STUDY PROTOCOL

Comparative Effectiveness of Family vs. Individually Focused Diabetes Education and Support

Family Support for Health Action (FAM-ACT)

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TERMS AND ABBREVIATIONS

CCDC – Center for Clinical Trials and Data Coordination (University of Pittsburgh)
CHW – Community Health Worker
CTCAE – Common Terminology Criteria for Adverse Events
COVID-19 – Coronavirus Disease of 2019
CRF – Case Report Form
DSMES – Diabetes Self-Management Education and Support
FAM-ACT – Family Support for Health Action
FQHC – Federally Qualified Health Center
HbA1c – Hemoglobin A1c
I-DSMES – Individual Diabetes Self-Management Education and Support
IRB – Institutional Review Board
PI – Principal Investigator
RA – Research Assistant
SAE – Serious Adverse Event
SP – Support Person

STUDY PERSONNEL

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This is a multicenter protocol for the FAM-ACT Study. All participant interaction and data collection will be completed at a U.S. Federally Qualified Health Center (FQHC) in Detroit, Michigan. The University of Pittsburgh PI will be responsible for study oversight, data management, and analysis. While there are two locations for research activities, they will not follow the same protocol. This protocol outlines the FQHC and University of Pittsburgh's roles.

PROTOCOL ADAPTATIONS RELATED TO COVID-19 PANDEMIC

The intervention initially had been designed to span 12 months as described in the 'original protocol' (v 1.0, May 13, 2019). The original protocol was used for the first 77 patient-support person dyads who enrolled in the study prior to March 2020, when the COVID-19 pandemic reached the United States and limits were placed on the conduct of in-person research activities. In response to the pandemic, several modifications were made to the protocol—including reducing the length of the intervention to 6 months—both to ensure the safety of study participants and research staff as well as to compensate for a temporary pause in enrollment due to pandemic-related restrictions on recruitment activities ('adapted protocol'). Differences between the two protocols are summarized in **Appendix 1**. The adapted protocol was put into effect in February 2021, when recruitment activities were permitted to restart, and will remain in effect throughout the duration of the study. This document describes the protocol that has been used since February 2021. For additional detail on the adaptations that were made to the protocol, see our 2022 publication in Trials[1].

RESEARCH PROTOCOL ABSTRACT

Diabetes self-management interventions have struggled to deliver relevant, effective, and sustainable support for at-risk adults with diabetes to improve key diabetes self-management behaviors, become more activated participants in healthcare and reduce diabetes complications. One largely untapped resource for this support is patients' family and friends. Three out of four adults with diabetes reach out to an unpaid family member or friend (a 'Support Person') for ongoing help with diabetes management.

However, diabetes management interventions to date lack structured and effective approaches to directly engage patients' family members in supporting successful diabetes management. The long-term goal of this research is to produce structured and evidence-based approaches that engage Support Persons (SPs) in helping at-risk adults initiate and sustain effective diabetes management behaviors. The objective of this study is to compare the effectiveness of a novel program—Family Support for Health Action (FAM-ACT)—to more traditional, individual patient-focused diabetes self-management education and support (I-DSMES). FAM-ACT uses three innovative approaches to enhance the impact of family support on diabetes management: 1) provide family members core behavioral strategies directed at specific roles in supporting diabetes medical and lifestyle management, 2) teach family members how to deliver support in ways that support patient autonomy, and 3) teach SPs ways to boost patients' activated participation in healthcare. Community Health Workers (CHWs) will deliver FAM-ACT to patient-SP dyads at an urban federally qualified health center using in-person meetings, phone/video call, or video conferencing via a HIPAA-compliant application, as appropriate. 268 patients with type 2 diabetes and poor glycemic control, together with a SP, will be randomized to receive either FAM-ACT or I-DSMES intervention over 6 months. The specific aims of this study are to 1) Determine the effect of FAM-ACT on patients' diabetes health outcomes compared to I-DSMES, and 2) Determine the effect of FAM-ACT on patient health behaviors and perceived support compared to I-DSMES. The main diabetes health outcome is change from baseline to 6 months in Hemoglobin A1c (HbA1c). Patient behavioral outcomes will include diabetes self-management behaviors and perceived social support and autonomy support from family.

This project is significant because it builds on prior CHW and peer support models to help at-risk diabetes patients with few resources achieve and sustain core health behaviors that underlie successful management of multiple risk factors for diabetes complications. Ultimately, this study will have a positive impact by producing a novel, scalable, evidence-based protocol and tools that leverage family support to help patients improve and sustain diabetes self-management behaviors.

Our long-term goal is to produce structured and evidence-based approaches that engage SPs in helping at-risk adults initiate and sustain effective diabetes management behaviors.

[1] Deverts DJ, Heisler M, Kieffer EC, Piatt GA, Valbuena F, Yabes JG, Guajardo C, Ilarraza-Montalvo D, Palmisano G, Koerbel G, Rosland AM. Comparing the effectiveness of Family Support for Health Action (FAM-ACT) with traditional community health worker-led interventions to improve adult diabetes management and outcomes: study protocol for a randomized controlled trial. Trials. 2022 Dec;23(1):1-22.

OBJECTIVE

The objective of this study is to compare the effectiveness of FAM-ACT to I-DSMES.

SPECIFIC AIMS

Aim 1. Determine the effect of FAM-ACT on patients' diabetes-related health outcomes compared to patient-focused DSME and care management. We hypothesize that FAM-ACT will improve diabetes health outcomes. The primary outcome is change in patient HbA1c from baseline to 6 months. Secondary patient outcomes include 12-month change in HbA1c, 6- and 12-month changes in patient blood pressure, and 6-month change in diabetes self-management behaviors, diabetes distress, patient activation, diabetes self-efficacy and perceived support.

Aim 2. Determine the effect of FAM-ACT on patient health behaviors and perceived support compared to I-DSMES. We hypothesize that FAM-ACT will improve patient diabetes self-management behaviors, perceived social support for diabetes, and perceived autonomy support from family more than I-DSMES over 6 months. We will also examine the impact of hypothesized moderators and mediators of improved self-management behavior (e.g. self-efficacy).

Aim 3. Examine the impact of the COVID-19 pandemic and associated social distancing guidelines on patients' ability to participate in the FAM-ACT program as well as on their ability to manage their diabetes.

RESEARCH ACTIVITIES

ACTIVITIES AT THE UNIVERSITY OF PITTSBURGH

There will not be any participant recruitment or enrollment at the University of Pittsburgh or UPMC facilities.

University of Pittsburgh facilities will be used for data management and analysis, maintaining data integrity, teleconferencing, video-conferencing with screen sharing, and safety oversight by the Principal Investigator, as described through this protocol.

The University of Pittsburgh is providing local Investigators and study staff with offices/workspaces, desktop computers, access to computer servers and internet, high-volume printers, meeting rooms, and teleconferencing and video-conferencing hardware and software.

ACTIVITIES AT THE FEDERALLY QUALIFIED HEALTH CENTER

The intervention site will be an urban, community-based U.S. Federally Qualified Health Center (FQHC) in Detroit, Michigan, that serves a clientele that is majority Latino/a and Spanish-speaking. The FQHC will be responsible for all study procedures involving direct interactions with participants including recruitment, assessment and intervention.

OVERVIEW OF STUDY DESIGN

The study will be a single-site parallel arm randomized controlled superiority trial with dyads consisting of an adult with type 2 diabetes ('patient') and a selected family supporter ('support person'). Dyads will be randomized 1:1 to either the FAM-ACT program or a traditional individual patient-focused I-DSMES program for 6 months. Assessments of both members of the dyad will be conducted at approximately 6 and 12 months following enrollment. Figure 1 provides a graphic representation of the study protocol.

