Using Digital Health, Financial Incentives, and Community Health Worker Support to Change Health Behavior

Study Protocol and Statistical Analysis Plan

NCT03939793

June 22, 2020

Protocol Details

Basic Info

Confirmation Number:	**dbhdjigf**
Protocol Number:	**832886**
Created By:	**HARTE, RORY**
Principal Investigator:	**KANGOVI, SHREYA**
Protocol Title:	**DFI CHW Engage Study**
Short Title:	**Engage Study**
Protocol Description:	**To test a hybrid intervention consisting of a digital health intervention coupled with financial incentives (DFI) combined with community health worker (CHW) support. The target population is low-income people with diabetes. Participants will be randomized to one of three arms: 1) DFI intervention, 2) hybrid DFI/CHW intervention, 3) usual care.**
Submission Type:	**Biomedical Research**
Application Type:	**EXPEDITED Category 6, Category 7 and Category 2**

Resubmission*
Yes

Hospital Sites
Will any research activities and/or services be conducted at a Penn Medicine affiliated hospital site?
No

Study Personnel

Principal Investigator

Name:	**KANGOVI, SHREYA**
Dept / School / Div:	**2100 - Health System**
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Address:	**423 Guardian Drive** **1233 Blockley Hall**
City State Zip:	**Philadelphia PA 19104-6021**
Phone:	**215-573-0295**
Fax:	**215-573-8779**
Pager:	
Email:	**shreya.kangovi@pennmedicine.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**
GCP Training Completed:	**No**
Training Expiration Date:	
Name of course completed :	

Disclosure of Significant Financial Interests*

Does any person who is responsible for the design, conduct, or reporting of this research protocol have a **FINANCIAL INTEREST**?

No

Penn Intellectual Property*

To the best of the Principal Investigator's knowledge, does this protocol involve the testing, development or evaluation of a drug, device, product, or other type of intellectual property (IP) that is owned by or assigned to the University of Pennsylvania? Please refer to the Patent and Tangible Research Property Policies and Procedures.

No

Certification

I have reviewed the *Financial Disclosure and Presumptively Prohibited Conflicts for Faculty Participating in Clinical Trials* and the *Financial Disclosure Policy for Research and Sponsored Projects* with all persons who are responsible for the design, conduct, or reporting of this research; and all required Disclosures have been attached to this application.

Yes

The following documents are currently attached to this item:

There are no documents attached for this item.

Biomedical Research

Clinical Trial*
Is this a clinical trial? Please note the following definition:Clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. See CFR 45.46.102(b)
Yes

If Yes, please be aware that for each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms. For more guidance, please see: https://irb.upenn.edu/homepage/how-to-submit/initial-submission/2018-common-rule. Please see: https://irb.upenn.edu/clinicaltrials for additional clinical trial requirements.

Investigator Initiated Trial*
Is this an investigator initiated trial? Please select "Yes" if ALL the following conditions are met:The research is subject to FDA regulations for human subjects research.The individual PI both initiates (plans and designs) and conducts an investigation and under whose immediate direction the investigational agent is administered or dispensed. The individual investigator has absolute responsibility and accountability and designs, conducts, monitors, manages the data, prepares reports and oversees all regulatory and ethical matters. See 21 CFR 312.3
No

Drugs or Devices*
Does this research study involve Drugs or Devices?
No

IND Exemption

For studies that fall under an IND exemption, please provide the number below

For studies including IND or IDE's, please provide the number(s) below

IDE Review*
NOTE: For research involving investigational devices, you are required to review the guidance on Managing Research Device Inventory. Consult the Penn Manual for Clinical Research: https://www.med.upenn.edu/pennmanual/secure/investigational-product-management-at-sites-not-using-investigational-drug-services-(ids).html Please check the box Yes if you have reviewed the guidance.
No

Research Device Management*
Please indicate how research device(s) will be managed.
Not Applicable (no investigational devices)

Drug, Herbal Product or Other Chemical Element Management *
Please indicate how drugs, herbal products or other chemical entities will be managed.
Not Applicable (no drugs, herbal products or other chemical entities)

Radiation Exposure*
Are research subjects receiving any radiation exposure solely because they are enrolled in this protocol? (e.g. X-rays, CT, Fluoroscopy, DEXA, pQCT, FDG, Tc-99m, etc.)?IF YES, the protocol must be approved by the RRSC (Radiation Research Safety Committee). Consult EHRS web site: www.ehrs.upenn.edu/protocols/radiohuman.html for more information.If you have questions, email jjesik@ehrs.upenn.edu or kavyap@upenn.eduIf your protocol includes Nuclear Medicine Procedures, the protocol must be reviewed by the Nuclear Med Operations Committee: https://redcap.link/NMOPS
No

Gene Transfer*
Does this research involve gene transfer (including all vectors) to human subjects? IF YES, the protocol must be approved by the Institutional Biosafety Committee. Consult EHRS web site: www.ehrs.upenn.edu/protocols/bio_humans.html for submission requirements If you have questions, call 215-898-4453. The protocol may also require review by the Senior Vice Provost for Research's Human Research Advisory Committee(HRAC). The IRB will notify the PI and study staff if this review is warranted.
No

Human Source Material*
Does this research include collection or use of human source material (i.e., human blood, blood products, tissues or body fluids)? IF YES, consult the EHRS web site: www.ehrs.upenn.edu/programs/bio/bbpathogens.html for information on OSHA Bloodborne Pathogens requirements (training, vaccination, work practices and Exposure Control Plan). If you have questions, call 215-898-4453.
Yes

Image Guided Biopsies*
Does the research involve imaging guided biopsy? IF YES, please contact the Clinical Imaging Core. See https://www.med.upenn.edu/cbi for more details. Any questions should be directed to the Director of Research Operations, Dept of Radiology, Kathleen Thomas.
No

Computerized Tomography (CT) Studies*
Does the protocol involve CT scans that are not considered standard of care and are being performed for research purposes?IF YES, complete the CACTIS Committee Application: https://is.gd/CACTIS and consult CACTIS website: http://www.uphs.upenn.edu/radiology/research/labs/cactis/ for application requirements.
No

CAMRIS and MRI Studies*
Is an MRI scan being performed for research only and NOT considered standard of care (example: specific scanner, parameters or solely for the purposes of research)?NOTE: Research/non-standard use of MRI may include but is not limited to any of the following: Situations in which MRI results may impact subjects current clinical care plan or treatment decisions, such as:The study requires a customized report with specifics regarding the study protocol (i.e., specific measurements or details); Introduction of a device of any kind during the MRI that is not used during a 'standard of care' type scan.Your MRI is not consistent with standard care time points for MRI imaging.Your MRI is not paid for by insurance.IF YES, consult CAMRIS website: https://www.med.upenn.edu/camris/application-and-faq.html for application requirements and required institutional consent form language.
No

Investigational Agent or Device within the Operating Room*
Does the research project involve the use of an investigational agent or device within the Operating Room?
No

Cancer Related research not being conducted by an NCI cooperative group*
Does this protocol involve cancer-related studies in any of the following categories? Therapeutic, Prevention, Supportive Care, Screening, Early Detection, or Diagnostic, Epidemiologic, Observational, Outcome, Ancillary or Correlative. For a description of these categories, see http://www.ctsrmc.org/submitting_a_protocol.php NCI Cooperative Groups are as follows:Alliance for Clinical Trials in OncologyNCI Clinical Trials Group (Canadian Cancer Society) (NCCTG)Children's Oncology Group (COG)NRG Oncology GroupECOG-ACRIN Cancer Research GroupSouthwest Oncology Group (SWOG) IF YES, the protocol must be submitted to the Cancer Center's Clinical Trials Scientific Review Committee for scientific review and approval prior to obtaining IRB approval. Consult the CTSRMC website: www.ctsrmc.org for application requirements
No

