrated diabetes and prenatal care program.[11 12] Participants will complete weekly self-monitored blood glucose logs on paper, which will be electronically sent to the EHR for provider review. Communication with the certified diabetes care and education specialists and CHWs will be via Epic's MyChart instance (Epic MyChart). A1c will be assessed, and PROs will be collected at pre-specified intervals similar to the intervention arm (i.e., approximately monthly).

Statistical analysis plan

Baseline characteristics

We will provide descriptive summaries and examine any potential differences in socio-demographic and clinical characteristics between the intervention and standard care groups using $\chi 2$- tests for categorical variables and independent 2 sample t-tests for continuous variables.

Primary and secondary hypothesis

Primary analyses will follow the intention-to-treat principle in which pregnant individuals will be analyzed in the group to which they were randomized, regardless of whether they receive the assigned intervention or discontinue prior to delivery. As this is a randomized trial, we will not adjust for baseline participant characteristics or participant engagement measures in the primary intention-to-treat analysis unless we identify statistically significant differences between the intervention and standard care groups. No interim analyses are planned. Multiple imputation will be considered for missing covariates.

Preplanned posthoc analyses

We will conduct subgroup analyses to determine the effect of the intervention among subgroups if there is a significant interaction effect between the subgroup of interest and the

treatment effect, including self-reported race and ethnicity, body mass index at randomization, gestational age at randomization, and baseline A1c at randomization. Exploratory analyses will also be conducted to assess the effect of the intervention on intermediate outcomes (e.g., social needs, T2D self-management, provider-patient communication), and the mediating and moderating roles of the intermediate outcomes.

Power calculations and sample size

Recent pharmacological intervention trials in pregnancies complicated by T2D have assessed medium effect sizes approximating absolute changes of 15 to 30%.[56 57] We target to detect a 25% absolute increase in the proportion of participants in the intervention versus standard care group with an A1c <6.5% by delivery (64% intervention vs. 39% control). A total sample size of 124 participants (62 per study arm) will provide at least 80% power to detect such a difference between the two groups after accounting for up to 10% loss-to-follow-up based on a one-sided Fisher's Exact test. The loss-to-follow-up rate of 10% is based on prior diabetes in pregnancy trials at our center.[32,33]

Compensation

Participants in both study arms will receive compensation of US$100 per month for participation in the trial from randomization to delivery for completion of study activities, including study surveys, attending study sessions, and reporting PROs, including clinical and social needs outcomes.

Ethics and dissemination

The OSU Institutional Review Board (IRB) has approved this protocol. All protocol amendments will be communicated for approval to the OSU IRB. We will follow CONSORT (i.e., Consolidated Standards of Reporting Trials) guidelines. We will submit study results for

publication in peer-reviewed journals and presentation at international meetings. We will attempt to publish all findings in open-access journals when possible, or in other journals with a concurrent uploading of the manuscript content into PubMed central for public access. Curated technical appendices and statistical code will be made available from the corresponding authors on request.

DISCUSSION

In this randomized controlled trial, we will examine the effect of a multi-component intervention (mHealth app, provider dashboard, CGM device, social needs referral, and team-based care) versus current standard of care for prenatal and diabetes care on glycemic control, patient reported outcomes, and pregnancy outcomes among Medicaid-insured pregnant individuals with T2D. The ACHIEVE trial brings together multiple technologies in an integrated and theory-driven framework to facilitate comprehensive, tailored, patient-centered, and team-based T2D management in pregnancy. If effective, ACHIEVE will advance health equity by addressing the pregnancy and diabetes care needs of a high-risk and underserved patient population.

Decreasing disparities in glycemic control and adverse pregnancy outcomes through addressing social needs

ACHIEVE is an intervention to address glycemic control and consequently adverse pregnancy outcomes and to improve the patient experience among Medicaid-insured pregnant individuals living with T2D. This is an at risk population that experiences a high burden of adverse pregnancy outcomes and inadequate glycemic control that are related to unmet social needs.[10] While clinical care is critical, it is insufficient as social needs, such as food security,

adequate housing, safe environment, and access to health care, also impact diabetes and pregnancy outcomes.[22] The ACHIEVE intervention aims to provide an integrated care ecosystem that incorporates digital communication, education, and remote care management to address the structural challenges faced by Medicaid-insured pregnant individuals living with diabetes and poor glycemic control.[58]

A multi-component intervention for proactive health transformation

ACHIEVE is an integrated multi-component intervention (mHealth app, provider dashboard, CGM, social needs referrals and team-based care), employs a Social Cognitive Theory paradigm, and is informed by prior informatics- and behavioral-based interventions to promote glycemic control among non-pregnant individuals with diabetes.[59-61] Few existing apps for prenatal care provide comprehensive evidence-based educational content, tracking tools, user-centered design (UCD), and the potential for integration with the EHR.[62 63] And for T2D in pregnancy, studies using a tailored mHealth app with CGM remain to be conducted.[33 64] ACHIEVE integrates health information technology (HIT) tools and a dynamic, closed-loop system so that patients and providers can track treatment goals and care pathways.