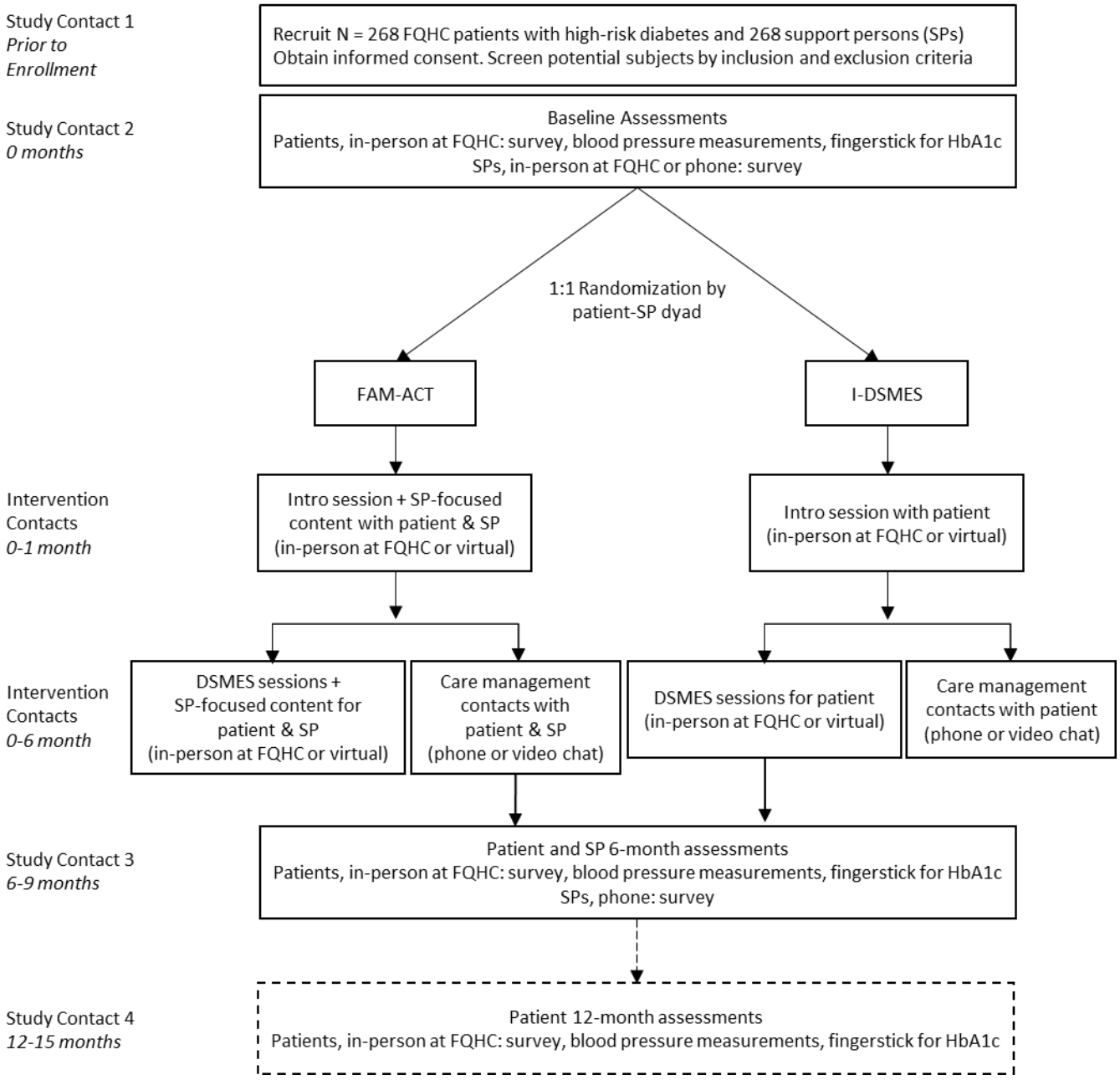


Figure 1. Overview of study design. Solid lines represent the standard protocol that all participants will follow; dotted lines represent an additional patient assessment that will be administered to patients whose 12-month assessment window opens while funding and resources still are available; T2D, type 2 diabetes mellitus; DSMES, diabetes self-management education and support; Dx, diagnosis; EMR, electronic medical record; FAM-ACT, Family Supporters for Health Action; SP, support person

RECRUITMENT, SCREENING, AND CONSENT

FQHC STUDY PATIENT CANDIDATE IDENTIFICATION AND CONTACT

Patients recruited by 'warm handoff' at the FQHC (FQHC clinical provider asks CHW or RA to meet with patient in-person in clinic to describe the study) will receive study information in person at the FQHC by the CHW or RA.

Patients recruited from the recruitment flyer hanging in the FQHC, handed out at community health-related events, and posted on the FQHC Facebook, Twitter, and Instagram sites will contact the study staff via the phone number provided on the flyer.

Patients identified by FQHC provider referral or FQHC EMR data pull will be mailed a study recruitment letter. They will have the opportunity to opt-out of the study by calling the study phone number. If they do not opt out within 3 days, the CHW will call the patient to continue the recruitment and screening process.

PARTICIPANT INFORMED CONSENT AND HIPAA AUTHORIZATION

FQHC RAs will conduct the informed consent and HIPAA authorization (patients only) process, as this is a minimal risk study. The staff will undergo extensive training with the PI, including online training in the process of conducting the informed consent process, in-person training and observation by the PI/Investigators, and role-play with PI/Investigators. The first two times any FQHC RA conducts an informed consent this will be observed by the FQHC Site Coordinator, who will continue observing informed consents conducted by that RA until there are no deficits noted. Informed consent documentation will be monitored and periodically audited by the FQHC Site Coordinator, Principal Investigator, and the University of Pittsburgh Center for Clinical Trials and Data Coordination (CCDC).

SP screening and consent

If a potential patient is eligible and interested in participating, the RA (RA) will then mail a recruitment letter and study information sheet to the potential SP[2], using the contact information provided by the patient.

The SP will have the opportunity to opt-out of the study by calling the study phone number. If they do not opt out within three days of mailing the letter, the FQHC RA or project coordinator will call the potential SP to obtain verbal consent. The FQHC RA or project coordinator will go over all points in the mailed materials about the FAM-ACT study, assess understanding, and encourage questions prior to requesting verbal consent. If the SP requires additional time to think over participation, the time will be given and the FQHC RA or project coordinator will call back or speak with them at a later time as to encourage sufficient time to decide to participate. Consented SPs will complete a baseline survey either by phone or in-person at the FQHC prior to the patient's enrollment.

Patient informed consent and enrollment

Once the SP is deemed eligible and is consented, an in-person enrollment visit will be scheduled with the patient. After the patient has read the consent form, they can request to take time to consider the information and schedule a 2nd visit to complete enrollment if they choose. During the informed consent process the RA will ask the patient questions to make sure they understand what is involved with the study. The patient will be allowed to think about sections in the consent and take time to digest the information. If they choose not to enroll at that time, they will be asked whether the team can contact them again if they have a newly-qualifying HbA1c at a later date. If the patient feels comfortable with what was presented to them in the consent and they are still interested in enrolling, the patient will be asked to sign the consent form, and a copy will be given to them for their records. If the patient consents to participate, a baseline survey and physiologic measurements (blood pressure, weight, fingerstick HbA1c).

[2] Only one family member will be able to enroll in the study as a SP for tracking and assessment purposes.

Randomization

Once both the patient and SP complete all of these steps, they will be randomized into one of the two study arms: FAM-ACT or I-DSMES.

ELIGIBILITY CRITERIA

INCLUSION CRITERIA

FQHC Adult Patient with Diabetes:

- Have a diagnosis of diabetes in the FQHC EMR Problem List (ICD10 codes E08.xx, E09.xx, E11.xx, E13.xx, O24.1x, O24.3x, O24.8x, O24.9x)
- Most recent HbA1c, done in the 3 months prior to screening phone call ≥7.5%
- If A1c not ≥ 7.5, can also qualify due to poor blood pressure control, defined as: Systolic BP >139mm Hg in the FQHC EMR (ECW) official vital sign field (not in note text etc) two or more times in the last 6 months, with the most recent SBP also being >139mm Hg
- Are 21 or over, and less than 75 years old, at the date of screening phone call
- Plan to use FQHC for health care over the next 12 months (after enrollment)
- Must be able to identify a family member or friend who is involved in their health care and willing to be contacted about participating in the study with the patient

Support Person:

- Expects to be able to attend intervention sessions in person if invited
- Must be at least 21 years old

EXCLUSION CRITERIA

FQHC Adult Patient with Diabetes:

- Was diagnosed with diabetes at age <21 years
- Has diagnosis (active or prior) of Alzheimer's Disease or Dementia in the FQHC EMR Problem List as of screening call date (ICD10 F01.50, F01.51, F02.80, F02.81, F03.90, F03.91, G23.1, G30.0, G30.1, G30.8, G30.9, G31.01, G31.09, G31.83)
- Preferred language in the FQHC EMR is not English or Spanish[3]
- Has concerns that may make it difficult to participate (ongoing health issues, personal events, etc.)
- Is pregnant or planning to become pregnant in the next 12 months
- Has diagnosis (active or prior) of Schizophrenia or other Psychotic/Delusional Disorder in the FQHC EMR Problem List as of screening call date. (ICD10 F20.xx, F21.xx, F22.xx, F25.xx, F28.xx, F29.xx)
- Has a life-limiting severe illness (e.g. chronic obstructive pulmonary disease requiring oxygen),
- Has a diagnosis of T1DM in the FQHC EMR Problem List (ICD10 E10.xx, O24.0x), or
- Has a diagnosis of gestational diabetes (ICD10 024.4x) without any other diabetes diagnoses

Support Person:

- Receives pay for caring for the patient
- Does not speak English or Spanish
- Lives in a nursing home or long-term care facility

[3] The FAM-ACT intervention and assessment materials are not available in any language other than English and Spanish and we do not have the resources to accommodate other languages. The FQHC study team RAs are required to be bilingual in English and Spanish to accommodate the Detroit area patient community. One example of a universal teaching tool used with our study population is called a "conversation map" and is only available in English and Spanish versions.