Processing of Materials*
Will the research involve processing (such as over encapsulating, or compounding)?
No

In-House Manufacturing of Materials*
Will the research involve processing (such as over encapsulating, or compounding)?
No

HIPAA / Protected Health Information
Does the research proposal involve accessing (viewing / using), collecting, or disclosing of protected health information (PHI) directly from participants or their medical or dental record for research purposes?
Yes

Indicate which item is provided with this submission:

Modified research informed consent document that incorporates HIPAA requirements

Cohort/data analysis tools used

Remote Study Visits
Does the research proposal involve conducting research visits remotely via any type of video conferencing software?
No

Remote Study Visits
Does the research proposal involve conducting research visits remotely via any type of video conferencing software?
No

CHPS Resources*
Does the research involve CHPS resources?
No

HUP Inpatient Nursing Resources
Does this research include an inpatient admission at HUP?
No

Pathology and Laboratory Medicine Resources*
Will samples be collected by hospital phlebotomy and/or processed or analyzed by any of the clinical laboratories of the University of Pennsylvania Health System?
Yes

Clinical Laboratory Services*
Will samples be collected by UPHS phlebotomy and/or analyzed by the hospital laboratory?
Yes

Anatomic Pathology Services*
Will tissue specimens (other than blood) be collected for clinical, diagnostic, or research purposes OR be processed through surgical pathology, cytopathology, neuropathology, or hematopathology?
No

Research Involves Apheresis, Cell Collection, and/or Blood Product Collection*
Does this research involve collection of blood products in the Penn Donor Center and/or the use of apheresis for treatment or collection of cells or other blood components?
No

Research involving blood transfusion or drug infusions*
Will your research involve blood transfusion or infusion of study drug in 3 Ravdin Apheresis Unit for research purposes?
No

Trial in Radiation Oncology
Is this research a prospective trial being done in Radiation Oncology, and if so, has this protocol been approved by the Radiation Oncology Protocol committee?
N/A

Study in Radiation Oncology
Is this research a retrospective study being done in Radiation Oncology, and if so, has this project been reviewed by the Radiation Oncology Clinical Research Group?
N/A

Use of UPHS services*
Does your study require the use of University of Pennsylvania Health System (UPHS) services, tests or procedures , whether considered routine care or strictly for research purposes? (UPHS includes all Penn hospitals and clinical practices, including the Clinical Care Associates network of community practices). Examples of UPHS services/tests/procedures includes the Clinical Translational Research Center (CTRC), laboratory tests, use of the pathology lab, cardiovascular imaging tests or radiology imaging tests (whether being billed via the Service Center or through UPHS), other diagnostic tests & procedures and associated professional services, etc.
Yes

Veteran's Affairs (VA) Patients or Subjects
Does your study involve data from Veteran's Affairs (VA) patients or subjects?
No

If yes, was this approved by the Philadelphia VA?

No

Out of State Research
Will any Penn personnel conduct any research activities outside of the State of Pennsylvania?
No

Research involving Virtua Health
Will any Penn personnel conduct any research activities at a Virtua Health site location, OR in collaboration with Virtua Health System personnel, OR using any Virtua Health System resources (e.g., medical records)?
No

Primary Focus*
Sociobehavioral (i.e. observational or interventional)

Protocol Interventions

x	**Sociobehavioral (i.e. cognitive or behavioral therapy)**
	Drug
	Device - therapeutic
	Device - diagnostic (assessing a device for sensitivity or specificity in disease diagnosis)
	Surgical
	Diagnostic test/procedure (research-related diagnostic test or procedure)
	Obtaining human tissue for basic research or biospecimen bank
x	**Survey instrument**
	None of the above

The following documents are currently attached to this item:

There are no documents attached for this item.

Sponsors

Department budget code

000 - 000 - 0 - 000000 - 0000 - 0000 - 0000

Funding Sponsors

Name:	**COMMONWEALTH FUND**
Type:	**UPENN Foundations**

Funding sponsors billing address
If you have selected a commercial or industry sponsor, please provide the appropriate address and contact information for the Sponsor for the purposes of billing for IRB review fees (initial review, continuing review and convened modification fees apply here). If the Sponsor is not industry/ commercial, this information is not necessary to provide with your application.

Funding sponsors gift
Is this research being funded by a philanthropic gift?
No

Regulatory Sponsor

IND/IDE Sponsor

none

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Industry Sponsor

None

Project Funding*
Is this project funded by or associated with a grant or contract?
Yes

Selected Proposals

Proposal No	**Title**
10070413	**Using Digital Health, Financial Incentives and Community Health Worker Support to Change Health E**

Sponsor Funding
Is this study funded by an industry sponsor?
No

Status of contract

The following documents are currently attached to this item:

There are no documents attached for this item.

Multi-Center Research

Penn as lead
1. Is this a multi-center study where Penn is serving as the Lead Site or the Penn PI is serving as the Lead Investigator?
No

Management of Information for Multi-Center Research

Penn irb of record
2. Is this a multi-center study where the Penn IRB will be asked to serve as the IRB of Record for other external study sites?
No

Other Sites

No other sites

Protocol

Abstract
Low-income Americans struggle to stay healthy in the face of real-life challenges such as housing insecurity or trauma. Two interventions show promise for promoting behavior change and improving health outcomes: digital health interventions coupled with financial incentives (DFI) and community health workers (CHWs). Yet, these interventions have limitations; DFI interventions have low uptake and high attrition among vulnerable populations, while CHW interventions are relatively resource intensive. We will conduct a 24-week randomized trial of a hybrid DFI/CHW intervention among a population of 150 low-income patients with diabetes. Participants will be randomized to one of three arms: 1) DFI intervention, 2) hybrid DFI/CHW intervention, 3) usual care. Participants assigned to DFI will receive a free wireless glucometer if they dont already have one and be eligible for a lottery incentive if they use their glucometer. Participants assigned to the hybrid DFI/CHW intervention will receive the same glucometer if they dont already have one and incentives. If they exhibit low adherence to self-monitoring or poor glucose control, they will also receive support from a CHW who would help patients to address underlying socioeconomic barriers and cope with setbacks. We hypothesize that compared to usual care and DFI alone, the hybrid intervention will lead to more glucose self-monitoring and greater improvements in glycosylated hemoglobin.

Objectives

Overall objectives
A trial of a hybrid DFI/CHW intervention that incorporates strategies for coping with failure among a population of low-income patients with diabetes. Diabetes is an ideal condition in which to test this innovative intervention; the challenges of carrying out healthy behaviors for patients with diabetes have been well described. In addition, the enormous public health and economic challenge of diabetes is concentrated among disadvantaged populations: 18% of African Americans and 16% of people without a high school education have diabetes. Finally, diabetes is a condition that is well-suited to the study of self-monitoring, which appears to be a key factor in behavior change: glucose self-monitoring improves

outcomes among insulin-requiring diabetics and glucometers are covered by Medicaid in all states. A diabetes-specific trial can provide valuable insights that can be extrapolated to other diseases. Digital health applications extend to monitoring of weight, medication adherence, physical activity, blood pressure and other conditions. IMPaCT is adaptable and has been tested across many diseases. If we establish the effectiveness of a hybrid DFI/CHW intervention in this population, we will be able to generalize the intervention more broadly to improve health among low-income patients. We will test an innovative hybrid of two of the most promising and synergistic approaches for improving health among low income people in a way that is guided by behavioral and social science. This study will provide new knowledge of the pathways to behavior change and has the potential to improve the health of low-income individuals.