A sustainable and scalable intervention

The patient mHealth app and provider dashboard of the intervention are embedded within an existing electronic health platform and REDCap.[50] In addition, the intervention enhances existing delivery systems, including the established Central Ohio Pathways HUB model to address social needs. Should efficacy of the ACHIEVE intervention be demonstrated, this program could be deployed across healthcare systems. To assist with future transferability of the intervention across clinical sites, we plan to provide technical and implementation documentation of the ACHIEVE intervention via GitHub.

Limitations and strengths

Limitations

First, this study is non-blinded to providers and patients as they need to be aware of intervention allocation. However, study arm will be blinded to those assessing and analyzing the association between the intervention and primary outcome (A1c), including both the laboratory staff and biostatistician. Second, this study is powered for a primary clinical outcome of glycemic control that is associated with adverse pregnancy outcomes, but is not specifically powered for adverse pregnancy outcomes. Should this intervention demonstrate efficacy for glycemic control, the next step would be larger clinical trial powered to detect whether adverse pregnancy outcomes can be prevented. Third, this intervention is focused on glycemic control during pregnancy, and periconception and postpartum glycemic control are not primarily addressed by this intervention. In the future, this intervention could be expanded to include these critical time periods. Finally, this single-site study is restricted to Medicaid-insured pregnant individuals with T2D and poor glycemic control. Hence, these findings may not necessarily be generalizable to all pregnant individuals with T2D.

Strengths

T2D is one of the most frequent chronic comorbid conditions in pregnancy. Medicaid-insured pregnant individuals experience a higher burden of T2D, associated adverse pregnancy outcomes, and unmet social needs.[18-20] We aim to develop a scalable model of care that addresses modifiable social needs that directly affect glycemic control. If this intervention proves to be efficacious, it may have major public health impact.

Contributors: KKV, JJJ, and NF designed the study. ASM and TH provided oversight for study design and implementation. NF with support from CS and RS led the design and implementation of the user-centered design phase. NF, KKV, and JJ with support from TS, AB, and LB led the RCT. XP provided statistical support and oversight. JH and CB led the assessment and implementation of social needs pathways. KKV, JJJ, and NF wrote the methods manuscript. All authors revised the manuscript for relevant scientific content and approved the final version of the manuscript.

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Patient and public involvement: Patients were involved in the design of this study. Refer to the Methods section for further details.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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TABLES AND FIGURES

Figure 1. ACHIEVE conceptual framework.

Figure 2. ACHIEVE intervention components.

Abbreviations: CGM: continuous glucose monitoring; EHR: electronic health record; PRO: patient reported outcome; SCT: Social Cognitive theory; T2D: type 2 diabetes.

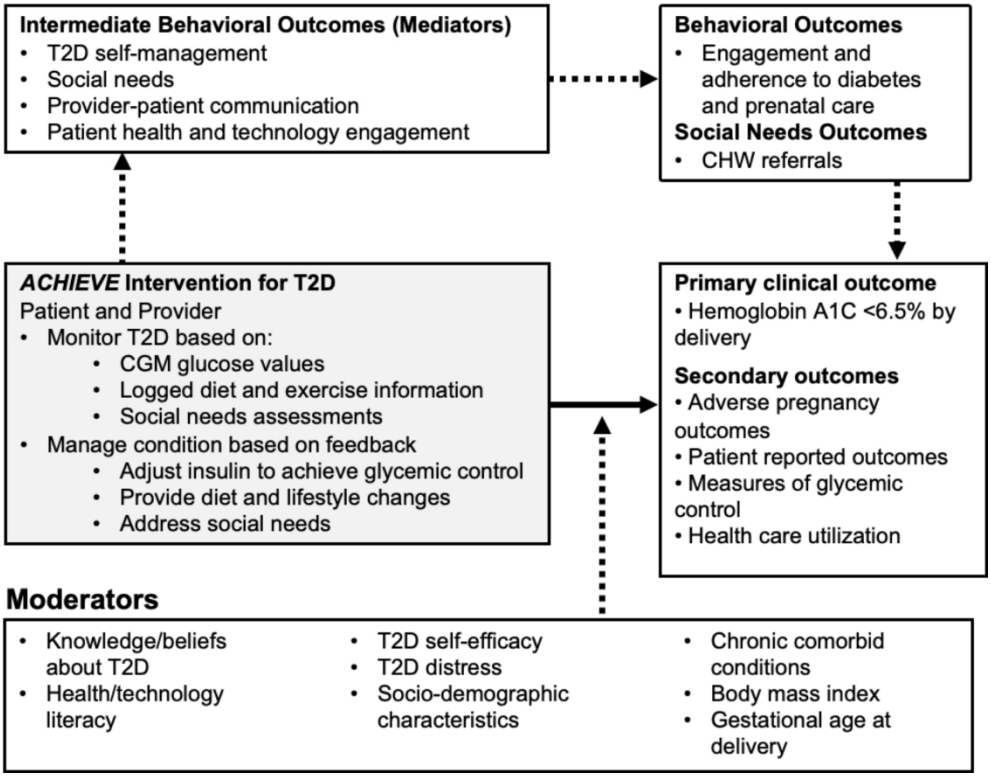
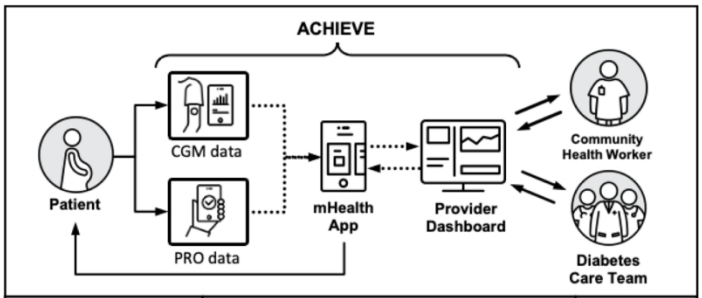