- Has self-reported serious mental illness (schizophrenia)
- Has a significant cognitive impairment (Alzheimer's Disease or Dementia)
- Has concerns that may make it difficult to participate (ongoing health issues, personal events, etc.)
- Has a life-limiting severe illness (e.g. chronic obstructive pulmonary disease requiring oxygen)

INTERVENTION ARMS

PROGRAM A: INDIVIDUAL PATIENT-FOCUSED DSMES (I-DSMES)

The I-DSMES intervention will focus on the FQHC patient only. The SP of patients assigned to this arm will not be invited to the sessions or care management contacts with the patient and CHW. They will be allowed to attend the diabetes self-management education sessions if they choose, however, the sessions will not be family-focused.

FQHC patients assigned to this arm will:

1. Take part in a one-hour introductory session designed to provide an overview of diabetes complications, how to set goals, and prepare for/participate in primary care appointments. During this session, the patient's diabetes complication risk profile will be discussed.

2. Be invited to 4-6 group diabetes self-management education sessions to be held at the FQHC or online using Pitt's HIPAA-compliant Zoom environment. In-person sessions at the FQHC will last approximately 1.5 hours whereas online sessions will be designed to last approximately 45 minutes. American Diabetes Association-approved 'Conversation Maps' will be used as a tool for patient education when feasible.

3. Complete an additional survey assessment and lab measures (blood pressure, weight and fingerstick blood HbA1c) with the study RA 6-months after enrollment. The SP will only complete one additional survey assessment 6 months after enrollment[4]. (*Some patients in both arms may be contacted 12-15 months post-enrollment to complete an additional assessment if the study still is active at the time that assessment window opens.*)

4. Receive care management contacts with a CHW every 2-4 weeks either in person or remotely (when necessary). The CHW will talk with the patient for approximately 20 minutes each time for the remainder of the 6-month enrollment period.

5. Patients who enrolled in the study prior to August 2020 will be contacted by phone for an additional, optional "FAM-ACT COVID" survey. The purpose of this survey is to determine how the events of the COVID-19 pandemic have affected patients' ability to participate in the intervention, and to care for their diabetes

PROGRAM B: SP-FOCUSED DSMES (FAM-ACT)

The FAM-ACT intervention will include patients and their SP together as much as possible. In this arm, the enrolled FQHC Patient and their SP (referred to as a dyad) will:

1. Take part in a one-hour introductory session designed to provide an overview of diabetes complications, ways the SP and patient can work together positively, and ways to set "SMART" health goals. During this session, results of a diabetes complication risk profile are discussed with the patient and support person and the dyad learns how to set goals together.

2. Be invited to 4-6 family-focused, group diabetes self-management education sessions to be held at the FQHC or online using Pitt's HIPAA-compliant Zoom environment. In-person sessions at FQHC will last approximately 2 hours each, whereas online sessions will be designed to last approximately 1 hour. American Diabetes Association-approved "Conversation Maps" will be used as a tool for providing patient education when

[4] In both arms, a +3 month assessment window will be permitted for both patient and SP assessments.

feasible. Additional family-focused topics will be discussed, such as patient-SP communication and SP roles in helping patients participate actively in healthcare provider appointments.

3. Complete additional survey assessments and lab measures (blood pressure, weight, fingerstick A1c, and lipids) with the study RA 6-months after enrollment. The SP will only complete one additional survey assessment 6-months after enrollment.

4. Receive care management contacts with a CHW every 2-4 weeks either in person or remotely (when necessary). The CHW will talk with the dyad for approximately 20 minutes each time for the remainder of the 6-month enrollment period.

5. Patients who enrolled in prior to August 2020 will be contacted by phone for an additional, optional "FAM-ACT COVID" survey. The purpose of this survey is to determine how the events of the COVID-19 pandemic have affected participants' ability to participate in the intervention, and to care for their diabetes

Additionally, the patient will have their FQHC electronic chart reviewed for diabetes-related visit, lab, and medication information for the period from 12 months prior to 24 months following their study enrollment date.

INTERVENTION PROCEDURES CONDUCTED IN BOTH STUDY ARMS

A trained and supervised CHW, CHW Manager, and/or RA at the FQHC will conduct all research participant contacts. Contacts at the FQHC will be supervised by the CHW Manager and Site PI. In-person diabetes self-management education group sessions will take place in a large conference room with other FQHC patients present. Online group sessions will be attended by study participants and the CHW(s). A study RA also may be present to assist with technical issues. Participant assessments will be completed in a private location at the FQHC or remotely via phone/video call or Zoom.

STUDY MEASURES

PATIENT MEASURES

Hemoglobin A1c (HbA1c)

To test HbA1c, two drops of blood will be removed by fingerstick (fingerprick with a sterile lancet) at each time points This is the standard method used to obtain blood for this laboratory test at the recruitment clinic site. FQHC Research Assistants (RAs) will be trained by the FQHC Site Coordinator and PI on using safe and effective technique, and will be provided all necessary safety equipment (e.g., gloves, hand sanitizer).

In the event that study staff are unable to meet in person with patients to conduct laboratory and vital sign assessments, either of the following two methods will be used to conduct the assessments:

a) If the patient is due to receive an HbA1c test, blood pressure measurement, or weight measurement as part of their routine clinical care within the approved study window for their baseline or 6-month assessment, the results of the test may be recorded from the patient's electronic health record rather than obtained via a study-staff conducted assessment. When appropriate, CHWs may contact patients to ask if they can schedule a time for their provider-ordered clinical assessment or labs on a day that would ensure it occurs within the study assessment window. At that time, the CHW will remind the patient that they or their insurance may be billed for the clinic visit or blood draw because it is indicated as a part of their clinical care.

b) If the method described in (a) is not practical, patients will be sent supplies so that they can perform the fingerstick at home. If feasible, participants also will be asked to test their HbA1c themselves using a home-testing device (e.g. A1cNow Self Check, pts Diagnostics).

Systolic blood pressure (SBP)

Patient blood pressure will be measured by a trained staff member using an oscillometric upper arm blood pressure monitor and following American Heart Association guidelines[5]. Two readings will be taken 2-5 minutes apart, and the average of these 2 readings will be used as the measure of blood pressure. If blood pressure data cannot be obtained at a dedicated study visit, blood pressure values recorded in the clinic EMR closest to the target assessment date, but within 2 weeks before and after, will be used.

Extended data collection

Patients in both arms will have their FQHC electronic chart reviewed for diabetes-related visit, lab, and medication information for the period from 12 months prior to 24 months following their study enrollment date. This information will be used to follow-up on possible missing data, and to offer future extended studies to this cohort.

Health behaviors and psychosocial behavior determinants

Health behaviors and psychosocial behavior determinants will be measured via self-report survey instruments. Surveys will be read aloud by a study RA in the participant's preferred language either in-person or by phone, and responses will be recorded by the RA. Select patient survey measures are presented in Table 1. All Spanish-language surveys were professionally translated.

Table 1. Select patient measures

MEASURE	CONCEPT CATEGORY	INSTRUMENT	BL	6M	12M[a]
Depression & anxiety symptoms	MHG	Patient Health Questionnaire (PHQ-4)(1)	X	X	
Self-rated health status	MHG	Self-rated health question (SF-1)(2)	X	X	
Functional status	MHG	PROMIS Physical Function Short Form 4a(3)	X	X	
Diabetes Distress	PBD	Problem Areas in Diabetes (PAID) - 5 for People with Diabetes(4)	X	X	X
Patient Activation	PBD	Patient Activation Measure -10 (PAM)(5)	X	X	X
Diabetes self-efficacy	PBD	Self-Efficacy for Managing Chronic Diseases Scale(6,7)	X	X	X
Goal setting behavior	PBD	Adapted from Patient Assessment of Chronic Illness Care (PACIC) Goal setting subscale(8)	X	X	X
Patient Activation in Medical Visits	PEH	Perceived Efficacy in Patient-Physician Interactions scale (PEPPI)(9,10)	X	X	X
Health literacy	Education /literacy	Health Literacy Screening Questions(11)	X		
Importance of diabetes	Competing factors	Single item: I have more important things in my life to take care of than diabetes to take care of now. (5-point scale, 1-strongly disagree to 5-strongly agree)(12,13)	X	X	

[5] Chobanian AV, Bakris GL, Black HR, et al. Seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. Hypertension. 2003;42:1206-1252

MEASURE	CONCEPT CATEGORY	INSTRUMENT	BL	6M	12M[a]
Diabetes self-care behaviors **healthy eating** **physical activity** blood sugar testing foot care	SMB	Summary of Diabetes Self-Care Activities Measure (SDSCA)(14)	X	X	X
Medication adherence	SMB	Summary of Diabetes Self-Care Activities Measure (SDSCA)	X	X	X
Smoking - cut down/quit attempt	HB	Behavioral Risk Factor Surveillance System (BRFSS)(15)		X	X
Smoking status	HB	Global Adult Tobacco Survey (GATS)(16)	X	X	X
Smoking - # cigarettes/day	HB	Global Adult Tobacco Survey (GATS)	X	X	X
Patient's General Perceived Social Support	GSS	ENRICHD Social Support Instrument (ESSI)(17)	X	X	
Patient overall satisfaction with SP support for diabetes	PSP	Patient overall satisfaction with SP support items created for CO-IMPACT Study(18)[,b]	X	X	X
Patient perceived supportive vs. non-supportive SP behaviors	PSP		X	X	X
Autonomy support ("supportive behaviors")		Important Other Climate Questionnaire (IOCQ)(19)			
Non-supportive behaviors		3 items created for this study[c]			
SP Helps with Medical Visits	SPBA	Items created for CO-IMPACT Study(18)	X	X	X
SP Roles in Patient Diabetes Management Care	SPBA	Items created for CO-IMPACT Study(18)[,d]	X	X	X
Impact of COVID on ability to manage diabetes	COVID-19 impact	Single item created for study[e]		X	X

BL, baseline; 6M, 6-month follow up; 12M, 12 month follow up; CO-IMPACT; Caring Others Increasing Engagement in Patient Aligned Care Teams Study; ENRICHD, Enhancing Recovery in Coronary Heart Disease Study; GSS, general social support; HB, health behaviors; PBD, psychological behavior determinants; PEH, patient engagement in healthcare PSP, patient perceptions of SP help; SP, support person; SRBA, SP roles, behaviors and attitudes; SMB, self-management behaviors

Bold type, change in measure from baseline to 6-months will be examined as a secondary outcome (see Study Analysis Plan, SAP)

[a]Per the COVID-adapted protocol, 12-month assessments will be completed only if study timeline permits.