Primary outcome variable(s)
Primary outcome: Adherence rate (constructed by summing the number of days in the study period that the glucometer was used divided by the total number of days in study period.)

Secondary outcome variable(s)
The secondary outcome measure will be change in glycosylated hemoglobin from baseline to 24 weeks follow-up assessment.

Background
In the 21st century, in the most developed country in the world, a black man living in poverty in Southwest Philadelphia dies of diabetes at the age of 45. He is not unique. Low-income Americans have higher rates of almost every disease and die 15 years sooner than wealthier counterparts who live just a few blocks away. Why and what can be done? Health and health inequity are heavily influenced by personal behaviors; staying healthy requires devoting energy and resources to performing certain behaviors (exercise, diet, medication adherence, etc.) and avoiding others (smoking, alcohol, etc.). Engaging in health-promoting behavior is challenging, especially in the face of socioeconomic barriers like food insecurity or joblessness. In essence, low-income individuals run a difficult race with a severe handicap. A conceptual framework is useful for understanding the hurdles that an individual must overcome in the path to healthy behavior. Figure 1 is a framework that draws from three evidence-based models for behavior-dependent outcomes: the Reasoned Action Approach, the Health Belief Model and the Transtheoretical Model (Stages of Change). For an individual to even intend to initiate a behavior, her attitudes, social norms, and self-efficacy must all fall in line. Once an individual intends to initiate a behavior, she can be thwarted by external barriers. If she manages to initiate a behavior, she will still require reinforcement in order to turn the behavior into a habit. Fortunately, there have been two categories of interventions that show promise for promoting behavior change and improving health outcomes: digital health interventions and community health workers (CHWs). Digital health interventions use computers, mobile phones or devices to encourage self-monitoring of health metrics like blood glucose or weight. By raising an individuals awareness of their metrics and attendant health risks, digital interventions can shift attitudes to promote healthy behavior (Figure 2A). Digital interventions can be augmented by behavioral economic engagement strategies such as lottery-based financial incentives, which serve to reinforce self-monitoring behavior so that it becomes a habit (Figure 2A). Our study team has run dozens of digital and financial incentives (DFI) interventions; these have significantly increased physical activity, improved glycemic control, smoking cessation rates, and helped people lose weight. The ongoing advances in technologies related to wearable tracking devices and point of-care testing are likely to fuel increasing interest in DFI interventions. Yet, recent meta-analyses show that these approaches are limited by low uptake and high levels of attrition over time. In one of our recent studies, the rate of adherence to daily glucose self-monitoring was only 60% over a 6-month period, even with the addition of lottery-based financial incentives. Increasing success rates, particularly among vulnerable populations, will likely require additional support to address underlying socioeconomic barriers that make it hard for low-income people to manage their health in the first place. Otherwise, struggling patients may find it self-defeating to monitor elevated sugars, weight or blood pressure without the necessary supports to correct them.15 Community health workers (CHWs) are trusted laypeople from the local community who can be hired and trained by healthcare organizations to support patients. Their shared identity with low-income patients allows CHWs to influence attitudes, shift social norms, bolster self-efficacy through strategies like motivational interviewing, and address socioeconomic barriers to healthy behaviors (Figure 2B). CHW interventions are increasingly being used to improve health in disadvantaged communities and can improve chronic disease outcomes, but often are disease-specific, difficult to scale across institutions or lacking in high-quality evidence. Our study team has developed a standardized, scalable CHW intervention called

IMPaCT, which has been tested in three randomized clinical trials and demonstrated to improve a range of outcomes including chronic disease control, mental health, access to care and quality of care while reducing total hospital days by 65%. Despite its effectiveness, like any intervention, IMPaCT does not work for all people. We recently conducted an in-depth process evaluation to understand factors contributing to non-response (defined as failure to improve chronic disease metrics such as glycemic control). We found, unsurprisingly, that all patients thought health behavior change was challenging and experienced set-backs. However, responders learned from these setbacks and increased their resolve, while non-responders became discouraged and shut down. These non-responders disengaged from their CHWs and also avoiding any self-monitoring that reminded them of their failure. Thus, we learned that in order to augment the effectiveness of IMPaCT -- and potentially other behavioral interventions including DFI interventions -- we would need to help patients cope with failure. A recent behavioral science experiment we conducted, has shown that walk test challenges can be helpful in predicting whether patients will be responders or non-responders. In summary, increasing healthy behaviors is challenging, particularly for low-income individuals who face socioeconomic challenges. DFI and CHW interventions can be effective, but have limitations. DFI interventions do little to address underlying socioeconomic challenges, and thus may have low uptake and high attrition among vulnerable populations. CHW interventions like IMPaCT can address these challenges, but are relatively resource intensive. Both DFI and CHW interventions may be less effective within a subgroup of people who are discouraged by failure.

Study Design

Phase*
Not applicable

Design
A blinded, 24-week trial of a hybrid DFI/CHW intervention among a population of low-income patients with poorly controlled diabetes. Participants would be randomized to one of three arms: 1) DFI intervention alone, 2) hybrid DFI/CHW intervention, 3) usual care. Participants assigned to the DFI alone arm would receive a free wireless glucometer if they dont already have one and be eligible for a lottery incentive if they use their glucometer. Participants assigned to the hybrid DFI/CHW intervention would receive the same glucometer if they dont already have one and lottery incentives. If, despite these strategies, they exhibited low adherence to self-monitoring or poor glucose control, they would also receive support from an IMPaCT CHW. The CHW support would incorporate two behavioral strategies which have been shown to help individuals cope with failure: positive affect induction and attribution retraining. Interventions: DFI Alone Arm: Participants will receive a free wireless glucometer if they dont already have one on the day of enrollment. To encourage habit formation, for the first 6 weeks of the trial, participants will be eligible for a daily lottery incentive for every day that they use their glucometer. We will use an approach similar to what we have used in prior DFI trials: the lottery will provide infrequent large payoffs (a 1 in 100 chance of a US$50 reward) and more frequent small payoffs (an 18 in 100 chance of a US $5 reward). The total average amount of financial incentives from these lotteries will be modest: an expected value of US$1.40 per day. Participants who draw the winning lottery number, but did not check their glucose the day prior will receive an automated text or e-mail message informing them what earnings they would have won had they used their glucometer. After 6 weeks, we will terminate the lottery but continue to monitor patients adherence to glucose self-monitoring. A clinician at the practice site will receive notifications if participants glucose is either extremely low or high (60 or 400 mg/dL). Participants with these readings will receive messages to contact their healthcare provider immediately. Hybrid DFI/CHW Arm: Participants in the hybrid intervention will receive a wireless glucometer if they dont already have one and financial incentives just as in the DFI intervention. However, any individuals who have low adherence (no self-monitoring) or elevated glucose readings (300 mg/dL) for 30% of days over any 2 week period in the first 12 weeks of the study will be assigned to receive ongoing CHW support for the duration of the 24-week study period (Figure 3). Based on prior studies, we estimate that 50% (25 of the 50 patients in to the hybrid intervention) will require support from a CHW. Once a CHW receives notification of a struggling patient, she will visit the patient at home within 1-2 days to initiate the IMPaCT intervention.