FIGURE 1

174x134mm (300 x 300 DPI)



Component	Proposed sub-component	SCT implications for patient
mHealth App	Report and monitor PROs (e.g., social needs, diet/exercise activity, and self-care) and CGM glucose data	Skills
	Manage T2D and pregnancy with data sharing	Skills
	Track care goals with educational information about care pathways on how to achieve goals	Knowledge & Beliefs
	Reminder function with calendar	Skills
	Video conferencing and messaging with provider	Skills
DEXCOM G7 PRO	Monitoring of glucose using a continuous glucose monitor and digital data transfer of measurements to provider via mHealth app	Skills
Rule-based algorithms / Digital Health Platform	Integrate patient and provider data between mhealth app, portal, and EHR	Self-efficacy
	Use rule-based algorithms to prioritize care goals, care pathways, and identify "out of range" values	Self-efficacy
	Automate PRO collection schedule	Skills
Provider Dashboard	Monitor patient PROs, CGM data, goals, and care or social need pathways	Skills
	Prioritize goals and care pathways based on recommendations	Knowledge & Beliefs
	Dashboard drill-downs about patient CGM and PRO data	Knowledge & Beliefs
	Communicate with diabetes care team and patient	Skills
	Document, track, and make social need referrals related to patient	Knowledge & Beliefs
Team-based Care	Manage patient focusing on active problem solving and motivational language (concordant with ADA and clinical guidelines for T2D in pregnancy): **Diabetes care team (physician, nurse, certified diabetes care and education specialist)** a. Glycemic control b. Diet and lifestyle modification c. Insulin pharmacotherapy **Community health worker** a. Social needs assessment and referrals	Self-efficacy
	Prioritize goals and care/social need pathways (over-ride system recommendations if required)	Self-efficacy
	Increase awareness of patient challenges and motivate adherence to care pathways	Knowledge & Beliefs
	Engage patient	Self-efficacy

FIGURE 2

111x192mm (300 x 300 DPI)

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym Page 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry Page 4
	2b	All items from the World Health Organization Trial Registration Data Set Page 4
Protocol version	3	Date and version identifier Page 4
Funding	4	Sources and types of financial, material, and other support Page 22
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors Page 22
	5b	Name and contact information for the trial sponsor Page 22
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities Page 22
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) Page 17
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention Page 6-7
	6b	Explanation for choice of comparators Page 7-8
Objectives	7	Specific objectives or hypotheses Page 8
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) Page 9

Methods: Participants, interventions, and outcomes		
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained Page 9
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) Pg 9-10
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered Page 13-16
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) Page 12-13
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) Page 11-13
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial Page 10
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended Page 11-12
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) Page 10-11 see Figure 1+2
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations Page 17-18
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size Page 10
Methods: Assignment of interventions (for controlled trials)		
Allocation:		
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions Page 9

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned Page 9
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions Page 9
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how n/a non-blinded
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol Page 11-12
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols Page 12
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol Page 13
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol Page 14-18
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) Page 17-18
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) Page 17-18

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed Page 9

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial Page 7
✓ Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct Page 8 Page 9
✓ Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor Page 8 9
Ethics and dissemination		
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval Page 4
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) Page 4
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) Page 10
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable Page 10
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial Page 9
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site Page 23
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators Page 22
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation Page 9-10
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions Page 18
	31b	Authorship eligibility guidelines and any intended use of professional writers Page 22
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code Page 18

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

not provided

n/a

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.