[b]Two items assessing patient's satisfaction with the support they receive from their SP and whether they feel like they would be worse off without their SP's help with their diabetes care

[c]Non-supportive behaviors will be assessed with 3 items structured similarly to the IOCQ items addressing SP irritation, criticism and argumentativeness.

[d]Example roles include suggesting questions prior to patients' health care appointments, accompanying the patient in the exam room, discussing the visit after it has ended

[e]"In the last six months, how have the COVID pandemic or social distancing rules affected your ability to manage your diabetes?" (5-point scale, 1-much harder to 5-much easier)

SUPPORT PERSON MEASURES

SP data will be measured via self-report survey, administered in-person or by phone by study RAs using the same method as patient surveys above, at baseline and 6-9 months post-baseline. Assessed constructs include psychological behavior determinants and SP roles in, behaviors relating to, and attitudes toward the patient's diabetes management. Select SP survey measures are presented in Table 2. As with the patient surveys, Spanish-language SP surveys were professionally translated.

Table 2. Select SP survey measures

MEASURE	CONCEPT CATEGORY	INSTRUMENT	BL	6M
Importance of diabetes	Competing factors	Single item: I have more important things in my life to take care of than helping <Patient> with their health care(5-point scale, 1-strongly disagree to 5-strongly agree)(12,13)	X	X
Self-efficacy for helping patient with diabetes	PBD	Self-Efficacy for Managing Chronic Diseases Scale (adapted for support person)(6,7)	X	X
Goal setting (help patient set goal)	SRBA	Adapted from Patient Assessment of Chronic Illness Care (PACIC) Goal setting subscale(8)	X	X
Supporter perception of patient empowerment	SRBA	DAWN Family Experience of Patient Involvement scale (DFEPI)(20)	X	X
Diabetes distress	SRBA	Problem Areas in Diabetes (PAID) - 5 for Family Members(4)	X	X
Caregiving burden	SP burden	DAWN Impact of Diabetes Profile - Family Members (DIDP-FM) plus additional question(20),[a]	X	X

BL, baseline; 6M, 6-month follow up; PBD, psychological behavior determinants; SP, support person; SRBA, SP roles, behaviors and attitudes
Bold typeface, measure will be examined as a secondary outcome (See Study Analysis Plan, SAP)
[a]In the last 6 months, how much of a burden has it been for you to help [Patient] manage their diabetes? (5-point scale: 1-very large burden to 5-no burden)

STATISTICAL CONSIDERATIONS

See Study Analysis Plan (SAP)

RISKS

POTENTIAL RISKS INVOLVED IN THIS STUDY

- Questionnaire assessments and collection of medical record information pose a risk for breach of confidentiality.
- Audiotaping of selected study procedures for fidelity monitoring purposes: it is possible that some participants may find being interviewed or audiotaped is stressful, and there is also a risk for breach of confidentiality.
- Fingersticks for HbA1c (FQHC Patients)
    - Patients may find these tests are uncomfortable, but the pain is typically minor and brief.
    - In about 10% of the cases, a small amount of bleeding under the skin will produce a bruise (hematoma). In rare cases, a small scar may persist for several weeks.
    - The risk of local infection is less than 1 in 1,000.

- Research assessments pose a small risk that patients will regret sharing certain medical or personal information with their SP. Rare risk of breach of confidentiality by the patient's medical providers beyond what the patient authorized.
- If patients choose to set goals to monitor blood pressure levels more frequently or adhere to prescribed blood pressure medication regimens more stringently, there is a small risk of symptomatic hypertension (high blood pressure). High blood pressure symptoms can include: headaches, blurry vision, increased fatigue, chest pain, irregular heartbeat, and blurry vision.
- If patients choose to set goals to monitor blood pressure levels more frequently or adhere to prescribed blood pressure medication regimens more stringently, there is a small risk of symptomatic hypotension (low blood pressure). Low blood pressure symptoms can include: temporarily at levels that are too low, feeling light-headed, dizzy, sweaty, and rarely have minor confusion.
- If patients choose to monitor blood sugar levels more frequently, adhere to prescribed diabetes medication regimens more stringently, or make changes to eating or activity habits, there is a small risk of symptomatic hyperglycemia (high blood sugars). High blood sugars symptoms can include: headaches, blurry vision, increased fatigue, chest pain, difficulty breathing and irregular heartbeat.
- If patients choose to set goals to monitor blood sugar levels more frequently, adhere to prescribed diabetes medication regimens more stringently, or make changes to eating or activity habits, there is a small risk of symptomatic hypoglycemia (low blood sugars). Low blood sugar symptoms can include: feeling lightheaded, dizzy, sweaty, and rarely have minor confusion.

STEPS THAT WILL BE TAKEN TO PREVENT OR TO MINIMIZE THE SEVERITY OF THE POTENTIAL RISKS

Breach of confidentiality

The study team will follow all Data Safety and Monitoring procedures in place at the FQHC and within the University of Pittsburgh data center. Data will be monitored by the University of Pittsburgh data center to assure confidentiality.

Fingerstick testing risks

FQHC. RAs (RAs) will be thoroughly trained in the procedure and will use appropriate safety equipment available for this level of blood testing (gloves, sterile lancets, use of topical germicide on patient's skin, biohazard box, etc.). Any unexpected events related to fingersticks that do occur will be reported first to clinicians at the local site and then to the study Principal Investigator. Patients who have had an HbA1c test performed at their local site as part of routine care in a two-week window prior to a study assessment will not be asked to repeat it for the assessment.

Home testing. Patients will receive an information sheet along with their home testing supplies that includes instructions on how to perform the home-testing and what safety measure should be taken. The RA will remind patients to use proper precautions to reduce risk of infection while walking them through the testing procedure.

Survey and interview assessment burden

FQHC patients and SP will be informed as part of their informed consent process and immediately prior to each interview that they can drop out of the study at any time and that they can refuse to answer any of the individual questions in the assessments.

Most of our assessment procedures have been pre-tested and validated by other researchers, which suggests that they are well tolerated by respondents. Moreover, we have pre-tested almost every item through previous large trials involving patients with diabetes or heart disease, some with SPs.

Audiotapes

FQHC research participants will be informed that they can refuse to be audiotaped, or stop audiotaping, at any time without affecting their participation in the study. Audiotape filed will be marked with Study IDs only, and will be destroyed immediately after internal fidelity review by authorized study staff. Tapes will not be transcribed.

Weight measurement

Weight measurements will be taken in a private area where only the participant and research staff member can view the result. FQHC research staff will be trained to respond professionally and with positive encouragement to weight measurement results.

Privacy and confidentiality[6]

Rigorous privacy and data security measures will be put in place to minimize the risk of breach of confidentiality. The rigorous privacy steps to maintain privacy and confidentiality are described in detail below:

It will be made clear to participants that no information gathered through study assessments will be shared with participants' clinicians unless the patient appears to be in danger (in cases of suicidality, for example) and Dr. Rosland (PI) or Dr. Valbuena (Site-PI) deems it necessary to contact the participant's physician. Electronic assessment data and analytic files will be maintained on secure servers that are protected in accordance with the University of Pittsburgh data security requirements. Only approved research personnel will have access to study files. Research data will be presented in aggregate statistics only. Throughout the study, IRB and HIPAA guidelines will be followed to ensure the privacy and integrity of the information we collect. All study personnel will complete training in maintaining patient confidentiality and will sign a written statement indicating that they will preserve the confidentiality of patient records as a condition of their employment. Any breach of confidentiality will be immediately reported to the PI and to the IRBs. In addition, any complaints or concerns expressed to the study staff by participants, providers, or anyone else affected by this study will be immediately reported to the PI and to the IRBs.