Study duration
Each participant will be in the study for 6 months. Due to the restrictions on in-person clinic visits due to COVID-19, follow-up study visits may need to be completed outside of the 6-month window (for collection of glucometer data and hemoglobin a1c values -- which cannot be obtained telephonically).

The intervention period of the study (during which patients may receive support from a CHW, and may participate in bi-directional texting) will be unchanged in duration.

Resources necessary for human research protection

Describe research staff and justify that the staff are adequate in number and qualifications to conduct the research. Describe how you will ensure that all staff assisting with the research are adequately informed about the protocol and their research related duties. Please allow adequate time for the researchers to conduct and complete the research. Please confirm that there are adequate facilities for the research.

Dr. Kangovi, the principal investigator (PI) of the proposed project, is a leading national expert on improving population health through community health workers (CHWs). She also has extensive experience with using mixed methods research to understand perspectives of low-income patients on health and health behaviors. Dr. Kangovi led the community-academic-health system team that designed the IMPaCT model. She has authored numerous scientific publications in publications such as NEJM, JAMA and Health Affairs and received over $20M in funding, including federal grants from the NIH to study health behavior, specifically how low-income patients respond to failed attempts at behavior change. Dr. Kangovi is the founding executive director of Penn Center for Community Health Workers, a national center of excellence dedicated to advancing health in low-income populations through effective CHW programs. Dr. Kangovi has experience with all the proposed methods, including adapting IMPaCT for use in new settings and developing behavioral interventions to support patients in coping with failure. In addition, Dr. Kangovi has worked previously with most members of the study team, including co-authorship of research papers. As PI, Dr. Kangovi will oversee the entire study and provide oversight for delivery of the CHW intervention. She will be responsible for the completion of all aspects of the study including data collection, analyses, presentations, manuscript development, and results dissemination. Dr. Judith Long is the Co-Director of the Center for Health Equity Research and Promotion (CHERP) at the Corporal Michael J. Cresenz VA Medical Center (CMCVAMC), and has been a core faculty member since CHERPs inception in 2001. Dr. Long has substantial administrative experience as the Chief of the Division of General Internal Medicine at the University of Pennsylvania (UPENN) Perelman School of Medicine. Her recent research focuses on interventions to reduce disparities in health using peer mentors, community health workers, and behavioral incentives. She has extensive experience directing clinical research trials to improve outcomes for patients with chronic diseases. She recently completed two randomized controlled trials (RCTs) of peer mentoring and financial incentives for adults with poorly controlled type 2 diabetes. With CEPACT support, she began investigating the long-term effectiveness of peer mentoring and leveraged that work to secure VA HSR&D funding (IIR 12-407) to evaluate whether former mentees can be trained to be effective peer mentors. Dr. Long has worked closely with Dr. Kangovi since 2010. Dr. Long will work closely with Dr. Kangovi on design, conduct, and analysis. Dr. Nandita Mitra is a Professor of Biostatistics at the Hospital of the University of Pennsylvania, Perelman School of Medicine and the Director of Statistics of the Masters in Health Policy Research Graduate Program at the University of Pennsylvania, and affiliated faculty member with the Center for Clinical Epidemiology and Biostatistics. Dr. Mitra conducts methodological and collaborative research in the areas of causal inference and outcomes research. Her methods research focuses on the development of statistical methods for the analysis of observational data, health economic data, and population-based genetic data. She has developed propensity score based methods for bias reduction in cost effectiveness and cancer risk studies. She has also developed regression based methods to assess the sensitivity of treatment effects to unmeasured confounding and hidden bias. She has been the lead statistician on Dr. Kangovis prior studies. These collaborations with the study team and other Penn faculty members have led to important publications in JAMA Internal Medicine, Statistics in Medicine, JAMA, Nature Genetics, Cancer Research, and JNCI. As a co-investigator and biostatistician on this study, Dr. Mitra will direct all analyses; assist with data interpretation, manuscript preparation, and presentations. Specifically, she will test our hypotheses with an intent-to-treat analysis using a modified Poisson regression model to obtain relative risk of low adherence and a linear regression model to obtain the between-arm difference in change in glycosylated hemoglobin. An information systems support fee of $609, for consultation with faculty members in the Center for Clinical Epidemiology and Biostatistics, is also applied to the budget for Dr. Mitra. Mr. Rory Harte is a Clinical Research Coordinator for the Perelman School of Medicine at the University of Pennsylvania. Mr. Harte has worked for the Penn Center for Community Health Workers for over four years, providing programmatic, research, and evaluation support. Mr. Harte began his work at Penn as a clinical research assistant on a PCORI-funded, multi-center randomized control trial. He was instrumental in subject enrollment, data collection, participant follow-up, and remuneration at multiple sites. He gained experience with both quantitative and qualitative data collection and analysis.

Mr. Harte was promoted to Clinical Research Coordinator and helped to transition the study into a clinical program embedded with the University of Pennsylvania Health System and the Corporal Michael J. Crescenz Veterans Affairs Medical Center. Additionally, Mr. Harte has worked as a clinical research coordinator on a behavioral science study in which he was responsible for reviewing literature and identifying useful survey instruments; developing study protocols; creating a research database and manual; meeting with clinic staff; supervising staff; and corresponding with the Institutional Review Board. Mr. Harte will work closely with Dr. Kangovi to oversee the day-to-day aspects of the study. Specifically, he will develop and maintain eligibility lists for recruitment purposes; coordinate and maintain IRB approval for the study; manage the tracking database of outcomes; supervise the work of the research assistant; assist with writing reports and correspondence with Commonwealth Fund; and coordinate quarterly meetings with all study team staff. The research assistant will have a minimum college education and will undergo a 1-week training which covers topics including survey interviewing, data entry, HIPPA and Human Subjects training. The research assistant will be responsible for interfacing with Way to Health platform, recruiting and enrolling patients, verbally administering the baseline and follow-up surveys, monitoring adherence and lottery, tracking laboratory results, and entering outcomes data.

Characteristics of the Study Population

Target population
Diabetes patients of low socioeconomic status living in high poverty zip codes of West/Southwest Philadelphia.

Subjects enrolled by Penn Researchers
150

Subjects enrolled by Collaborating Researchers
0

Accrual
We will enroll 150 patients (50 in each arm) from the Penn Rodebaugh Diabetes Center at the Perelman Center for Advanced Medicine.

Key inclusion criteria
Key inclusion criteria: We will enroll patients who meet the following eligibility criteria: 1) Penn Medicine patients diagnosed with diabetes mellitus (based on ICD-10CM codes from the year prior to study enrollment); 2) glycosylated hemoglobin 9% within the past 6 months; 3) requires insulin; 4) uninsured/publicly insured; 5) residents of high-poverty ZIP codes in West/Southwest Philadelphia; 6) have access to a cellphone with unlimited text message capabilities; 7) greater than or equal to 18 years of age.

Key exclusion criteria
Key exclusion criteria: We will exclude patients who: 1) already have pumps that do continuous glucose monitoring; 2) were previously enrolled in the study; 3) are unwilling/unable to provide informed consent; 4) currently have a community health worker; 5) are in another study that asks participants to monitor their blood sugar.6) unable to speak and read comfortably in the English language

Vulnerable Populations

	Children Form
	Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form
	Fetuses and/or Neonates Form
	Prisoners Form
	Other
x	**None of the above populations are included in the research study**

The following documents are currently attached to this item:

There are no documents attached for this item.

Populations vulnerable to undue influence or coercion
The consent form is explicit about the absence of any consequences with respect to employees refusal to be involved in the protocol as a research participant altogether. The informed consent form is explicit about the absence of any consequences to refusing to participate in the study. We will be reimbursing participants up to $200 over the course of the six month study period, as well as $20 upon completion of an optional in depth qualitative interview. We feel this is a modest amount so that the compensation will not be unduly coercive even though we expect most of the participants to be low income and minority.

Participant recruitment
Please describe the plan to equitably identify and recruit a diverse group of participants that is reflective of the population under study. If this is a multicenter protocol, the recruitment plan should describe the local (Penn) site's plan. Describe:how potential participants may be identified (review of medical records, Slicer Dicer, DAC reports including referrals from physician offices and clinics);who may approach potential participants;methods to achieve sample diversity and inclusiveness;what information may be presented to or discussed with them; andthe context and setting in which recruitment will happen.
Each week, study coordinators will receive automated lists of eligible patients with upcoming appointments throughout Penn Medicine. Trained research assistants will call these patients and ask if they would be willing to plan additional time during their clinic visit for study enrollment. When interested patients arrive to their clinic visit, the research assistant will obtain written informed consent and begin the study. We will primarily be working with the Rodebaugh Diabetes Clinic. We have established relationships with clinic providers and staff and we were invited to conduct our study at the clinic. The providers at the clinic have approved our recruitment procedures and are aware that we will be contacting their patients to invite them to participate in this study. We will obtain PHI from the Penn Data Store for the purposes of recruitment. Patients will need to be contacted before appointments in order to ensure they budget enough time to participate. In order to call patients, we need their name and phone number. We need to know patients zip codes because it is part of the inclusion criteria. If we did not limit our recruitment list by zip code, the number of patients to contact would be immense and unmanageable. We need to know patients date of birth to confirm they are over the age of 18 years old. We need to know patients medical record number and date of birth to verify their identity. The following is an excerpt pulled from the Notice of Privacy Practices that all patients are required to review: as an academic medical center Penn Medicine supports research and may contact you to invite you to participate in certain research activities. Given this information, it is our understanding that patients do not have to agree to be contacted ahead of time. In addition to calling potential study participants, we will also send recruitment mail cards to Penn Medicine patients who may be eligible for the Engage study. We will obtain mailing information via the Data Analytics report we already receive as part of our study recruitment process. . We are currently using a report from Penn Data Analytics to identify potentially eligible participants for recruitment phone calls. We propose to use this same list to identify potentially eligible participants to whom we may send recruitment post cards. We will not be expanding the pool of participants we are contacting under this new proposed recruitment strategy. Rather, we will be employing a new method (mail) to reach the same participants we may otherwise be attempting to contact via phone.We have attached a copy of our proposed mail card to this submission. In order to track which participants have agreed or not agreed to be in the study and why,

we store information about all screened patients in redcap. This information includes, first name, last name, medical record number, age, gender, clinic, problem list, and insurance. This information is used to confirm their eligibility prior to contacting them via phone. The phone script is in the RA manual that is attached.

Recruitment Materials
Is the research team using any recruitment materials? These may include but are not limited to: phone call scripts, radio/video scripts, flyers/brochures, internet postings, email, letters to potential participants, letters to patient physicians, My Penn Medicine (MPM), other direct messaging, etc. For guidance regarding recruitment materials, please review the IRB's guidance on Participant Recruitment Materials online:https://irb.upenn.edu/recruitment
No

Use of Penn Media & Social Media Services
Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?
No

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject compensation*
Will subjects be financially compensated for their participation?
Yes

The following documents are currently attached to this item:

There are no documents attached for this item.

If there is subject compensation, provide the schedule for compensation per study visit or session and total amount for entire participation, either as text or separate document

Participants will receive a $50 pre-paid gift card upon completion of enrollment (baseline survey and laboratory testing) and $50 upon completion of a 3 month follow up visit for glucometer data extraction and finally $100 gift card at the 6 month follow-up assessment (baseline survey, laboratory testing, and glucometer data extraction.) Participants who complete a qualitative interview will receive an additional $20 gift card. We are submitting a piece of paper that we would like to give to participants explaining when they can expect to be paid for the study. We hope this will offer clarity to the process used for uploading money onto ClinCards.We have uploaded a copy of this document below. Due to restrictions on in-person non-essential research visits due to COVID-19, we propose to split 3-and 6-month study compensation into 2 payments. For 3-month study visits, we will look to conduct adverse event screening with patients telephonically, for which they will receive 1 half ($25) of their 3-month compensation. As soon as is safely possible, will aim to complete an in-person 3-month visit, to collect biometric data (from patient glucometes). At the completion of this component of the 3-month visit, patients would be provided with the other half ($25) of their 3-month compensation. Simliarly, for 6-month follow-up we will aim to complete adverse event screening and psychometric surveys via telephone, for which subjects will be compensated 1 half $50) of the 6-month compensation. Then, as soon as possible, we will look to complete the 6-month biometric data collection for glucometer data and hemoglobin a1c testing. At the completion of these steps, participants would receive the other half ($50) of the 6-month follow-up compensation. o Due to the COVID-19 pandemic, we have been delayed in completing study follow-up visits. Given that participants are not able to complete follow-up visits as scheduled we have not been able to dispense follow-up compensation to study participants at the anticipated times (approximately 3- and 6- months post-enrollment). In order to honor the financial expectations we set with participants, we propose to attempt to send follow-up payments to participants with whom we are unable to meet due to COVID, regardless of whether they complete any follow-up activities. Specifically, for any patients whose planned follow-up date has already passed, we will aim to provide the full follow-up visit compensation amount via ClinCard as soon as possible. For patients with future planned follow-up visit dates, if the date of their planned follow-up arrives, and we are still unable to meet with them due to COVID, we will aim to issue their full visit compensation via ClinCard

as close to that time as possible. As outlined in a prior modification (approved 4/1/20), we will look to complete some follow-up visit activities telephonically during this time for partial compensation (in addition to the compensation described above). Additionally, once safety restrictions are lifted and non-essential in-person research visits resume, we will look to meet with as many participants as is feasible to complete in-person follow-up activities, for further partial compensation. Participants will be compensated for these follow-up activates as outlined in the previously approved modification. We will attempt to alert patients via phone and/or mail ahead of an electronic transmission of payment. For participants who no longer have the CliniCard we issued to them earlier in the study, we will attempt to issue a new CliniCard via mail as soon as possible.