All surveys and interviews will be conducted in-person or from a private office with a closed door. To minimize the risk of loss of confidentiality, there will be no personally identifying data on survey assessments. Paper copies of all consent forms will be kept in a locked filing cabinet at the FQHC. We will create a secure electronic tracking file that maps the subject's identifying information to the arbitrary study identifier, which will serve as the participant's primary identifier for all analytic files. Survey assessments will be conducted in person for all patients and responses will be entered into the database thru tablets as the interview is being conducted. The SP surveys may be done over the telephone or in-person, depending on the SP's needs. All survey assessments will be available on paper as a backup in case electronic systems are not accessible or need to be completed over the telephone. If a paper survey assessment is used, it will contain the participant's study ID but no identifying information, and be stored in a locked filing cabinet until the data is double entered into the electronic study database.

After the required data retention period, all personal identifiers will be removed from the data and linkage codes will be destroyed. The resulting de-identified data will be maintained in secure University of Pittsburgh server storage.

Patient-SP relationship

We will reduce the risk of patient-SP conflicts through several strategies. These include the following: We specifically structure the SP's role as assistive to the patient. This is conveyed repeatedly in study contacts. For example, SPs are instructed to discuss any concerns with patients in a non-judgmental manner and to offer choices. They are instructed to encourage the patient to be the main contact for the patient's health care providers whenever possible. Our

[6] Enrolled FQHC patients will be asked about ways family members and friends help or hinder their health management in general. Enrolled FQHC patients will be asked for more detailed information about the SP who is also a consented and enrolled study participant. The participant's descriptions of how third parties interact with the participant around diabetes and health management will be collected and recorded. The third parties will not be identified by name.

previous study experiences suggest that under these arrangements, patients welcome the supporter person's instrumental and emotional support.

Clear and redundant presentation through printed participant guidelines for patients and support people to structure their roles encourage effective communication. This information is repeated in smaller chunks throughout the study timeline, both per the schedule and in response to study events.

FQHC CHWs will be trained to detect possible signs of conflict during their contacts with participants and their scripts will include a range of responses and guidance on selecting the appropriate response. All participants can also spontaneously report a concern by calling the FQHC staff.

Conflict resolution strategies range in intensity from tailored CHW messages to the involvement of a site clinical health psychologist, and to termination of participation if necessary to protect participants from distress.

FQHC patients' willingness to share their health information with their SP will be explicitly confirmed in their written consent. We will thoroughly explain to patients the type of information that will be included in CHW contacts with SPs. To minimize the risk of patient regret oversharing health information, we are stipulating that the SP should be someone who is already regularly involved in the patient's health care. No information will be shared with a SP before it is shared directly with the patient. In addition, only information that is directly related to diabetes management and management of risk of diabetes complications will be included in written or oral communications with the SPs. Thus, information shared with the SPs will exclude information on potentially sensitive topics, such as psychiatric care or sexual health. The FQHC CHW will be thoroughly trained by the PI in protocols for reviewing diabetes-relevant data from the medical record prior to each phone call to a patient. The review process will be tested prior to intervention start and monitored by the PI throughout the intervention through a random sample of documents (sampled more frequently at the beginning of the study). Patients and SPs will be reminded at every study contact that they can decline participation at any time and that the patient can terminate their SP's participation in care at any time.

SP caregiving burden

Prior studies involving chronically ill patients and already-involved supporters show that caregiver burden does not increase, and often decreases, following this type of intervention. We will include reminders in SP contacts that they can call the FQHC study staff they are experiencing increased caregiving related stress or burden.

Hypoglycemia or hypotension

Alternatives: Patients may choose not to take steps that will lower their sugar or blood pressure levels. Precautions: Patients will be advised to make small changes in their self-care regimens over time and not large changes at once. They will also be advised to discuss any changes in medication regimen or physical activity routines with their healthcare providers before proceeding. All those participating in intervention sessions will be trained on how to recognize common symptoms of hypoglycemia and hypotension, and how to self-treat minor episodes. We expect that SPs in Program B (Family-Focused) will become more skilled at recognizing and managing hypoglycemia and hypotension. Safeguards: Participants will be advised to notify their healthcare providers if experiencing these effects more than once, and they will be advised to seek emergency care for severe symptoms.

Hyperglycemia or hypertension

Alternatives: Patients may choose not to take steps that increase their sugar or blood pressure levels. Precautions: Patients will be advised to make small changes in their self-care regimens over time and not large changes at once. They will also be advised to discuss any changes in medication regimen or physical activity routines with their site healthcare providers before proceeding. All those participating in intervention sessions will be trained on how to recognize common symptoms of hyperglycemia and hypertension and how to self-treat minor episodes. We expect that SPs (FAM-ACT) will become more skilled at recognizing and managing hyperglycemia and hypertension. Safeguards: Participants will be advised to notify their health care providers if experiencing these effects more than once, and they will be advised to seek emergency care for severe symptoms.

Steps that will be taken in the event that a clinically significant, unexpected disease or condition is identified during the conduct of the study include the following.

- The study Principal Investigator (Dr. Ann-Marie Rosland), Pittsburgh Project Coordinator, FQHC Site PI (Dr. Felix Valbuena), and the FQHC Site Coordinator/CHW Manager will be notified.
- FQHC patients will be referred to their healthcare provider at their local site, or to emergency medical services, if appropriate. FQHC study staff will offer to directly contact the participant's local healthcare providers with the patient's permission.
- SPs will be advised to contact their own healthcare provider, or referred to emergency medical services if appropriate.

If a SP shows/expresses signs of suicide, the FQHC research team will follow the FAM-ACT SP Suicide Protocol attached in the appendices and supporting documents. This protocol is a clinically significant plan for an unexpected condition.

Individuals may choose to not be in the study and continue their current/usual FQHC care for diabetes.

Specific endpoints or other circumstances that will result in discontinuing a subject's participation

If study participants experience a significantly disabling health event (e.g. disabling stroke that makes continued participation difficult) they may be removed from active participation in the intervention but, if the participant does not elect to completely withdraw, they will still be retained in the study and contacted for planned study assessments and included in Intent To Treat study analyses. If FQHC patient-participants experience a significant separation in relationship with their SP (e.g. divorce from a spouse) the SP may be removed from active participation in the intervention, but, if the participants do not elect to completely end the SP's participation, the SP will be retained in the study and contacted for planned study assessments.

Any participant will be discontinued from study participation if they exhibit violent, threatening, or harassing behavior towards study or FQHC site staff. Any participant will be discontinued from study participation if they experience incarceration or are placed on parole during their participation period.

Female patients who become pregnant during study participation may be discontinued from the study and will be advised to seek medical advice regarding diabetes management during pregnancy with their usual healthcare provider as soon as possible.

BENEFITS

Participants may experience direct benefits from participation in this study. All patient and SPs may learn new information about diabetes symptoms, healthy behaviors, and self-care. In addition, FAM-ACT assigned participants may learn how SPs can effectively support healthy behaviors and health care. This may improve the quality of patients' diabetes management and outcomes and may improve SPs' healthy behaviors and lower the risk of developing diabetes or diabetes complications (if the SP also has diabetes).

Because diabetes is prevalent in this community and results in substantial morbidity, health care utilization, and costs, we feel the study's potential benefits outweigh the low risk of minimal harm to participants.

Participants will be mailed a layperson-friendly summary of trial results from the trial after all main analyses have been completed.

DATA AND SAFETY MONITORING PLAN

Standardized clinical data collection protocols will be in place for the clinical trial as documented in study procedures documents. The PI, in collaboration with the Clinical Trials Coordinating Center (CCDC) at the University of Pittsburgh, will ensure that the study is conducted according to the protocol and will be responsible for carrying out the Data Safety and Monitoring Plan (DSMP).

Weekly study team meetings, monthly data review, and periodic site visits (approximately 4 per year) will be used to review that all data quality and IRB policies and procedures are being followed. This will include ensuring that (1) all participants understand, agree to, and sign a written consent form before participating; (2) strict adherence is maintained to communication regarding the participants' right to withdraw or refuse to answer questions; (3) staff maintain confidentiality both by protecting hard-copy and electronic data collection forms and by avoiding all unauthorized conversations about individual patients; (4) consent forms and identifying information are kept separately from study related information about patients' sociodemographics, clinical characteristics, disease self-care, service use, and outcomes; (5) all identifying information is kept locked at all times and sensitive computer files are maintained on a secured server; (6) coding of ambiguous responses is handled in a way that is consistent and clear across data collectors and over time; and (7) participants are informed in writing how to contact the study PI, study project coordinators (FQHC & University of Pittsburgh), and relevant IRB office with any questions or concerns.

The CCDC will use a web-based data entry and tracking system with password protection layers that will be used to restrict access to certain staff. The CCDC will incorporate clinical, data management, and statistical expertise in the creation of the data entry and tracking system, especially as it relates to the development of the case report forms. Key features of the data management and web design plan we will implement are described in subsequent sections.

DATA COLLECTION AND FORM DEVELOPMENT

Each case report form (CRF) will be developed by CCDC in conjunction with the clinical study team. In order to make sure that important study forms are not overlooked, CRFs will be considered across the following categories: 1) screening & baseline information; 2) follow up visits, tests, and procedures; 3) adherence to study treatment; 4) adverse experiences; 5) concomitant medications; 6) clinical endpoints; and 7) subject treatment, follow up, and vital status. This allows initial discussions on CRF development to center around each of the categories, and prevents particular forms from being missed.

The tracking system will generate a schedule of data collection for each participant and automatically send reminders to the clinical study coordinators when a data collection visit or call is due. The study staff will log into the data entry and tracking system, enter the participant's study ID, then choose the visit to be viewed; the appropriate set of forms will be generated for that participant based on the visit number. To minimize missing data, all of the study forms will have certain key fields that are required before form submission. Pop-up windows will also be used to remind the study coordinator or data entry personnel that particular fields are empty upon form submission and give reasons as to why incomplete data was submitted. Each CRF will be made available on the study website for review and download by study personnel at any time.

A subset of the CRFs will include the ability for the investigators to electronically "sign off" on the submitted information. These CRFs include those that are deemed critical (i.e. adverse events).

DATA ENTRY AT CLINICAL SITE

Data will be entered electronically via a password-protected Web-based data entry system, but paper versions of forms will be provided for manual entry in case of technical issues. The system will be created using ASP.NET programming, with the data stored using MS SQL Server. When the study coordinator logs in and enters the participant study ID for which data are being entered, the screens generated will match the paper form(s) most recently created for that study ID. The study staff will not be able to enter data for forms not generated for that study ID or visit. Similarly, the Web-based data entry screens will have out-of-range and other limits that will not permit the entry of inappropriate data.

PARTICIPANT ELIGIBILITY, & RANDOMIZATION

The data entry process will begin during the online participant enrollment into the clinical trial. The clinical site will have the ability to generate a participant ID upon initiation, which will unlock screening forms that will be completed to assess the study inclusion and exclusion criteria detailed in the protocol. The CCDC will utilize an "eligibility checklist" which is pre-populated with information from all questions that directly relate to inclusion and exclusion criteria. By not having a separate form with checkboxes for each criterion, this will prevent any data entry errors which may result in ineligible randomizations.

Once the eligibility criteria are met and confirmed, the clinical site will submit the randomization form for the subject, and the Web-based system will return the participant's study arm assignment (I-DSMES or FAM-ACT). Any information collected that identifies the participant will be deleted from the study database immediately after being reviewed by the CCDC coordinator or staff.

STUDY DESIGN TRACKING

The CCDC tracking and reporting systems are integrated within the web-based data management. The tracking system will include programmed follow-up time periods to ascertain which subjects are due for what milestone visit or contact. In addition, a calendar will be created to facilitate scheduling of follow-up visits. The customized tracking system will be used to generate reports to monitor study progress and for presentation at Investigator meetings. These reports will include detailed recruitment numbers, serious adverse events (SAEs), and outstanding forms.

DATA QUALITY CONTROL

The CCDC has several systems programmers and data managers who will design and maintain the data entry/checking programs as well as maintain the databases, generate reports, and provide long-distance support for data entry personnel. In addition, appropriate documentation and other training materials will be made available on the study website for data entry personnel. If necessary, a system programmer will visit study personnel in person to resolve problems not easily addressed on the phone or via remote monitoring methods.

During data entry, a number of strategies will be employed to ensure quality of data: use of standard methods of data collection and recording already specified in study protocols, careful programming of the data management system, detailed documentation of computer operations and data editing procedures, and regular meetings with project staff to review any changes in procedure. The CCDC will verify all data, program out-of-range data checks into data entry fields, and evaluate the full data process within and across forms. A typical variable may be subjected to two kinds of range checking: impossible values (e.g., negative blood pressure) and suspicious values (e.g., SBP > 300). The former will be coded into the data entry system, restricting such values from being entered. CCDC personnel will check suspicious values from the enrollment of the first participant to the data-cleaning phase, at which point logical checks will be performed, and outliers will be analyzed. The CCDC will also utilize centralized statistical monitoring, which provides an efficient and cost-effect alternative to on-site visits.

Audit logs track changes to information previously submitted and recorded on electronic forms and will be used to ensure data integrity. Information on the person responsible for the change, the date of the change, the previous entry in the data field, the new entry in the data field, and the reason for the change are recorded and displayed in the electronic forms audit trail.

DATA & SAFETY MONITORING

The CCDC will work with the clinical investigators to develop and formalize a data & safety monitoring plan for the study which will include specifics for a site initiation visit, interim monitoring visits, for-cause visits (if necessary), and close-out visit. Due to the nature of the intervention, we anticipate this can be done remotely rather than on-site. Our risk-based monitoring plan will focus on:

- Eligibility confirmation: The FQHC RA, FQHC CHW, or FQHC Site Coordinator will review all screening-related CRFs and confirm eligibility with electronic signature prior to randomization.
- Consent monitoring: the clinical site will be able to upload signed participant consents to a secure repository, where the CCDC coordinator will be able to monitor them in real time.
- Complete ascertainment of primary and key secondary outcomes: The CCDC coordinator will be notified in real time if there are instances of missing outcomes, which will allow the coordinator to query the clinical site and resolve the issue.
- Serious adverse events and protocol violations: The CCDC coordinator is notified of all SAEs and protocol violations as they occur.

The FQHC clinic Site Coordinator will be able to upload source data to the study website, where a CCDC coordinator will be able to complete a full review of source data verification of critical elements as well as regulatory documents; and participant informed consents. At the conclusion of the audit, a summary of the site visit findings will be discussed with the PI, the Site PI and study personnel. A detailed summary report will document the audit findings and can be supplied to the Study Investigators, NIDDK program staff, and the study personnel. This information will also be kept in the electronic regulatory management system.

Protocol alerts

In addition, the CCDC will work with the clinical team to define "protocol alerts" for the study. This would include email notifications for the following situations: a participant meeting enrollment criteria, a form or set of forms that need to be electronically signed by the Site PI, submission of SAEs, submission of protocol deviations, and other safety issues such as death. In addition, alert values for blood pressures and symptoms will be established. The study staff will notify the Site Coordinator, the subject, and, for FQHC patients the subject's physician whenever there are results outside of these values because of the clinical implications of a value substantially out of normal range. Outstanding protocol alerts will be reviewed on a monthly basis with the PI.

Serious adverse events

FQHC RAs conducting assessments and the FQHC CHWs implementing the intervention will follow a strict protocol that includes immediate reporting of adverse events and potential problems. Additionally, a section of the informed consent document that will be given to each participant will provide contact information for both the Principal Investigator and the University of Pittsburgh IRB to facilitate self-report of adverse events. The CCDC will notify the appropriate entities (i.e., Pittsburgh IRB, NIDDK) regarding all study-related serious adverse events within reporting guidelines listed in the study protocol. The CCDC will categorize all SAEs according to the NCIs Common Terminology Criteria for Adverse Events (CTCAE). A designated safety monitor (the PI or Site-PI) will be tasked with adjudicating all SAEs with the aid of discharge summaries uploaded to the web-based data management system. On a monthly basis, SAEs will be reviewed by the Principal Investigator. In addition, we will compile a comprehensive annual report detailing all study-wide serious adverse events, including those events that are study related and those unrelated to study participation. Additionally, site-specific SAE summary reports will be created for each site's local IRB annual renewal submission, which will also be included on the electronic regulatory management system.

Should new information become available during the course of this research that may indicate that the risks of harm to participants have significantly increased, the PI will inform participants, so they may reconsider their willingness to stay in the study.

Data management, security, and confidentiality

The EWI (Enterprise Web Infrastructure) is backed up with the Symantec NetBackup system. The backup images are processed through an IBM ProtectTier appliance and stored on IBM DS8870 storage arrays. All EWI servers get a daily operating system backup in the form of a full or differential backup. The backup schedule has daily differential and bi-weekly full backups for all EWI servers. The backup images have a retention period of 60 days. They are replicated to a secondary IBM DS8870 storage array located at a designated site at the study Coordinating Center. This protects the backup images in the event of a catastrophic event at the RIDC data center.

EWI sites with a backend database server also receive a daily backup. All EWI database servers have a daily full backup and daily log backups. EWI database servers running MS SQL Server utilize a specialized NetBackup SQL backup agent. Any EWI database server running MySQL have a daily backup in the form of daily local dump and then have the exported database files backed up during the daily operating system backup. These again are replicated to the aforementioned University of Pittsburgh site. The backup methods used are proven methods for recovery. Partial file restores and full site restores have been performed upon a request from a department.

The CCDC will use resources from the University of Pittsburgh Center for Research on Health Care Data Center which is complaint with the FDA 21 CFR part 11 protocols. Access to data will be controlled through password and authentication policies. Only approved individuals will have access to data. Password policies control the length and

variability of the user password selection. Audit trails will be implemented to log date, time, individual, changed values, and rationale for all data changes.