Study Procedures

Suicidal Ideation and Behavior
Does this research qualify as a clinical investigation that will utilize a test article (ie- drug or biological) which may carry a potential for central nervous system (CNS) effect(s)? Centeral nervous system(CNS) effect: the ability of a test article to enter into and potentially interact with the central nervoous system (brain and spinal cord). Clinical Investigation: Any experiment that involves a test article and one or more human subjects that either is subject to requirements for prior submission to the Food and Drug Adminstration (FDA) under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or is not subject to the requirements for prior submission to the FDA under these sections of the act, but, the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.
No

Procedures
Participants interested in enrolling into the study will go through the following procedures: Step One: Consent and Goal-Setting 1. Explain the study to the patient using the consent form. Obtain two signed copies of the consent. 2. Use the IMPaCT goal card to help the patient choose a reasonable HbA1c goal to reach by the end of the six month study period. Step Two: 1. Administer the baseline redcap survey. Step Three: The Walk Tests (All parts of Step Three are optional and patients will be asked if they want to participate in this part of the study) 1. Take the patient to the walk test area. Ask the patient to sit at rest in a chair for a few minutes. During this time, explain the walk test to the patient: We would like you to participate in 2 or 3 walk tests. These tests can help us understand how you may react to this study, which asks you to monitor your blood glucose. We will ask you to complete a short walk test, 2 or 3 times. Before the test starts, check for contraindications, baseline oxygen saturation via pulse ox, pulse, and blood pressure. Patients should use their usual walking aids during the test(cane, walker, etc.). 3. Contraindications to administering the 1 minute walk test are: 1) resting heart rate of more than 120, 2) a systolic blood pressure of more than 180 mm Hg, 3) and a diastolic blood pressure of more than 100 mm Hg. If at the study visit, a patient cannot participate in the walk test because of a contraindication, the patient can complete all other aspects of the study. If the patient has any of these contraindications or a Sp02 less than 88%, this constitutes a clinical emergency and the principal investigator should be contacted immediately. 4. If no contraindications exist, set the timer to 1 minute. Assemble all necessary equipment (timer, clipboard, worksheet, cones) and move to the starting point. 5. Trial One (Practice Trial) a. After explaining the instructions, position the patient at the starting line. Say Start now, or whenever you are ready. b. Record the number of laps the patient walked from the tick marks on the worksheet. And record the additional distance covered (the distance in the final partial lap). Calculate the total distance walked. c. Congratulate the patient on their good effort and offer a drink of water. d. Give the patient a rest period. (Vitals will not be repeated before trials 2 and 3) 6. Trial Two (Performance Trial) a. After a rest period, ask participants to complete a second walk test with the goal of exceeding their prior performance (total distance walked) by 40%. (You should calculate the distance and just tell them that, not the percent). b. Conduct the walk test as above. c. After the walk test, tell the patient if they succeeded or failed at reaching their goal. 7. Trial Three (Outcomes Trial) a. Offer participants the choice of repeating their walk trial. "Now, I'd like to give you the option of doing another walk test to see if you can improve. Do you want to try again?" If they choose not to do Trial 3, leave their Trial 3 performance distance walked blank and move on. b. Repeat the walk test as above. c. After the completion of all the walk tests, thank the patient. Step Four: Set up Way to Health Account 1. Enter the patient into the way to health platform. 2. Test that they provided

the correct phone number using contact verification technology. Step Five: Labs 1. Walk the patient to the laboratory to have their blood drawn for HbA1c evaluation. 2. Provide the patient with a gift card and half page sheet with payment information Step Six: How to Use the Glucometer 1. Provide the patient with a glucometer if they don't already have one. 2. Review the user guide with the patient and answer any questions they may have about using their glucometer. 3. Reinforce/explain to the patient not to delete their glucose reading log from the glucometer because we will extract the log from the glucometer at subsequent visits. Abnormal Blood Glucose Safety Protocol: The study clinician will be notified by the way to health platform if participants glucose is either extremely low or high (60 or 400 mg/dL) and respond accordingly. The study clinician will contact these patients to address the issue. Step Seven: CHW escalation 1. The way to health platform will notify the study team of any individuals who have low adherence (no self-monitoring) or elevated glucose readings (300 mg/dL) for 30% of days over any 2 week period in the first 12 weeks of the study. These individuals will be assigned to receive ongoing CHW support for the duration of the 24-week study period 2. The study team should notify the CHW and send them the patients redcap ID. The CHW will follow up with the patient in 1-2 days. Step Eight: 3 Month Follow Up 1. One month prior, contact the patient to set a date/time for their 3 month follow up appointment. (If patients are unable to be reached, then we will send a letter to their home requesting that they contact us to set up a follow-up appointment.) 2. At the appointment, obtain the blood glucose log of readings from the patients glucometer. 3. Provide the patient with a gift card. Follow up visit is concluded. 4. The window to complete all 3-month follow-up procedures may be extended in cases where patients were prevented from completing visits within the original window due to COVID-19 restrictions. Step Nine: 6 Month Follow Up and Labs 1. One month prior, contact the patient to set a date/time for their 6 month follow up appointment. (If patients are unable to be reached, then we will send a letter to their home requesting that they contact us to set up a follow-up appointment.) 2. At the appointment, obtain the blood glucose log of readings from the patients glucometer. 3. Administer the follow up redcap survey 4. Walk the patient to the laboratory to have their blood drawn for HbA1c evaluation. 5. Provide the patient with a gift card. Follow up visit is concluded. 6. The window to complete all 6-month follow-up procedures may be extended in cases where patients were prevented from completing visits within the original window due to COVID-19 restrictions. Any Engage Study patients screened for recruitment into routine care community health worker programs at Penn Medicine will have their enrollment deferred until their study participation is complete. We will track all screened patients that are deferred because of Engage Study participation and contact them afterwards to offer enrollment into our routine care community health worker program. You may also be contacted during this study as a part of our quality review. If this happens you will just be asked a few questions about how the study has been going and your experiences with the steps listed above.

The following documents are currently attached to this item:

There are no documents attached for this item.

Deception
Does your project use deception? Deception could be considered any direct misinformation presented to the subject or omission of key information pertaining to the design or nature of the project.
No

International Research
Are you conducting research outside of the United States?
No

Analysis Plan
Hypotheses 1. We hypothesize that over the 24-week study period, compared to usual care, the hybrid intervention will lead to a higher rate of adherence to daily glucose self-monitoring. 2. Our secondary hypothesis is that compared to DFI alone, the hybrid intervention will lead to a higher rate of adherence to daily glucose self-monitoring. 3. Our exploratory hypotheses are that compared to usual care and DFI alone, the hybrid intervention will lead greater improvements in glycosylated hemoglobin. Outcome measures The primary and secondary outcome measures will be adherence rate (constructed by summing the number of days in the study period that the glucometer was used divided by the total number of days in study period). The exploratory outcome measure will be change in glycosylated hemoglobin from baseline to 24 weeks follow-up assessment. Statistical analyses We will test our hypotheses with an intent-to-treat analysis using a modified Poisson regression model to obtain relative

risk of low adherence and a linear regression model to obtain the between-arm difference in change in glycosylated hemoglobin. We will adjust these models for any unbalanced baseline covariates to increase efficiency. For exploratory purposes, we will do a per protocol analysis focusing on the subgroup of patients in the hybrid intervention who actually received CHW support, as compared to the patients in the DHI alone arm who would have received support based on low adherence or elevated glucoses. We will also explore predictors of adherence and glycosylated hemoglobin across all three arms. Sample size calculations Based on a similar 24-week trial, we assume that the adherence rate in the usual care arm will be 40% and the rate in the hybrid intervention will be 80%. In the prior trial, the adherence rate in the usual care arm was 47%; however this trial had a lower risk population (higher income and lower baseline glycosylated hemoglobin), and a longer financial incentive period. In this same trial, the adherence rate for the DFI alone arm was 70%; therefore the estimate of 80% adherence in the hybrid DFI/CHW arm seems reasonable. Using a two-sample comparison of proportions (usual care versus hybrid), we will require a sample size of 28 patients per arm to detect these differences with 80% power, assuming a Type I error rate of 0.05. Given the vulnerability and transience of this patient population, it is important to account for loss to follow-up, which we assume based on prior trials to be 20%. Therefore, we estimate that we will have to enroll 34 patients in each arm to end up with our minimal sample size. Our planned enrollment of 50 patients in each arm will easily allow us to meet this threshold. Our planned sample size will also allow us to detect a difference between DFI alone and hybrid arms (the secondary outcome), assuming the DFI arm has an adherence rate of 48% and the hybrid arm has a rate of 80%. In reality, we might see higher adherence than 48% in the DFI alone arm based on a prior similar trial as above in which the DFI arm had a 70% adherence. However, it is possible in this trial focusing on a vulnerable population, DFI alone may result in lower adherence. Missing data Efforts will be made to collect complete information on patients including 3 attempts to contact each patient via telephone and the provision of honoraria for completion of follow-up. We will check the medical record of those lost to follow-up and extract from the electronic medical record any relevant glycosylated hemoglobin that occurred within 4 weeks of the study completion date. We will track all missing values and assess the pattern of missing data and whether the missingness is non-ignorable. If appropriate, we will consider statistical methods such as multiple imputation.