PARTICIPANT PRIVACY

It will be made clear to participants that no information gathered through study assessments will be shared with participants' healthcare providers unless the patient appears to be in danger (in cases of suicidality, for example) and Dr. Rosland (PI) or Dr. Valbuena (Site-PI) deems it necessary to contact the participant's physician. Electronic assessment data and analytic files will be maintained on secure servers that are protected in accordance with the University of Pittsburgh data security requirements. Only approved research personnel will have access to study files. Research data will be presented in aggregate statistics only.

Throughout the study, IRB and HIPAA guidelines will be followed to ensure the privacy and integrity of the information we collect. All study personnel will complete training in maintaining patient confidentiality and will sign a written statement indicating that they will preserve the confidentiality of patient records as a condition of their employment. Any breach of confidentiality will be immediately reported to the PI and to the IRBs. In addition, any complaints or concerns expressed to the study staff by participants, providers, or anyone else affected by this study will be immediately reported to the PI and to the IRB.

All surveys and interviews will be conducted in-person or from a private office with a closed door. To minimize the risk of loss of confidentiality, there will be no personally identifying data on survey assessments.

CONFIDENTIALITY AND ACCESS TO DATA

Access to the study data includes authorized representatives of the sponsor of the study, National Institutes of Health or authorized representatives that they delegate, such as representatives from monitoring or auditing companies. Investigators will have access to data/samples for purposes of conducting this research study. De-identified data may be shared with investigators conducting other research.

After the required data retention period, all personal identifiers will be removed from the data and linkage codes will destroyed. The resulting de-identified data will be maintained in the secure University of Pittsburgh server.

STUDY WITHDRAWAL

No additional data will be collected on participants who provide informed consent but are later determined to be ineligible to participate, or on participants who withdraw from the study. A coded identifier will be added to a "do not contact" list maintained only for the duration of the recruitment phase in order to prevent such individuals from being re-solicited. Any research data already collected while the participant was a consented participant will be maintained according to overall study guidelines unless the participant requests that the data be removed and destroyed.

COMPENSATION/PARTICIPANT PAYMENT

FQHC patients will receive a $50 incentive for each completed assessment, and SPs will receive a $25 incentive for each completed assessment. Patients who complete a 12-month assessment will receive an additional $30. There will not be a partial payment offered for partially completed assessments. All research study participants must complete the assessment to their fullest ability to receive their full payment at that time point.

In recognition of the time and contribution of those patients completing the COVID-19 survey as a phone call separate from other study surveys, we will select at random 3 participants to receive a $50 gift card.

TABLE OF REFERENCES

1. Kroenke K, Spitzer R, Williams J, Lowe B. An ultra-brief screening scale for anxiety and depression: The PHQ–4. Psychosomatics. 2009;50(6):613–21.

2. Ware JE. How to score and interpret single-item health status measures: a manual for users of the of the SF-8 health survey:(with a supplement on the SF-6 health survey). QualityMetric, Incorporated; 2001.

3. Dewitt B, Feeny D, Fischhoff B, Cella D, Hays RD, Hess R, et al. Estimation of a preference-based summary score for the Patient-Reported Outcomes Measurement Information System: The PROMIS®-Preference (PROPr) Scoring System. Med Decis Making. 2018 Aug;38(6):683–98.

4. McGuire BE, Morrison TG, Hermanns N, Skovlund S, Eldrup E, Gagliardino J, et al. Short-form measures of diabetes-related emotional distress: the Problem Areas in Diabetes Scale (PAID)-5 and PAID-1. Diabetologia. 2010 Jan;53(1):66–9.

5. Hibbard JH, Stockard J, Mahoney ER, Tusler M. Development of the Patient Activation Measure (PAM): conceptualizing and measuring activation in patients and consumers. Health Serv Res. 2004 Aug;39(4 Pt 1):1005–26.

6. Lorig K, Stewart A, Ritter P, Gonazalez V, Laurent D, Lynch J. Outcomes Measures for Health Education and other Health Care Interventions. Thousand Oaks, CA: Sage Publications; 1996.

7. Bodenheimer T, Lorig K, Holman H, Grumbach K. Patient self-management of chronic disease in primary care. JAMA. 2002 Nov 20;288(19):2469–75.

8. Glasgow RE, Wagner EH, Schaefer J, Mahoney LD, Reid RJ, Greene SM. Development and validation of the Patient Assessment of Chronic Illness Care (PACIC). Med Care. 2005 May;43(5):436–44.

9. Maly RC, Frank JC, Marshall GN, Robin M, Reuben DB. Perceived Efficacy in Patient–Physician Interactions (PEPPI): Validation of an instrument in older persons. Journal of the American Geriatrics Society. 1998;46(7):889–94.

10. ten Klooster PM, Oostveen JC, Zandbelt LC, Taal E, Drossaert CH, Harmsen EJ, et al. Further validation of the 5-item Perceived Efficacy in Patient-Physician Interactions (PEPPI-5) scale in patients with osteoarthritis. Patient Education and Counseling. 2012 Apr;87:125–30.

11. Chew LD, Bradley KA, Boyko EJ. Brief questions to identify patients with inadequate health literacy. Family Medicine. 2004;36(8):588–94.

12. Kerr EA, Heisler M, Krein SL, Kabeto M, Langa KM, Weir D, et al. Beyond comorbidity counts: how do comorbidity type and severity influence diabetes patients' treatment priorities and self-management?[see comment]. Journal of General Internal Medicine. 2007;22(12):1635–40.

13. Zulman DM, Rosland AM, Choi H, Langa KM, Heisler M. The influence of diabetes psychosocial attributes and self-management practices on change in diabetes status. Patient Educ Couns. 2012 Apr;87(1):74–80.

14. Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. Diabetes Care. 2000 Jul;23(7):943–50.

15. Behavioral Risk Factor Surveillance System Survey Questionnaire. Centers for Disease Control and Prevention (CDC); 2003.

16. Global Adult Tobacco Survey Collaborative Group. Tobacco Questions for Surveys: A Subset of Key Questions from the Global Adult Tobacco Survey (GATS). Centers for Disease Control and Prevention (CDC); 2011.

17. Mitchell PH, Powell L, Blumenthal J, Norten J, Ironson G, Pitula CR, et al. A short social support measure for patients recovering from myocardial infarction: the enchrid social support inventory. Journal of Cardiopulmonary Rehabilitation. 2003 Nov;23(6):398–403.

18. Rosland AM, Piette JD, Trivedi R, Lee A, Stoll S, Youk A, et al. Effectiveness of a health coaching intervention for patient-family dyads to improve outcomes among adults with diabetes: a randomized clinical trial. ePublished before print. JAMA Netw Open. 2022;

19. Williams G, Lynch M, Ryan R, Sharp D, Deci E. Validation of the important other climate questionnaire: Assessing autonomy support for health-related change. Families, Systems, & Health. 2006;24(2):179–94.

20. Kovacs Burns K, Nicolucci A, Holt RIG, Willaing I, Hermanns N, Kalra S, et al. Diabetes Attitudes, Wishes and Needs second study (DAWN2™): Cross-national benchmarking indicators for family members living with people with diabetes. Diabet Med. 2013 Jul 1;30(7):778–88.

APPENDICES & SUPPORTING DOCUMENTATION

APPENDIX 1. COVID-19 PANDEMIC RELATED PROTOCOL ADAPTATIONS

The table below summarizes adaptations made to the FAM-ACT study protocol to accommodate restrictions on research recruitment and conduct during the COVID-19 pandemic. For additional detail on these adaptations see our 2022 publication in *Trials*:

Deverts DJ, Heisler M, Kieffer EC, Piatt GA, Valbuena F, Yabes JG, Guajardo C, Ilarraza-Montalvo D, Palmisano G, Koerbel G, Rosland AM. Comparing the effectiveness of Family Support for Health Action (FAM-ACT) with traditional community health worker-led interventions to improve adult diabetes management and outcomes: study protocol for a randomized controlled trial. Trials. 2022 Dec;23(1):1-22.