The following documents are currently attached to this item:

There are no documents attached for this item.

Data confidentiality

- x **Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.**
- x **Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords.**
- x **Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.**
- x **Wherever feasible, identifiers will be removed from study-related information.**

  A Certificate of Confidentiality will be obtained, because the research could place the subject at risk of criminal or civil liability or cause damage to the subject's financial standing, employability, or liability.

  A waiver of documentation of consent is being requested, because the only link between the subject and the study would be the consent document and the primary risk is a breach of confidentiality. (This is not an option for FDA-regulated research.)
- x **Precautions are in place to ensure the data is secure by using passwords and encryption, because the research involves web-based surveys.**
- x **Audio and/or video recordings will be transcribed and then destroyed to eliminate audible identification of subjects.**

Subject Confidentiality

To ensure that participant confidentiality is maximized, only trained, designated research staff will be given access to participants medical records and research data, including informed consent forms. Data management will occur through REDCap , a secure web application and back-end database model, developed at Vanderbilt University with collaboration from a consortium of institutional partners. RAs,

CHWs and clinicians will enter data directly into REDCap, which obviates the need for transferring written data into electronic form; this significantly improves the quality of data. Penn has licensed its own version of REDCap housed on our own servers located within a University of Pennsylvania Health System (UPHS) data center inside the UPHS firewall and therefore afforded the same network protections as all UPHS sensitive clinical data. REDCap was developed specifically around HIPAASecurity guidelines and is recommended to Penn Medicine researchers by our Office of Human Research. Relevant HIPAA-compliant features include password-protected access to the system, restriction of access to specific clinical trial data to designated users, audit trails of access and data updates, and built-in de-identification functions that can be used when exporting data for analysis. REDCap has been disseminated for use locally at other institutions and currently supports 170 academic/non-profit consortium partners on six continents and 13,000 research end-users (www.project-redcap.org). RAs and goal-supporters can access REDCap through a web-based interface and securely input data from any location at the time of data collection minimizing the need for travelling with either electronic or paper versions of sensitive information. Audio recordings of qualitative interviews will be temporarily stored on a password protected, PGP-Netshare encrypted HIPAA secure network drive behind the firewall of the Division of General Internal Medicine server. This network drive was established per the advice and recommendation of the Division of General Internal Medicines UPHS affiliated Local Support Provider within Penn Medicine Academic Computing Services. Once the audio files are uploaded to the transcription service website and the written transcripts are returned the audio recordings will be destroyed. Interview transcripts will then be uploaded to REDCap. Written communication to study participants will also be stored on this drive which is accessible only by members of the research team. A unique participant identifier will be used for linkage of Personal Health Information (PHI) to research databases. The unique study identification number, and no other identifying information, will be used on all data collection instruments. The only paper forms that will be used in this study are: 1) informed consent documents and 2) human subject vouchers for participant incentives. These paper forms will be securely stored in a locked cabinet in the School of Medicine. One exception to the utilization of paper forms is as follows: In the event that data is unable to be directly entered into REDCap for any reason (e.g. due to a technological system failure), a paper copy of the corresponding Data Collection Instrument will be utilized and the Data will then be transcribed from the paper form and entered into REDCap immediately after any technological issues are rectified. The paper form will be retained as a source document. Research material will be obtained from participant surveys and from glucometers. All participants will provide informed consent for access to these materials. Research material that is obtained will be used for research purposes only. The Penn Medicine Academic Computing Services (PMACS) will be the hub for the hardware and database infrastructure that will support the project and is where the Way to Health web portal is based. The PMACS is a joint effort of the University of Pennsylvania's Abramson Cancer Center, the Cardiovascular Institute, the Department of Pathology, and the Leonard Davis Institute. The PMACS provides a secure computing environment for a large volume of highly sensitive data, including clinical, genetic, socioeconomic, and financial information. Among the IT projects currently managed by PMACS are: (1) the capture and organization of complex, longitudinal clinical data via web and clinical applications portals from cancer patients enrolled in clinical trials; (2) the integration of genetic array databases and clinical data obtained from patients with cardiovascular disease; (3) computational biology and cytometry database management and analyses; (4) economic and health policy research using Medicare claims from over 40 million Medicare beneficiaries. PMACS requires all users of data or applications on PMACS servers to complete a PMACS-hosted cybersecurity awareness course annually, which stresses federal data security policies under data use agreements with the university. The curriculum includes Health Insurance Portability and Accountability Act (HIPAA) training and covers secure data transfer, passwords, computer security habits and knowledge of what constitutes misuse or inappropriate use of the server. We will implement multiple, redundant protective measures to guarantee the privacy and security of the participant data. All investigators and research staff with direct access to the identifiable data will be required to undergo annual responsible conduct of research, cybersecurity, and HIPAA certification in accordance with University of Pennsylvania regulations. All data for this project will be stored on the secure/firewalled servers of the PMACS Data Center, in data files that will be protected by multiple password layers. These data servers are maintained in a guarded facility behind several locked doors, with very limited physical access rights. They are also cyber-protected by extensive firewalls and multiple layers of communication encryption. Electronic access rights are carefully controlled by University of Pennsylvania system managers. We will use highly secure methods of data encryption for all transactions involving participants financial information using a level of security comparable to what is used in commercial financial transactions. We believe this multi-layer system of data security, identical to the system protecting the University of Pennsylvania

Health Systems medical records, greatly minimizes the risk of loss of privacy. Each subject will be assigned a unique identifier without identifying information, and data will be entered into an electronic database using only the unique identifier. Only trained study staff will have access to the code that links the unique identifier to the subjects identity. Electronic data will be stored on secure, password-protected firewalled servers at the University of Pennsylvania. The OneTouch Reveal® web app is a diabetes management tool that can help you track your blood sugar from your compatible iOS or Android wireless device and easily share your readings with your healthcare professional and family members. Participants will only have a numeric study ID entered into the application, so there is no risk of loss of confidentiality or personal information.

Sensitive Research Information*

Does this research involve collection of sensitive information about the subjects that should be excluded from the electronic medical record? [NOTE: This does not apply to: 1) research information that would not normally be included in the electronic medical record or 2) information that is in the electronic medical record as part of clinical care.]

No

Subject Privacy

Privacy refers to the person's desire to control access of others to themselves. Privacy concerns people, whereas confidentiality concerns data. Describe the strategies to protect privacy giving consideration to the following: The degree to which privacy can be expected in the proposed research and the safeguards that will be put into place to respect those boundaries. The methods used to identify and contact potential participants. The settings in which an individual will be interacting with an investigator. The privacy guidelines developed by relevant professions, professional associations and scholarly disciplines (e.g., psychiatry, genetic counseling, oral history, anthropology, psychology).