ORIGINAL PROTOCOL	ADAPTED PROTOCOL
ELIGIBILITY CRITERIA	
The study planned to examine 5-year diabetes-specific cardiac risk (UK Prospective Diabetes Study [UKPDS] score) as a secondary outcome. Thus, adults with diabetes were eligible to participate if (a) their most recent HbA1c is ≥8.0% and/or (b) have poor blood pressure control (SBP >150mm Hg), recorded in the FQHC EMR at least twice in the past 6 months, with the most recent SBP being >150mm Hg.	Because UKPDS score was dropped as an outcome (see Outcomes/Secondary outcomes), poor blood pressure control no longer is being used as an inclusion criterion, thus requiring all patient participants to qualify based on their HbA1c. Eliminating the blood pressure criterion effectively reduces the size of our eligible patient pool. To compensate for this limitation, the HbA1c criterion has been lowered to ≥7.5%.
LENGTH OF INTERVENTION PROTOCOL	
Both the FAM-ACT and I-DSMES interventions were designed to last 12 months, with the introductory and DSMES sessions completed during the first 6 months of the protocol, and CHW care management contacts continuing throughout the subsequent 6 months. Most study contacts occurred in the first 6 months of the 12-month period.	The intervention has been condensed to 6 months to compensate for (a) the several-month pandemic-related pause in research recruitment and (b) the additional time needed to make substantial changes to the study and intervention. The shorter protocol permits full sample recruitment, with time to complete the protocol, within the timeframe of study funding.
INTRODUCTORY AND DSME SESSION DELIVERY	
Intervention sessions were designed to be delivered in-person at the FQHC, with each session lasting 1.5 to 2 hours. Conducting the group sessions in-person enables the CHW to use the ADA-approved DSMES Conversation Maps® and other visual aids. This hands-on approach is designed to encourage participant engagement with the material and give participants an opportunity to interact with other patients with diabetes. The face-to-face setting also facilitates communication and relationship-building between participants and the CHW.	To accommodate restrictions on in-person and group contact during the height of the pandemic, introductory sessions and DSMES sessions for both interventions have been redesigned for virtual platform delivery (Zoom). Several changes were made to both the structure and content of the sessions, including reducing the duration of the sessions to 45-60 minutes, replacing the DSMES Conversation Maps® with online PowerPoint slides and creating revised facilitator guides that are better suited to virtual delivery of the DSMES intervention.
BIWEEKLY CARE MANAGEMENT CONTACTS	
CHW contacts were designed to be delivered predominantly by phone or video chat, but also in-person at the FQHC during clinical visits, or at the participant's home if necessary.	To accommodate social distancing guidelines and participant and CHW health precautions, in-person care management contacts have been eliminated.

ORIGINAL PROTOCOL	ADAPTED PROTOCOL
PARTICIPANT MATERIALS	
Per the original procedure, the CHW was responsible for distributing workbooks and printed handouts. Workbooks were to be given to participants when they met with the CHW for the introductory session, and topical handouts were to be distributed during the relevant DSMES session.	To accommodate those who attend sessions virtually, patients now receive all educational materials at their baseline assessment. *FAM-ACT only*: If the patient and SP live together, the patient also is given the SP's materials. If they live separately, the RA will mail the SP their materials.
OUTCOMES	
Primary outcome: The original primary outcome was change in patient HbA1c from baseline to 12 months post-baseline, reflecting the original intervention length of 12 months.	**Primary outcome:** The primary outcome was revised to change in HbA1c from baseline to 6 months, reflecting the adapted intervention length of 6 months.
Secondary outcomes: The original analysis plan included 6-month and 12-month change in patient UKPDS score as a secondary outcome. The calculation of UKPDS score is based on HbA1c, SBP, cholesterol levels, and smoking status.	**Secondary outcomes:** Change in UKPDS score has been dropped as a secondary outcome because patient cholesterol cannot be measured reliably without in-person assessment. A substantial number of first wave patients became eligible for their 6-month assessment while restrictions on in-person research activities were in effect.
SAMPLE SIZE	
See analysis plan	
DATA COLLECTION	
HbA1c: Per the original protocol, patients were to have their HbA1c assessed at 3 time points: baseline, 5 to 7 months post-baseline and 11 to 13 months post-baseline. All assessments were to be conducted by study RAs using the fingerstick method described above.	**HbA1c:** To accommodate pandemic-related restrictions on in-person research activities, 2 additional HbA1c assessment methods have been incorporated into the protocol. *Clinic measures*. Tests unable to be obtained in-person during the assessment window will be recorded from patients' EMRs rather than obtained via a study staff-conducted assessment. *Home testing*. Patients may be offered the option to self-test their HbA1c using a fingerstick device (e.g. A1cNow® Self Check, pts Diagnostics) sent to their home.
Survey assessments: As part of the original protocol, SPs were to be assessed by survey at 2 timepoints: baseline and 11-13 months post-baseline.	**Survey assessments:** Because the duration of the study protocol was decreased from 12 to 6 months, SPs now will be surveyed at baseline and 6-9 months post-baseline.

CHW, community health worker; DSMES, diabetes self-management education and support; EMR, electronic medical record; FAM-ACT, Family Support for Health Action; FQHC, Federally Qualified Health Center; HbA1c, hemoglobin A1c; I-DSMES, individual patient-focused diabetes self-management education and support; SBP, systolic blood pressure; SP, support person; UKPDS, UK Prospective Diabetes Study

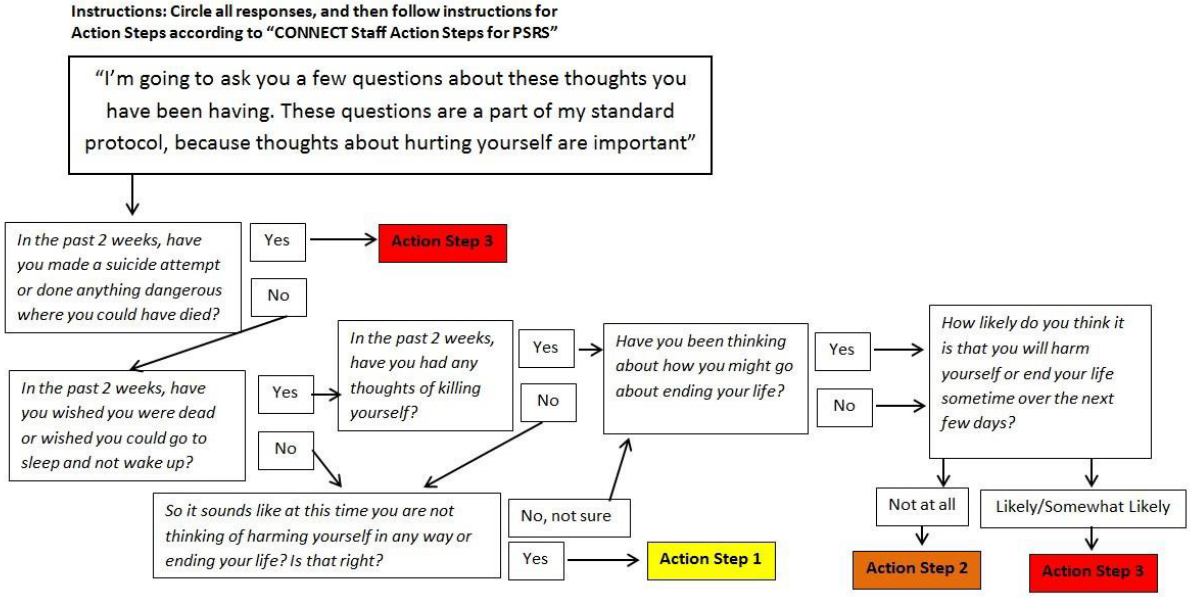
APPENDIX 2. FAM-ACT STUDY GUIDE TO SUICIDAL PARTICIPANTS

Suicidal Ideation: If a FAM-ACT participant volunteers information about suicidal ideation, like:

- I'd rather not be alive anymore
- I want to sleep and never wake up
- I can't take it anymore
- I don't know what I might do

The FQHC research study team member will complete the *Participant Suicide Risk Screening Questions* on the next page, and follow the instructions for the correct action step.

Participant Suicide Risk Screening Questions:



Action Step 1:

In-Person or on the telephone:

If the respondent reports NO active suicidal thoughts, plans, or intent, reply to the patients with the following bullets, and continue the study:

- Thank you for your responses. I am glad that you are not thinking of harming yourself. Any thoughts that you would be better off dead are worrisome and I strongly suggest that you talk with your regular mental health professional or doctor about this soon.
- I would like to give you this list of Mental Health providers in case you may have these thoughts again.
- I would also like to give you the toll-free **National Suicide Prevention Lifeline: 1-800-273-8255.** The National Suicide Prevention Lifeline is a national network of local crisis centers that provides free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week. We're committed to improving crisis services and advancing suicide prevention by empowering individuals, advancing professional best practices, and building awareness

Action Step 2:

In-Person or on the telephone:

If the respondent reports ANY active suicidal thoughts or plan but indicates that he/she has NO intent to act on those thoughts within the next few days, provide him/her with the same information provided in **Action Step 1.**

Action Step 3:

On-Site at FQHC:

If the respondent reports that it is either "somewhat likely" or "likely" that he or she will "harm himself (or herself) or end his (or her) life over the next few days," or engaged in suicidal or high-risk behavior, provide him/her with the following information:

- I am very concerned about your thoughts of harming yourself (or high-risk behavior) and I think it is very important that you speak with a mental health professional about these thoughts right away. What I would like for you to do now is talk with the FQHC mental health specialist currently here.

On the Telephone with the Participant or Off-Site:

If the respondent reports that it is either "somewhat likely" or "likely" that he or she will "harm himself (or herself) or end his (or her) life over the next few days," or engaged in suicidal or high-risk behavior, provide him/her with the following information:

Call the National Suicide Prevention Lifeline number together with the participant immediately: Lifeline: 1-800-273-8255

The National Suicide Prevention Lifeline is a national network of local crisis centers that provides free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week. We're committed to improving crisis services and advancing suicide prevention by empowering individuals, advancing professional best practices, and building awareness.

*If the participant is severely distressed and the FQHC Research Study Team Member feels the participant may hurt themselves imminently, they should call 911.