Study personnel will interview patients in designated private rooms in the clinic in order to explain the study and request informed consent. If informed consent is granted, all interviews will be performed in private settings. In the case of follow-up surveys, if the survey will take place over the phone, the RA will ensure that the patient has the privacy desires to conduct the interview. The study protocol will comply with the Final Privacy Rule of the Health Insurance Portability and Accountability Act. The research computing environment has a security component required due to HIPAA; federal, state, and research compliance regulations. During IMPaCT Intervention Activities: IMPaCT Partners will be trained extensively on protecting patient privacy. For instance, they will always ensure that patients are able and willing to speak privately over the phone or during home visits before beginning any conversation. Throughout the study, staff will safeguard participant privacy, only breaking confidentiality in cases of 1) threat to harm self or others, 2) mandated reporting of child abuse or neglect. Interested participants will have their demographic characteristics entered into the Way to Health portal. Enrollment will include a description of the voluntary nature of participation, the study procedures, risks and potential benefits in detail. The enrollment procedure will provide the opportunity for potential participants to ask questions and review the consent form information with family and friends prior to making a decision to participate. Participants will be told that they do not have to answer any questions if they do not wish and can drop out of the study at any time, without affecting their medical care or the cost of their care. They will be told that they may or may not benefit directly from the study and that all information will be kept strictly confidential, except as required by law. Subjects will be given a copy of the consent document. All efforts will be made by study staff to ensure subject privacy.

Disclosures

Will any data or specimens from Penn participants OR other research generated work product (e.g., intellectual property) be disclosed to any individuals, entities, or vendors, etc. outside of Penn?

No

Data Protection*

x	**Name**
x	**Street address, city, county, precinct, zip code, and equivalent geocodes**
x	**All elements of dates (except year) for dates directly related to an individual and all ages over 89**
x	**Telephone and fax number**
x	**Electronic mail addresses**
x	**Social security numbers**
x	**Medical record numbers**
	Health plan ID numbers
	Account numbers
	Certificate/license numbers
	Vehicle identifiers and serial numbers, including license plate numbers
	Device identifiers/serial numbers
	Web addresses (URLs)
	Internet IP addresses
x	**Biometric identifiers, incl. finger and voice prints**
	Full face photographic images and any comparable images
	Any other unique identifying number, characteristic, or code
	None

Does your research request both a waiver of HIPAA authorization for collection of patient information and involve providing Protected Health Information ("PHI") that is classified as a "limited data set" (city/town/state/zip code, dates except year, ages less than 90 or aggregate report for over 90) to a recipient outside of the University of Pennsylvania covered entity?
No

Tissue Specimens Obtained as Part of Research*
Are Tissue Specimens being obtained for research?
No

Tissue Specimens - Collected during regular care*
Will tissue specimens be collected during regulator clinical care (for treatment or diagnosis)?
No

Tissue Specimens - otherwise discarded*
Would specimens otherwise be discarded?
No

Tissue Specimens - publicly available*
Will tissue specimens be publicly available?
No

Tissue Specimens - Collected as part of research protocol*
Will tissue specimens be collected as part of the research protocol?
No

Tissue Specimens - Banking of blood, tissue etc. for future use*
Does research involve banking of blood, tissue, etc. for future use?
No

Genetic testing
If genetic testing is involved, describe the nature of the tests, including if the testing is predicative or exploratory in nature. If predictive, please describe plan for disclosing results to subjects and provision

of genetic counseling. Describe how subject confidentiality will be protected Note: If no genetic testing is to be obtained, write: "Not applicable."
Not applicable

Consent

1. Consent Process

Overview
When interested patients arrive at the clinic, the CRC or RA will obtain their written informed consent. The trained recruiter will provide a detailed description of the voluntary nature of participation, study procedures, risks and potential benefits. The potential participant will be provided the opportunity to ask questions and review the consent information with family and friends prior to making a decision to participate. Participants will be told that they do not have to answer any questions if they do not wish and can drop out of the study at any time, without affecting their medical care or the cost of their care, or that of their spouse of partner. They will be told that they may not benefit directly from the study and that all information will be kept strictly confidential, except as required by law. All participants will be given a copy of the signed informed consent form. For participants who are offered the opportunity to participate in a qualitative interview, and elect to do so, we will repeat the above procedures with an interview-specific additional consent document. Participants will have the opportunity to discuss the consent document with research personnel, and will be informed about the voluntary nature of participation in the interview. Participants will receive a signed copy of the additional consent documentation. We additionally have proposed to conduct qualitative interviews with the 2 Community Health Workers serving patients within this study. We will consent these Penn Medicine staff members using the attached consent form. Due to COVID-19 we have requested a waiver of written documentation of consent, due to the significant challenges posed by obtaining documentation of consent given pandemic precautions limiting in-person visits, and the limited access to technology among our study population.

Children and Adolescents
Not applicable

Adult Subjects Not Competent to Give Consent
Competence will be assessed by the interviewer and we will exclude patients who cannot or will not give consent.

2. Waiver of Consent

Waiver or Alteration of Informed Consent*
Waiver of written documentation of informed consent: the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context

Minimal Risk*

Impact on Subject Rights and Welfare*

Waiver Essential to Research*

Additional Information to Subjects

Written Statement of Research*
No

If no written statement will be provided, please provide justificiation

Due to the current COVID-19 pandemic, we are unable to meet study participants in-person, therefore prohibiting us from sharing a physical copy of the written statement of research. However, all

participants consenting to participate in qualitative interviews who were previously enrolled as participants in the Engage RCT were previously provided with a physical copy of the overall study consent form, which explains the overall goals of the research project, and refers to the qualitative interview process.

The following documents are currently attached to this item:

There are no documents attached for this item.

Risk / Benefit

Potential Study Risks
A potential risk of this study is a breach of participant confidentiality. We will minimize this risk by linking individual identifying information with participant ID numbers only in one single secure file. Due to the financial incentives in this study, we will be collecting social security numbers so that we can complete W-9 forms for participants. Social security numbers only will be used to generate W-9 forms and will be deleted once they are no longer needed. We will also collect home addresses to mail incentive payments. This will be done through a University of Pennsylvania approved partnership with Greenphire ClinCard. Accidental disclosure of social security numbers could lead to identity theft. We will use commercial-grade encryption to protect social security information in transit. Names and addresses will be stored in encrypted databases. These data will be viewable only by the respective participants and the study coordinator. All other members of the research team will be able to view only participant ID numbers. There will be no functionality in the web application to export a dataset with identifiable information. Even the study arms will be identified by code letters until both the statistician and PI agree that analysis is complete.

Potential Study Benefits
Participants may benefit by improving control of their diabetes through increased self-monitoring of their blood glucose level.

Alternatives to Participation (optional)

Data and Safety Monitoring
Data will be monitored by the Principle Investigator and other investigators throughout the data collection and analysis process. We will have an internal safety review that is blinded to arm and a quarterly discussion of adverse events. We will ask patients about any medical incidents and hospitalizations at the 3 and 6 month follow up visits and record their responses. A nurse practitioner will then determine if medical incidents and hospitalizations are study related. Study related events will be discussed with our internal DSMB.

The following documents are currently attached to this item:

There are no documents attached for this item.

Risk / Benefit Assessment
There is a very low ratio of risk to benefit in this study. There is minimal risk to participation in the study.

General Attachments

The following documents are currently attached to this item: