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A. Background

Older African Americans with diabetes are a highly vulnerable population, as tragically demonstrated by their disproportionate share of deaths due to COVID-19. In addition to having a high susceptibility to external insults, older patients with diabetes suffer from the highest rates of cardiovascular and microvascular complications as well as hypoglycemia.[1] For many African Americans, these risks are compounded by high rates of comorbid illnesses, functional impairment, and socioeconomic risks.[2]

To address the needs of older patients with diabetes, multiple organizations have called for a personalized approach to setting risk factor goals and self-care plans.[3,4] The American Geriatrics Society (AGS)[5] and the American Diabetes Association (ADA)[6] have published recommendations urging individualized glycemic goals (hemoglobin A1C (A1C) <7.5%, <8.0%, or <8.5%) for three strata of older patients (healthy, complex, very complex). The guidelines also acknowledge the importance of addressing individualized socioeconomic risks that are barriers to self-care management such as cost-related non-adherence and food insecurity.[7] Despite widespread agreement by experts, the clinical impact of this highly personalized approach to diabetes care for older adults has been rarely studied in controlled trials.[8] Interventions designed to personalize diabetes care must overcome multiple challenges to implementation including the brief clinical encounter, lack of patient engagement between encounters, and lack of systems to leverage community-based self-care resources.

B. Purpose

We propose to address these knowledge and care gaps by integrating two evidence-based interventions designed to personalize glycemic goals, engage patients and enhance self-care: **Managing Diabetes to Gain Opportunities for a More Active Life (My Diabetes GOAL)** and **CommunityRx.** The **My Diabetes GOAL** intervention is designed to engage older patients in personalized goal setting and chronic disease management.[8,9] The intervention consists of a screening survey delivered through the electronic health record (EPIC®) patient portal (MyChart®) to assess health status, hypoglycemia risk, barriers to care, and treatment preferences. A diabetes nurse then discusses the survey results with the patient to arrive at personalized diabetes goals and provides telephonic care management. **CommunityRx (CRx)** is a theory-driven and evidence-based[10] community resource referral information system, developed and iterated in partnership with stakeholders across health and social care sectors and local residents.[11,12] During clinical encounters, a printed list of vetted resources (a "HealtheRx") is auto-generated, providing patients with personalized information to address basic needs such as food and housing, physical and mental wellness, disease self-management and caregiving. In a real-world trial conducted by the PIs, CommunityRx increased knowledge about and self-efficacy, or confidence, in finding community resources for self-care.[12,13] Based on models of shared decision making in minority populations[14,15] and the Grey model for self-care,[16] the combination of these scalable interventions would be expected to have additive benefits for self-care and clinical outcomes.

Across the University of Chicago Practice Network, we will conduct a three-arm parallel pragmatic randomized controlled trial (1) Attention Control vs. 2) My Diabetes GOAL vs. 3) My Diabetes GOAL + CommunityRx) among 505 older, predominantly African American patients. We will pilot test the study among 12 additional participants. During the trial we will address the following aims:

1. Evaluate the impact of My Diabetes GOAL vs. My Diabetes GOAL + CRx vs. Attention Control Arm on processes of personalized diabetes care:

a. Patients' experience and satisfaction with goal-setting communication and EHR documentation of goals;
b. Patients' decisional conflict regarding goals of diabetes care;
c. Patients' self-report of diabetes care goals.

2. Evaluate the impact of My Diabetes GOAL vs. My Diabetes GOAL + CRx vs. Attention control on self-care:
a. Diabetes self-efficacy and self-management behaviors (e.g., physical activity);
b. Knowledge and utilization of community-based resources.

3. Evaluate the impact of My Diabetes GOAL vs. My Diabetes GOAL + CRx vs. Attention control on clinical outcomes and health care utilization:
a. Glycemic control and hypoglycemia;
b. Geriatric syndrome symptom burden (e.g. depression, falls, incontinence);
d. Functional status;
e. ED visits and unplanned hospitalizations.

Personalizing diabetes care in older African American patients with strategies that acknowledge personal preference, barriers to self-care and community connections have the potential to improve the overall quality of life while minimizing adverse drug events like hypoglycemia. The likelihood of sustainability and replicability of My Diabetes GOAL and CRx are high because both can be delivered remotely, and both leverage existing clinical staff, electronic health record systems, and community resources.[17]

C. Methodology

Potential study subjects will be identified and pre-screened through the electronic medical record of the University of Chicago. Physician assent will be obtained to approach a patient. Then a research assistant will approach the potential participant to explain the purpose, intervention and potential benefits/risks of participating in this study. All human subjects will be consecutively screened for inclusion and enrolled as described in Section P. Recruiting Methods. A research assistant will conduct informed consent with eligible subjects prior to any study procedures.

Electronic Health records will be a critical source of data on key processes of care that are affected by My Diabetes GOAL including goal setting measures (documenting personalized goals of diabetes care, proportion following ADA recommendations, proportion choosing alternative goals) as well as referrals to care management and frequency of phone contacts. The EHR will also be the primary source of data for risk factor levels (glycosylated hemoglobin, blood pressure, cholesterol levels), medications, and health care utilization (outpatient visits, care management services, ER visits, and hospitalizations). These data are continually collected as a part of routine care. If participants receive care outside of the UChicago system during the duration of the study and their most recent A1C is not available in the EMR via Care Everywhere, we will ask the participant to self-report the A1C and offer the option for them to securely upload their results via REDCap survey link to be stored with the rest of their study data. Previously consented subjects that receive care outside of UChicago Medicine will be resent the original signed informed consent for review and asked to complete an addendum to the consent to include this upload option. All future subjects will have this upload option included in an updated informed consent. We will ask subjects for permission to access their medical records for these purposes.

Subjects will be randomized in a 1:1:1 ratio to the attention control, MDG, or MDG+CRx groups. All subjects will be asked to complete surveys upon enrollment, at 6 months, and 12 months. This will be a single-blind study, and subjects will be blinded to the different groups.

Attention control Arm: These subjects will receive monthly calls with a member of the study team.

My Diabetes GOAL Arm: Subjects will be asked to complete a survey, complete goal setting conversation with diabetes nurse, and monthly telephonic care management calls. Care management calls include review of 1) risk assessment and treatment preferences, 2) goal setting discussion 3) medication management, and referrals to hospital-based services such as diabetes education classes.

MDG + Community Rx Arm: Subjects will receive the same intervention above as well as receive vetted, personalized referrals near the subject's location to human, social and other community-based supports aligned with their diabetes goals and other needs. Beginning with the first monthly telephone care management call, the nurse will launch CommunityRx, enroll the patient, and utilize NowPow to produce a "prescription" HealtheRx that can be printed, delivered by MyChart, text message, and/or or e-mail, according to the patient's preference. This will be repeated at each subsequent monthly call.

All participants in the study will receive reminders by phone, e-mail, or MyChart message for scheduling monthly calls and follow-up surveys.

Participants in all three arms will complete a baseline survey (by phone, video or online) and at 6 months and 12 months. Please see Table 1 for list of outcomes and corresponding methods to obtain the data. If needed to supplement healthcare utilization data, we will obtain health insurance claims for the participant. The informed consent process will inform study participants of the rationale for accessing these data and request participants' permission to do so, if need be.

Table 1. Outcomes and Data Collection

Aim	Outcome	Source
Aim 1	Shared decision making questionnaire[94,95]	Survey
	Decisional Conflict[96]	Survey
	Documentation of A1C goal	EHR
	Patient self-report of A1C goal	Survey
Aim 2	Diabetes self-efficacy[97]	Survey
	Diabetes self-care inventory[98]	Survey
	Medication adherence	Survey
	Dietary adherence	Survey
	Physical activity adherence [99]	Survey
	Knowledge and utilization of community-based resources[12]	Survey / NowPow
Aim 3	Glucose control (A1C)	EHR or Survey
	Hypoglycemia (self-reported)[81-83]	Survey
	Hypoglycemia requiring medical assistance	EHR
	<u>Geriatric syndromes</u> Depression[100] Falls[101] Cognitive Impairment[102] Frailty[103] Urine Incontinence[104] Polypharmacy	Survey and EHR

	Functional status Disability of (Instrumental) Activities of Daily Living[105,106] Lower Extremity Strength using 5-Repeated Chair Stands[107] Gait speed using 8-Foot Usual Walk[107]	Survey
	Quality of life (SF-8)[108]	Survey
	ED visits and unplanned hospitalizations	EHR/Medicare claims

Following the trial, we will conduct a brief, qualitative research study. Qualitative data collected via focus groups will be used to interpret or triangulate findings from the main trial outcomes analysis. Focus group discussions will probe 1) participants' experiences with the intervention and attention control information; 2) participants' interpretations of preliminary findings, and; 3) participants' thoughts and ideas about opportunities for dissemination of findings to communities of interest.

To support Domain 2 of the qualitative protocol (i.e., participants' interpretations of preliminary findings), we will conduct one interim analysis in March 2024 when 100% of participants have finished their 6-month survey and about 75% participants will have finished their 12-month follow-up survey. The purpose of the interim analysis is to provide findings to share with study participants for their feedback and interpretation of mechanisms. We will not change any intervention components based on the interim analysis findings. The outcomes studied in the interim analysis will be A1C, and self-reported outcome data, including patient self-report of A1C goal, Diabetes Self-Care Inventory, medication adherence, knowledge, use of and need for community-based resources and hypoglycemia.

D. Duration

The duration of the protocol is approximately 12 months. Subjects will be asked to complete surveys upon enrollment, at 6 months, and at 12 months. We anticipate the surveys to take up to 25 minutes to complete. Telephone calls with study team members in all arms should take approximately 10-20 minutes to complete. Qualitative focus groups may take 45-60 minutes to complete.

E. Location

Research under this protocol will be conducted by researchers in the Departments of Internal Medicine at the University of Chicago (located at 5841 S. Maryland Ave., Chicago, IL, 60637). Additional research (e.g., data preparation and analyses) will be conducted in Dr. Elbert Huang's research offices, located in the Medical Center 2007, Room B214 and Dr. Stacy Lindau's research laboratory, located in the Medical Center 2050, rooms R-311 and R-315.

The surveys will be conducted via phone, video, or online (Redcap). Subjects who have technical difficulties completing the survey online may ask to meet with the study team in person to complete the online survey in person, but with support. Support means helping patients login into their MyChart accounts if necessary, supplying a laptop for their use or providing printouts or other help needed to complete the surveys. These meetings will only occur at the University of Chicago Hospitals, and due to the COVID-19 pandemic, may be conducted via secure ZOOM meetings or via telephone.

F. Special Precautions

Protected health information (PHI) will be collected for research purposes and special precautions will be made to protect these data. In addition to the unique identifier applied by REDCap software, we will use the subject's name, telephone number and email address to facilitate scheduling and completion of the follow-up surveys. We will use the subject's name and medical record number (MRN) to access their electronic medical record to assess their eligibility for the study and outcomes data if subjects agree. From EMR data, we will access the participant's health insurance payer and unique beneficiary identification to obtain their health insurance claims, if needed. We will compensate participants by gift card, and will use their name and address for compensation payment purposes.

Certain survey data elements collected in the REDCap database will be sent securely to NowPow, a systematic resource referral platform, to generate the HealtheRx. Elements of PHI sent to NowPow to generate a personalized HealtheRx include: participant name, participant home address, date of birth and other non-PHI data elements. Data will be securely transferred from REDCap to NowPow through a custom secure integration created by the Center for Research Informatics. In addition to other non-PHI data elements, respondent address is necessary to better tailor the community resource information provided on the personalized HealtheRx.

Metadata generated by use of the NowPow system will be provided to the research team via Globus (https://rcc.uchicago.edu/documentation/_build/html/data-transfer/index.html#globus-online) on a regular basis (see documentation below). NowPow is a company serving dozens of blue chip health systems using rigorous data protocols and therefore operates its technology in a manner that meets the strict HIPAA and security criteria standards of these organizations.

Qualitative interviews will be audio recorded and transcribed using AWS Transcribe by Amazon. AWS Transcribe has been reviewed by the University of Chicago Biological Sciences Division's Information Security Office and approved for this use. Interviews will be de-identified upon transcription.

Because PHI will be accessed and collected for this program of research, there is a risk of loss of confidentiality. To protect confidentiality, we will implement a plan to protect data in all its forms from improper use and disclosure using HIPAA compliant policies and procedures; see Section N. Procedures to Maintain Confidentiality for more information.

Use of Globus for file transfer

A Globus endpoint will be created by the Biological Sciences Division's Information Services pointing to the lindau-lab file share on PRFS. The endpoint will be configured to force encryption of the data channel. A dedicated subdirectory within the file share will be created, and a guest collection will be created permitting authorized users to access that subdirectory. NowPow will be granted access to that collection, and will use Globus (either the client or API) to transfer files into the dedicated subdirectory where they may be retrieved by an analyst in the Lindau Lab.

G. Experimental controls and use of placebos

Participants in this study will be enrolled in attention control, the MDG intervention, or MDG + CRx intervention.

Usual care for diabetes at the University of Chicago is constantly evolving and has features that are important to describe and acknowledge. Since 2018, Dr. Huang has been co-chair for diabetes quality improvement at University of Chicago Medicine. University of Chicago has high rates of poor diabetes control based on the quality measure of A1C>9.0%. To reduce rates of poor control, the ambulatory quality improvement team has: 1) conducted system wide outreach to patients to get an A1C test, 2) installed Best Practice Alerts to remind physicians to order lab tests for diabetes, 3) installed point of care testing to primary care clinics, 4) created new drug prescribing SmartSet modules, and 5) organized and vetted patient education materials. University of Chicago also has diabetes education programs, a specialized pharmacist designated to solve problems with high drug prices. This collection of interventions has been associated with steady decline in the rates of poor control (29.2% in April 2019 to 26.6% in March of 2020).

To reduce the chance that benefits from the My Diabetes GOAL arms are due to attention alone, we will also conduct monthly calls to attention control subjects but will not discuss specific issues related to diabetes care. These calls will also help to ensure retention of attention control subjects in the study.

To reduce bias, we will blind participants to the arm of the intervention at the time of enrollment.

H. Type and number of experimental subjects

Individuals will be contacted for enrollment using methods described below in Section P. Recruiting Methods. Individuals will be contacted, screened for inclusion, recruited for study participation and participate in the informed consent process. We plan to enroll up 517 patients (12 in the pilot, 505 in the RCT). We will determine trial arm assignment through a random number generator. Patients will be blinded to study hypotheses and will be unaware of allocation. Our data analyst will be blinded to the treatment allocation of patients.

Inclusion Criteria:

- Males and females 60 years of age or older
- A1C 7.5% or greater
- Clinical encounter at UChicago practice in prior year
- Have access to a cell phone and provides the research interviewer with the cell phone number with internet access OR have a personal email address.

Exclusion Criteria:

- Patients unable to provide consent for themselves (specifically with a diagnosis of Alzheimer's disease and related dementias) and complete outcome assessments
- Terminal illness
- Living in an institutional setting (non-community dwelling)
- Unable to read, write, or speak English or Spanish
- Recent enrollment in My Diabetes GOAL or Community Rx Trials

I. Statistical analysis

An intention-to-treat analysis principle will be applied to all patients' outcomes, regardless of ineligibility and actual intervention provided. Multiple imputation will be used to impute missing

values for those data missing at random.[112] We will conduct analyses using observed data as main analyses and imputed data as part of sensitivity analyses.

Aim 1: To compare continuous outcomes such as the decisional conflict score, we will use a linear mixed model (LMM) over the three study groups. To compare processes that are binary (e.g., patients self-reporting a goal) at 12 months, a chi-squared test and a logistic regression model will be used and the latter method will adjust for patients' potential confounders such as age, gender, race, health status, and duration of diabetes. In addition, we will use the generalized estimating equations (GEE) and generalized linear mixed model (GLMM) (which may be computationally intensive) to model proportion of patients with documented goal over time (baseline and 12 months) and test the effects of treatment, time, and interaction between treatment and time.

Aims 2 and 3: To compare self-care continuous outcomes and clinical continuous outcomes including A1C (primary outcome) over the three study groups, a repeated measure analysis of variance via LMM will be performed to model one outcome over time and test the effects of treatment, time and their interaction. Clinic will be considered as random effects in a LMM to account for within-site association. We will fit an unadjusted model first and then an adjusted model adjusting for baseline outcome and participant-level potential confounders as mentioned above. Normality will be checked and appropriate data transformation will be performed if data highly skewed. The p-value for the group comparison between MDG and MDG+CRx in A1C at 12 months will be used for the primary objective analysis at the two-sided significance level of 5% (consistent to the power justification (below)). Multiple pairwise comparisons will be conducted to compare between groups at each time point and compare the multiple time points within a group. All the multiple comparisons and analyses of all the secondary outcomes will be considered to be exploratory and will not spend the overall type I error rate of 5%. To compare each of binary outcomes such as utilization of community-based resources, we will use GEE and GLMM for group comparisons, as mentioned in analyses of Aim 1. To compare health care use (ED and hospitalizations), we will use both Poisson and negative binomial regression models. If the health care use data are zero-inflated (i.e., >50% of patients who have no service use), we will use both zero-inflated Poisson and zero-inflated negative binomial models.

Sensitivity analyses: We will also assess the impact of our interventions across patient subgroups (age group, health status, baseline A1C group, and diabetes duration with different thresholds).

Interim analyses: We will apply the statistical methods above to all the available data including baseline, all 6-month follow-up data, and about 75% 12-month follow-up data.

Qualitative interview data will be systematically collected and analyzed using rapid qualitative methods.[117] Rapid qualitative methods are well-suited for mixed methods studies and commonly used in implementation science studies when quick understanding of qualitative data is needed to inform next steps or to help interpret or triangulate findings. Rapid qualitative methods use constant comparison of data to inform continued data collection, and analysis is conducted during data collection through the use of text summaries.

Focus groups will be audio-recorded to ensure the accuracy of participants' responses. Researchers will create a data analysis template that includes a neutral domain name that corresponds with each focus group question. Trained researchers will listen to the audio of each focus group session and create a summary of each domain, with space for other observations that may occur during data collection. Then, all text summaries will be collated into one matrix (focus group x domain) and assessed for similarities and differences across responses and by

domain. Matrices may also be set up by individual focus group or by respondent study arm (e.g., pooling all responses for those who participated in the intervention group), if appropriate. Matrices will be analyzed for gaps in the data, emergent themes and to generate summaries of responses from participants in each study arm.

Addition of a Usual Care Arm

To assess whether the experience of the participants within the trial differs from patients at UCM who did not participate in the trial during the study timeframe, we will include a Usual Care Arm based on the original eligibility criteria used to generate the ACRES recruitment lists of patients and include retrospective outcomes data (A1C and medications between 9-23-2020 to 9-16-2024).

Among the 167 patients who were enrolled in attention control arm, 133 patients had an A1C result in EHR at 12 month follow up by May of 2024. These patients had an average reduction of 0.97% (SD 1.64%) in A1C from baseline to 12 month. Based on our literature review, we found no consistent pattern for A1C change in usual care arms in behavioral intervention trials published in 2023 and 2024.[118-129] Based on this finding, we assume no A1C change will be observed in our usual care arm. By a two-sample t-test, a sample size of 39 in the usual care arm would guarantee ≥ 90% power to detect at least 0.97% difference in A1C with the common SD of 1.64% between the attention control arm and usual care arm with a two-sided significant level of 5%. To account for up to 20% of subject attrition at 12 months, the final total sample size of the usual care arm is 49.

For simplicity, we plan to conduct a 1:1 matching for the usual care arm vs attention control arm (i.e., 167 patients will be included in the usual care arm). The matching procedure involves three steps. First, we identify all the potential usual care arm patients using the original eligibility criteria and have CRI generate a deidentified (except month and year of dates) list of patients at UCM excluding those who were enrolled in the study and ages over 89. Second, we will only include patients who have an A1C >= 7.5% within our trial recruitment time (09-23-2021 to 07-07-2023). Third, we use R MatchIt package to perform the matching. We use exact matching on A1C group (7.5-8, 8-8.5, 8.5-9.5, 9.5+) and the calendar quarter using month and year when the A1C test was conducted. This step ensures patients who are enrolled in the usual care arm have similar A1C values and baseline dates as the attention control arm. We will also use propensity score matching on other covariates, such as age, gender, race/ethnicity. After the matching, we test the balance of the data on these covariates.

J. Potential risks and benefits

This program of research involves no more than minimal risk or no more risk than is encountered in routine medical and psychological examinations. The risks of participation in this protocol include a potential loss of confidentiality or psychological or emotional discomfort associated with the interview questions. Every effort will be made to ensure subject confidentiality and that risks due to loss of confidentiality are minimal compared to the protocols in place to protect human subjects' data. To date, more than 113,000 individuals have participated in CommunityRx intervention studies with no known adverse events or breaches of confidentiality. All data collected from human subjects will be collected using standard survey procedures. The surveys will be conducted via telephone or online. Psychological and/or emotional discomfort associated with the survey questions is possible. Subjects will be informed that they can decline to answer any question and can terminate the survey at any time. Explanatory statements will be included in the surveys to help the interviewer monitor and respond appropriately to discomfort, including termination of the survey if necessary.

Alternatives to participation include not participating in the research; participation is completely voluntary. Additional protections against these risks are described in Sections M and N, Informed Consent and Confidentiality, respectively.

There is no direct benefit to human subjects involved in the research beyond the information provided during attention control and the My Diabetes Goal and CommunityRx interventions. However, subjects may see an improvement in their health through additional screening for risks associated with their chronic disease, improved communication with their physician, referrals to beneficial resources that they may not be aware of, which could improve patient outcomes.

Risks include a breach of confidentiality and psychological or emotional discomfort associated with the interview questions; both minimal and reasonable in relation to the anticipated benefits to research participants and people with Diabetes.

K. Monitoring of safety

The proposed data collection presents no more than minimal risk or no more risk than is encountered in routine medical or psychological examinations. As described, no surveys will be conducted without explicit documentation of informed consent and individuals will be provided with appropriate information about confidentiality when enrolling in the study and will indicate acceptance of these risks upon consent. Because we are not proposing a multi-site clinical trial, a Phase III trial, or a drug study, this study will not employ a Data and Safety Monitoring Board. Procedures are in place to ensure confidentiality and provide full informed consent as discussed below.

The research team has listed the Principal Investigators and study coordinator phone numbers on all study correspondence and forms. The purpose of the phone numbers is to provide respondents with a number to call if they have questions about any aspect of the study.

The subjects will be monitored via their survey responses and screened for any potential risks for harm. If the research study diabetes care manager conducts telephonic care management with patients, they will also be monitored for safety by a registered nurse as the diabetes care manager is a registered nurse.

Research staff will strictly adhere to the procedures for enrolling participants and collecting data as outlined by the investigators. At the conclusion of the study, all hard copy materials, with the exception of the consent copies, will be destroyed and electronic files will be deleted or archived in password-protected files. Informed consent documents (paper or electronic) will be stored for at least 6 years following the completion of the study (defined by the last publication related to the study). Due to the small sample sizes associated with the pretest, these data will not be made publicly available.

We will review the contents of the informed consent document together with patients, and ask follow up questions about the study. We will make sure to let patients know they can ask questions they may have, and that they understand that participation in the study is completely voluntary.

Also, because the baseline survey is interviewer-administered, the research assistants will continue to query whether or not the subject continues to understand their participation throughout the study. Subjects can refuse to answer any question or decline to participate at any time.

If they opt to participate and complete the survey, we will continue to check-in with them and ask follow up questions about their participation in the study. We will withdraw them from the study if requested at any time, and ensure that they understand what the purpose of the study is.

We have listed the Principal Investigators' and study coordinator phone numbers on all study correspondence and forms. The purpose of the phone numbers is to provide respondents with a number to call if they have questions about any aspect of the study. If concerns regarding a participant's safety are endorsed within the health-related social needs screening, REDCap will deliver an alert to the research assistant (RA) after survey completion that the participant screened positive for safety concerns, without revealing the survey contents. The respondent will receive the contact information for the 24/7 domestic abuse hotline. During the study, should a subject express intent to harm themselves or others, we will contact a health or public safety professional. We will give only the subject's name, contact information, and why we feel he or she is at risk of harming themselves or others. This report will not be linked to their survey information. Subjects have the right to refuse to speak to the mental health professional. If the survey procedure results in the observation or suspicion of elder or child abuse, all research personnel will act in compliance with Illinois State law in regards to mandatory reporting of abuse.

L. Payment

All subjects enrolled in the trial will be paid for completing each survey. Subjects enrolled in the study will receive a $25 gift card by mail in compensation for completion of the baseline survey (approximately 25 minutes). They will receive $50 in compensation after the completion of the 6 month survey. They will finally receive $75 after completing the 12 month survey. Subjects may receive up to $150 total for completing the study. Compensation will not be prorated for partial completion of surveys but every effort will be made to allow for ample time to complete the surveys and participants can refuse to answer any question they do not want to answer. Participation is voluntary.

Subjects will be entered into a raffle to win a $50 gift card if they participate in 4 monthly phone calls (up to 3 times in the study period). Each verification (one at 4-months, one at 8-months, and one at 12-months) counts as one raffle entry. Within 3 months of each verification, they will receive an email notification about whether they are the raffle winner. If they're the winner, they will receive their compensation by mail within 4 weeks of e-mail notification.

Subjects who complete the qualitative focus group will receive a $50 Amazon or Target gift card by mail upon completion of the focus group.

M. Informed Consent

The research team will obtain informed consent from all subjects and will use paper or an e-consent process developed in partnership with REDCap and used previously by our research team.

We will call patients and ask them if they would be interested in participating in the study. If they are interested, subjects will have the option to have the consent e-mailed, faxed, or mailed to them for review. Subjects may also have the option of e-signing the consent in a form in REDCap, or meeting a member of the study team to sign the consent in person. Once received, we will review the document together and if the patient consents to participate, they will sign the

document and either fax or email a scanned copy of the consent back to the research office, or mail it back to the study research office.

Research interviewers will guide subjects through the informed consent document, providing statements to address: that the study involves research; the study's purpose, duration, procedures followed, risks and benefits, alternatives to participation, and confidentiality of records; to whom they should direct questions or contact in case of research-related injury; and statements regarding voluntary participation, refusal to participate, and discontinuation of participation. The researcher will provide adequate time for the potential subject to ask questions and will answer these questions before requesting their signature to document consent. The researcher will walk the subject through the consent process via phone or video and, if they choose to participate, they will electronically sign the consent form in REDCap by typing their full name into the signature field and verifying their identity by entering their date of birth. A copy of the signed consent form will be shared with them via e-mail.

We are requesting a waiver of documentation of consent for participation in the qualitative interviews/focus groups, and will obtain verbal consent immediately before data collection. Similar to the process for consent for participation in the RCT, researchers will guide participants through an informed consent script and ask for their verbal consent before proceeding with the interview. A copy of the informed consent script will be emailed to the participants for their records. The informed consent document is enclosed in this submission for review.

No surveys or interviews with human subjects will be conducted without explicit documentation of the informed consent process executed with each participant. Paper consent forms will be printed in large font and written in easily understandable language. Paper consent forms will be printed in duplicate, with a copy each going to the respondent and to the Huang and Lindau Laboratory receipt control. Paper forms will be kept secure in locked cabinets in locked rooms. Consent documents will be received at the Huang and Lindau Laboratory by Ms. Nathan, Senior Research Project Manager, to confirm participation in the study for data collection, validation, and data analysis purposes.

N. Confidentiality

The proposed research with human subjects, presents no more than minimal risk or no more risk than is encountered in routine psychological examinations. Any potential risks may be due to emotional or psychological discomfort associated with the surveys or a breach of confidentiality. As described in detail above, no surveys will be completed without explicit documentation of informed consent and written authorization for the use and disclosure of identifiable data will be sought and obtained for all subjects enrolled in this study. All individuals will be provided appropriate information about privacy and confidentiality when enrolling in the study and will indicate acceptance of these risks upon consent/authorization.

The research team has strict and secure procedures for protecting against and minimizing potential risks to human subjects' data. All survey data will be entered directly into REDCap, a password-protected database managed by the Center for Research Informatics (CRI) at the University of Chicago (cri.uchicago.edu). CRI provides a HIPAA-compliant data storage and computing environment that has achieved security accreditation by the Biological Sciences Division's Risk Management Group. Data will be saved to the secure servers at the University of Chicago via a secure wireless connection on a secure, password-protected tablet, or research

staff will enter REDCap data directly on departmental computers using the secure, password-protected network. Data are backed up at the end of each collection day. Data will never be stored locally.

We will use Mosio, a text messaging platform, to facilitate the text message protocol for human subjects in the intervention group and manage survey scheduling and reminders for all participants. To this end, REDCap will retain certain data elements to Mosio via REDCap's secure API. Mosio provides a secure messaging and data storage environment and has been approved for use by the University of Chicago Information Security Office. Only approved researchers on the study team will have access to data stored by Mosio and will have the ability to securely download data directly to password-protected computers.

REDCap will integrate electronically with NowPow (www.nowpow.com) to facilitate generation of the HealtheRx. Data will be pushed from REDCap to NowPow via a custom secure integration to create the participant's profile in NowPow, including name, address, date of birth and other non-PHI data. Any data sent to NowPow from REDCap to generate the personalized HealtheRx will be assigned a secondary unique ID in order to prevent any connection to the subjects' responses in REDCap. NowPow is seamless, secure and HIPAA-compliant. Data are backed up automatically and encrypted in-transit, at-rest, and end-to-end. De-identified metadata will be transferred to researchers in the Lindau Laboratory using the Globus system; details described above. All devices used by researchers to collect or access research files will be encrypted. Only approved research analysts will have access to files that link participant's PHI to their unique identifiers for the purposes of creating analytic datasets.

REDCap will integrate electronically with the Mosio texting platform (www.mosio.com) to facilitate the text message protocol for human subjects in the intervention group and manage survey scheduling and reminders for all participants. To this end, REDCap will push the subject's name, telephone number and date of enrollment to Mosio via REDCap's secure API. Mosio provides a secure messaging and data storage environment and has been approved for use by the University of Chicago Information Security Office. Only approved researchers on the study team will have access to data stored by Mosio and will have the ability to securely download data directly to computers within the UCM network.

All hard copies of project materials will be stored in locked file cabinets in locked offices at University of Chicago. Laptop computers used to collect data will be encrypted and password protected. All data transmitted to secure servers will be encrypted. Analytic files will either be de-identified prior to analysis or limited to the minimum amount of data necessary to accomplish the intended research purposes per the HIPAA Privacy Rule. Any analytic datasets will limit the use or disclosure of PHI to the minimum necessary, if any at all, to accomplish the intended research purposes. Only IRB-approved researchers on this protocol will have access to data. These controls meet or exceed the strictness of practices legislated and enforced by the University of Chicago Biological Sciences Division and hospitals for protected health information.

Procedures are in place to ensure confidentiality and provide informed consent as discussed above. Numeric coding of surveys/interviews and secure containment of files that link participant's responses from PHI will also minimize this risk. Finally, the research team will provide a contact phone number that will be included on all study correspondence and forms. The purpose of this phone number is to provide respondents with a single number to call if they have questions about any aspect of the study.

O. Bibliography (please refer to the end of the document)

P. Recruiting methods

Given the shift to telehealth appointments at UCM and shelter-in-place orders due to the COVID-19 pandemic, we are planning to conduct this study completely remotely. We will also work with CRI to create an ACRES Report to obtain a list of eligible patients. Researchers will contact patients by phone and explain that patients may be eligible for a research study and screen patients for eligibility if the patient is interested. If the patient is eligible, researchers will send them an e-consent form using REDCap that is able to be filled out online or other methods described earlier. The e-consent process is one that has been developed successfully in our lab.

Dr. Elbert Huang and Dr. Stacy Lindau lead the My Diabetes, My Community trial - a three-arm parallel pragmatic randomized controlled trial among older, predominantly African American patients with type 2 diabetes seen at the University of Chicago. A dementia diagnosis and inability to complete the study on their own are two of the exclusion criteria for the trial. During screening, it is possible for research assistants to contact patients living with dementia or their caregivers. When a patient with dementia and their caregiver are identified and screen out in the MDMC trial, there is an opportunity to ask whether they would be interested in participating in another trial they may be eligible for - the CommunityRx-Caregiver trial. The MDMC research assistant would ask if the patient is interested in hearing more about a trial they may be eligible for and whether it is ok to share their phone number with the CommunityRx-Caregiver team. In receiving verbal consent to share their phone number with the CommunityRx-Caregiver team, the MDMC research assistant will document this in the patients' screening data in REDCap and notify the MDMC Project Manager (PM). The MDMC PM will then flag this record to the CommunityRx-Caregiver PM. Jyotsna Jagai, who is also on the MDMC staff. A CommunityRx-Caregiver team member will then follow-up with the patient about participating in the CommunityRx-Caregiver study.

If we are able to safely approach patients in-person again, as we have done in prior trials in this setting, we will review the informed consent and study procedures with them.

In addition to recruiting via ACRES reports and CRI data mart, we will use the ITMs research profile website, https://bethenewnormal.org/, and researchmatch.org to post our study and to use it as a recruiting tool for eligible subjects.

Once their participation in the RCT is complete, a purposeful sample of participants will be approached for inclusion in a focus group. Researchers will contact participants by email, text message and phone. In order to appropriately capture data relative to each study arm, we will purposefully recruit participants based on study arm.

Research interviewers will explain that the participant may be eligible for a research study and, if interested, further screen for eligibility. Recruitment scripts for the various modes of contact have been submitted for review with this protocol. If eligible, researchers will guide participants through the informed consent process as described in Section M. Informed Consent.

Q. Notification of physician

Notification of the subject's treating physician for permission to enroll will occur using a multi-pronged approach. First, we will educate all treating physicians and residents working in the target clinics about the study prior to study enrollment and give treating physicians (along with their patients) the opportunity to opt out of study participation. Secondly, we will use these

education sessions to identify how treating physicians wish to be contacted for permission (e.g., via text, email, phone, text page or through the electronic medical record system). We will use that communication as documentation of treating physician permission.

R. Anticipated coordination

Inter-departmental faculty coordination will be facilitated by regular research meetings attended by Drs. and Huang (PIs) and other Co-Investigators and key personnel. Faculty will also regularly communicate by email and phone calls as necessary. Co-Principal Investigator Dr. Elbert Huang (Professor of Medicine) will oversee enrollment of subjects in the Primary Care Clinic and the University of Chicago PBRN Clinics (https://pbrn.uchicago.edu/).

S. Pregnancy test

Not applicable.

T. Exclusion of women, minorities and/or children

This study will not exclude women, minorities or children.

U. Drugs

No drugs will be given to subjects as part of this study.

References

REFERENCES

1. Huang ES, Laiteerapong N, Liu JY, John PM, Moffet HH, Karter AJ. Rates of complications and mortality in older patients with diabetes mellitus: the diabetes and aging study. *JAMA Intern Med.* Feb 1 2014;174(2):251-258.
2. De Marchis EH, Hessler D, Fichtenberg C, et al. Part I: A Quantitative Study of Social Risk Screening Acceptability in Patients and Caregivers. *Am. J. Prev. Med.* Dec 2019;57(6 Suppl 1):S25-S37.
3. Brown AF, Mangione CM, Saliba D, Sarkisian CA, California Healthcare Foundation/American Geriatrics Society Panel on Improving Care for Elders with D. Guidelines for improving the care of the older person with diabetes mellitus. *J. Am. Geriatr. Soc.* May 2003;51(5 Suppl Guidelines):S265-280.
4. Inzucchi SE, Bergenstal RM, Buse JB, et al. Management of hyperglycemia in type 2 diabetes: a patient-centered approach: position statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care.* Jun 2012;35(6):1364-1379.
5. Moreno G, Mangione CM, Kimbro L, Vaisberg E. Guidelines abstracted from the American Geriatrics Society Guidelines for Improving the Care of Older Adults with Diabetes Mellitus: 2013 update. *J. Am. Geriatr. Soc.* Nov 2013;61(11):2020-2026.
6. Kirkman MS, Briscoe VJ, Clark N, et al. Diabetes in older adults. *Diabetes Care.* Dec 2012;35(12):2650-2664.
7. Berkowitz SA, Karter AJ, Corbie-Smith G, et al. Food Insecurity, Food "Deserts," and Glycemic Control in Patients With Diabetes: A Longitudinal Analysis. *Diabetes Care.* Mar 19 2018.

8. Munshi MN, Segal AR, Suhl E, et al. Assessment of barriers to improve diabetes management in older adults: a randomized controlled study. *Diabetes Care.* Mar 2013;36(3):543-549.
9. Huang ES, Nathan AG, Cooper JM, et al. Impact and Feasibility of Personalized Decision Support for Older Patients with Diabetes: A Pilot Randomized Trial. *Medical decision making : an international journal of the Society for Medical Decision Making.* Jul 2017;37(5):611-617.
10. Grey M, Schulman-Green D, Knafl K, Reynolds NR. A revised Self- and Family Management Framework. *Nurs. Outlook.* Mar-Apr 2015;63(2):162-170.
11. Lindau ST, Makelarski J, Abramsohn E, et al. CommunityRx: A Population Health Improvement Innovation That Connects Clinics To Communities. *Health Aff. (Millwood).* Nov 01 2016;35(11):2020-2029.
12. Lindau ST, Makelarski JA, Abramsohn EM, et al. CommunityRx: A Real-World Controlled Clinical Trial of a Scalable, Low-Intensity Community Resource Referral Intervention. *Am. J. Public Health.* Apr 2019;109(4):600-606.
13. Tung EL, Abramsohn EM, Boyd K, et al. Impact of a Low-Intensity Resource Referral Intervention on Patients' Knowledge, Beliefs, and Use of Community Resources: Results from the CommunityRx Trial. *J. Gen. Intern. Med.* Mar 2020;35(3):815-823.
14. Montori VM, Gafni A, Charles C. A shared treatment decision-making approach between patients with chronic conditions and their clinicians: the case of diabetes. *Health Expect.* Mar 2006;9(1):25-36.
15. Peek ME, Lopez FY, Williams HS, et al. Development of a Conceptual Framework for Understanding Shared Decision making Among African-American LGBT Patients and their Clinicians. *J. Gen. Intern. Med.* Jun 2016;31(6):677-687.
16. Schulman-Green D, Jaser S, Martin F, et al. Processes of self-management in chronic illness. *J Nurs Scholarsh.* Jun 2012;44(2):136-144.
17. Burwell SM. Setting value-based payment goals--HHS efforts to improve U.S. health care. *The New England journal of medicine.* Mar 5 2015;372(10):897-899.
18. Huang ES, Basu A, O'Grady M, Capretta JC. Projecting the future diabetes population size and related costs for the U.S. *Diabetes Care.* Dec 2009;32(12):2225-2229.
19. Severe Outcomes Among Patients with Coronavirus Disease 2019 (COVID-19) - United States, February 12-March 16, 2020. *MMWR. Morb. Mortal. Wkly. Rep.* Mar 27 2020;69(12):343-346.
20. Preliminary Estimates of the Prevalence of Selected Underlying Health Conditions Among Patients with Coronavirus Disease 2019 - United States, February 12-March 28, 2020. *MMWR. Morb. Mortal. Wkly. Rep.* Apr 3 2020;69(13):382-386.
21. Laiteerapong N, Karter AJ, Liu JY, et al. Correlates of quality of life in older adults with diabetes: the diabetes & aging study. *Diabetes Care.* Aug 2011;34(8):1749-1753.
22. Sudore RL, Karter AJ, Huang ES, et al. Symptom burden of adults with type 2 diabetes across the disease course: diabetes & aging study. *J. Gen. Intern. Med.* Dec 2012;27(12):1674-1681.
23. Biessels GJ, Staekenborg S, Brunner E, Brayne C, Scheltens P. Risk of dementia in diabetes mellitus: a systematic review. *Lancet Neurol.* Jan 2006;5(1):64-74.
24. Gregg EW, Li Y, Wang J, et al. Changes in diabetes-related complications in the United States, 1990-2010. *N. Engl. J. Med.* Apr 17 2014;370(16):1514-1523.
25. Saydah SH, Imperatore G, Beckles GL. Socioeconomic status and mortality: contribution of health care access and psychological distress among U.S. adults with diagnosed diabetes. *Diabetes Care.* Jan 2013;36(1):49-55.
26. Tao X, Li J, Zhu X, et al. Association between socioeconomic status and metabolic control and diabetes complications: a cross-sectional nationwide study in Chinese adults with type 2 diabetes mellitus. *Cardiovasc. Diabetol.* April 05 2016;15(1):61.

27. Rawshani A, Svensson AM, Rosengren A, Eliasson B, Gudbjornsdottir S. Impact of Socioeconomic Status on Cardiovascular Disease and Mortality in 24,947 Individuals With Type 1 Diabetes. *Diabetes Care.* Aug 2015;38(8):1518-1527.
28. Osborn CY, de Groot M, Wagner JA. Racial and ethnic disparities in diabetes complications in the northeastern United States: the role of socioeconomic status. *J. Natl. Med. Assoc.* Spring 2013;105(1):51-58.
29. Kanaya AM, Adler N, Moffet HH, et al. Heterogeneity of diabetes outcomes among asians and pacific islanders in the US: the diabetes study of northern california (DISTANCE). *Diabetes Care.* Apr 2011;34(4):930-937.
30. U.K. Prospective Diabetes Study Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet.* 1998;352(9131):837-853.
31. Holman RR, Paul SK, Bethel MA, Matthews DR, Neil HA. 10-year follow-up of intensive glucose control in type 2 diabetes. *N. Engl. J. Med.* Oct 9 2008;359(15):1577-1589.
32. Gerstein HC, Miller ME, Byington RP, et al. Effects of intensive glucose lowering in type 2 diabetes. *N. Engl. J. Med.* Jun 12 2008;358(24):2545-2559.
33. Zinman B, Wanner C, Lachin JM, et al. Empagliflozin, Cardiovascular Outcomes, and Mortality in Type 2 Diabetes. *The New England journal of medicine.* Nov 26 2015;373(22):2117-2128.
34. Ryan DH, Espeland MA, Foster GD, et al. Look AHEAD (Action for Health in Diabetes): design and methods for a clinical trial of weight loss for the prevention of cardiovascular disease in type 2 diabetes. *Control. Clin. Trials.* Oct 2003;24(5):610-628.
35. Gregg EW, Chen H, Wagenknecht LE, et al. Association of an intensive lifestyle intervention with remission of type 2 diabetes. *JAMA.* Dec 19 2012;308(23):2489-2496.
36. Rejeski WJ, Ip EH, Bertoni AG, et al. Lifestyle change and mobility in obese adults with type 2 diabetes. *The New England journal of medicine.* Mar 29 2012;366(13):1209-1217.
37. Sinclair A, Morley JE, Rodriguez-Manas L, et al. Diabetes mellitus in older people: position statement on behalf of the International Association of Gerontology and Geriatrics (IAGG), the European Diabetes Working Party for Older People (EDWPOP), and the International Task Force of Experts in Diabetes. *J Am Med Dir Assoc.* Jul 2012;13(6):497-502.
38. Munshi M. Managing the "geriatric syndrome" in patients with type 2 diabetes. *Consult Pharm.* Apr 2008;23 Suppl B:12-16.
39. Zhang JX, Bhaumik D, Huang ES, Meltzer DO. Change in Insurance Status and Cost-related Medication Non-adherence among Older U.S. Adults with Diabetes from 2010 to 2014. *J Health Med Econ.* 2018;4(2).
40. Langford AT, Sawyer DR, Gioimo S, Brownson CA, O'Toole ML. Patient-centered goal setting as a tool to improve diabetes self-management. *The Diabetes educator.* Jun 2007;33 Suppl 6:139S-144S.
41. Haas L, Maryniuk M, Beck J, et al. National standards for diabetes self-management education and support. *Diabetes Care.* Jan 2014;37 Suppl 1:S144-153.
42. Peek ME, Odoms-Young A, Quinn MT, Gorawara-Bhat R, Wilson SC, Chin MH. Race and shared decision-making: perspectives of African-Americans with diabetes. *Soc. Sci. Med.* Jul 2010;71(1):1-9.
43. Williams GC, Lynch M, Glasgow RE. Computer-assisted intervention improves patient-centered diabetes care by increasing autonomy support. *Health psychology : official journal of the Division of Health Psychology, American Psychological Association.* Nov 2007;26(6):728-734.
44. Robert Wood Johnson Foundation. Health Care's Blind Side: Unmet Social Needs Leading To Worse Health. 2011.

45. Bachrach DP, H; Wallis, K; Lipson, M. Addressing Patients' Social Needs: An Emerging Business Case for Provider Investment. *The Commonwealth Fund.* 2014(https://www.commonwealthfund.org/publications/fund-reports/2014/may/addressing-patients-social-needs-emerging-business-case-provider).
46. Valentijn PP, Schepman SM, Opheij W, Bruijnzeels MA. Understanding integrated care: a comprehensive conceptual framework based on the integrative functions of primary care. *Int J Integr Care.* Jan-Mar 2013;13:e010.
47. Lai YF, Lum AYW, Ho ETL, Lim YW. Patient-provider disconnect: A qualitative exploration of understanding and perceptions to care integration. *PLoS One.* 2017;12(10):e0187372.
48. Wagner L, Lacey MD. The hidden costs of cancer care: an overview with implications and referral resources for oncology nurses. *Clin J Oncol Nurs.* Jun 2004;8(3):279-287.
49. Billioux A, Verlander K, Anthony S, Alley DE. Standardized screening for health-related social needs in clinical settings: The Accountable Health Communities screening tool 2017. https://nam.edu/wpcontent/uploads/2017/05/Standardized-Screening-for-Health-Related-Social-Needs-in-ClinicalSettings.pdf.
50. *Integrating Social Care into the Delivery of Health Care*. Washington, D.C.: National Academy of Medicine; 2019.
51. Grey M, Knafl K, McCorkle R. A framework for the study of self- and family management of chronic conditions. *Nurs. Outlook.* Sep-Oct 2006;54(5):278-286.
52. Gill TM. Geriatric medicine: it's more than caring for old people. *Am. J. Med.* 2002;113:85-90.
53. Lindau ST, Makelarski JA, Chin MH, et al. Building community-engaged health research and discovery infrastructure on the South Side of Chicago: science in service to community priorities. *Prev. Med.* Mar-Apr 2011;52(3-4):200-207.
54. Peek ME, Ferguson MJ, Roberson TP, Chin MH. Putting theory into practice: a case study of diabetes-related behavioral change interventions on Chicago's South Side. *Health Promot Pract.* Nov 2014;15(2 Suppl):40S-50S.
55. Chin MH, Goddu AP, Ferguson MJ, Peek ME. Expanding and sustaining integrated health care-community efforts to reduce diabetes disparities. *Health Promot Pract.* Nov 2014;15(2 Suppl):29S-39S.
56. Huang ES. Goal setting in older adults with diabetes. In: Munshi MN, Lipsitz LA, eds. *Geriatric Diabetes*. New York: Informa Healthcare USA; 2007.
57. Huang ES, Gorawara-Bhat R, Chin MH. Self-reported goals of older patients with type 2 diabetes mellitus. *J. Am. Geriatr. Soc.* Feb 2005;53(2):306-311.
58. Huang ES, Brown SES, Meltzer DO. Older patients' preferences regarding diabetes-related treatments and complications. *J. Am. Geriatr. Soc.* 2006;54(4 Supplement):S6.
59. Peek ME, Wilson SC, Gorawara-Bhat R, Odoms-Young A, Quinn MT, Chin MH. Barriers and facilitators to shared decision-making among African-Americans with diabetes. *J. Gen. Intern. Med.* Oct 2009;24(10):1135-1139.
60. Huang ES, Nathan AG, Cooper JM, et al. Impact and Feasibility of Personalized Decision Support for Older Patients with Diabetes: A Pilot Randomized Trial. *Medical decision making : an international journal of the Society for Medical Decision Making.* Jun 16 2016.
61. Huang ES, Gandra N, Zhang Q, Chin MH, Meltzer DO. The impact of functional status and comorbid illness on the expected benefits of intensive glucose control in older diabetes patients. *J. Am. Geriatr. Soc.* 2007;55(4 Supplement):S213.
62. Lee SJ, Lindquist K, Segal MR, Covinsky KE. Development and validation of a prognostic index for 4-year mortality in older adults. *JAMA.* Feb 15 2006;295(7):801-808.
63. Makelarski JA, Lindau ST, Fabbre VD, et al. Are your asset data as good as you think? Conducting a comprehensive census of built assets to improve urban population health.

Journal of urban health : bulletin of the New York Academy of Medicine. Aug 2013;90(4):586-601.
64. Lindau ST, Vickery KD, Choi H, Makelarski J, Matthews A, Davis M. A Community-Powered, Asset-Based Approach to Intersectoral Urban Health System Planning in Chicago. *Am. J. Public Health.* Oct 2016;106(10):1872-1878.
65. Lindau ST, James R, Makelarski JA, Sanders E, Johnson D. Comments From the South Side of Chicago on New Haven's Inspiring Initiative. *Am. J. Public Health.* Jul 2012;102(7):e3-4; author reply e4-5.
66. Andersen RM. Revisiting the behavioral model and access to medical care: does it matter? *J. Health Soc. Behav.* Mar 1995;36(1):1-10.
67. Andersen RM, Rice T, Kominski G. *Changing the U.S. Health Care System: Key Issues in Health Services Policy and Management.* Vol 3. San Francisco: Jossey-Bass; 2007.
68. Chopra A. Calling All Innovators – Health Care Innovation Challenge Open for Great Ideas 2011; https://www.whitehouse.gov/blog/2011/12/07/calling-all-innovators-health-care-innovation-challengeopen-great-ideas.
69. International RTI. Evaluation of the Health Care Innovation Awards: Community Resource Planning, Prevention, and Monitoring. Third Annual Report 2017. https://downloads.cms.gov/files/cmmi/hcia-communityrppm-thirdannualrpt.pdf.
70. Bandura A. *Self efficacy: the exercise of control*. New York: WH Freeman; 1997.
71. Bandura A. Guide for constructing self-efficacy scales. Self-Efficacy Beliefs of Adolescents: Information Age Publishing; 2006:307-337.
72. Jennings LA, Reuben DB, Evertson LC, et al. Unmet needs of caregivers of individuals referred to a dementia care program. *J. Am. Geriatr. Soc.* Feb 2015;63(2):282-289.
73. Gallagher D, Ni Mhaolain A, Crosby L, et al. Self-efficacy for managing dementia may protect against burden and depression in Alzheimer's caregivers. *Aging & mental health.* Aug 2011;15(6):663-670.
74. Churchill SS, Kieckhefer GM. One Year Follow-up of Outcomes from the Randomized Clinical Trial of the Building on Family Strengths Program. *Matern Child Health J.* Jun 2018;22(6):913-921.
75. Ryan P, Sawin KJ. The Individual and Family Self-Management Theory: background and perspectives on context, process, and outcomes. *Nurs. Outlook.* Jul-Aug 2009;57(4):217-225 e216.
76. Ciolino JD, Jackson KL, Liss DT, et al. Design of healthy hearts in the heartland (H3): A practice-randomized, comparative effectiveness study. *Contemporary clinical trials.* Aug 2018;71:47-54.
77. Makelarski JA, DePumpo M, Boyd K, et al. Implementation of Systematic Community Resource Referrals at Small Primary Care Practices to Promote Cardiovascular Disease Self-Management. *Journal for healthcare quality : official publication of the National Association for Healthcare Quality.* Nov 20 2019.
78. Juszczak E, Altman DG, Hopewell S, Schulz K. Reporting of Multi-Arm Parallel-Group Randomized Trials: Extension of the CONSORT 2010 Statement. *JAMA.* Apr 23 2019;321(16):1610-1620.
79. Huang ES, Brown SE, Ewigman BG, Foley EC, Meltzer DO. Patient perceptions of quality of life with diabetes-related complications and treatments. *Diabetes Care.* Oct 2007;30(10):2478-2483.
80. Karter AJ, Warton EM, Lipska KJ, et al. Development and Validation of a Tool to Identify Patients With Type 2 Diabetes at High Risk of Hypoglycemia-Related Emergency Department or Hospital Use. *JAMA Intern Med.* Oct 1 2017;177(10):1461-1470.
81. Clarke WL, Cox DJ, Gonder-Frederick LA, Julian D, Schlundt D, Polonsky W. Reduced awareness of hypoglycemia in adults with IDDM. A prospective study of hypoglycemic frequency and associated symptoms. *Diabetes Care.* Apr 1995;18(4):517-522.

82. Moffet HH, Adler N, Schillinger D, et al. Cohort Profile: The Diabetes Study of Northern California (DISTANCE)--objectives and design of a survey follow-up study of social health disparities in a managed care population. *Int. J. Epidemiol.* Feb 2009;38(1):38-47.
83. 6. Glycemic Targets: Standards of Medical Care in Diabetes-2020. *Diabetes Care.* Jan 2020;43(Suppl 1):S66-S76.
84. Chien-Wen T, Phillips RL, Green LA, Fryer GE, Dovey SM. What physicians need to know about seniors and limited prescription benefits, and why. *Am. Fam. Physician.* Jul 15 2002;66(2):212.
85. Piette JD, Heisler M, Wagner TH. Cost-related medication underuse: do patients with chronic illnesses tell their doctors? *Arch. Intern. Med.* Sep 13 2004;164(16):1749-1755.
86. Chew LD, Bradley KA, Boyko EJ. Brief questions to identify patients with inadequate health literacy. *Fam. Med.* Sep 2004;36(8):588-594.
87. Sarkar U, Schillinger D, Lopez A, Sudore R. Validation of self-reported health literacy questions among diverse English and Spanish-speaking populations. *J. Gen. Intern. Med.* Mar 2011;26(3):265-271.
88. Hager ER, Quigg AM, Black MM, et al. Development and validity of a 2-item screen to identify families at risk for food insecurity. *Pediatrics.* Jul 2010;126(1):e26-32.
89. Ross CE, Wu CL. The links beweteen education and health. *Am. Sociol. Rev.* 1995;60(5):719-745.
90. Ramirez-Zohfeld V, Seltzer A, Xiong L, Morse L, Lindquist LA. Use of Electronic Health Records by Older Adults, 85 Years and Older, and Their Caregivers. *J. Am. Geriatr. Soc.* Mar 11 2020.
91. Schneider J, Makelarski JA, Van Haitsma M, et al. Differential access to digital communication technology: association with health and health survey recruitment within an African-American underserviced urban population. *Journal of urban health : bulletin of the New York Academy of Medicine.* Jun 2011;88(3):479-492.
92. 5. Facilitating Behavior Change and Well-being to Improve Health Outcomes: Standards of Medical Care in Diabetes-2020. *Diabetes Care.* Jan 2020;43(Suppl 1):S48-S65.
93. 12. Older Adults: Standards of Medical Care in Diabetes-2020. *Diabetes Care.* Jan 2020;43(Suppl 1):S152-S162.
94. Kriston L, Scholl I, Holzel L, Simon D, Loh A, Harter M. The 9-item Shared Decision Making Questionnaire (SDM-Q-9). Development and psychometric properties in a primary care sample. *Patient Educ. Couns.* Jul 2010;80(1):94-99.
95. Doherr H, Christalle E, Kriston L, Harter M, Scholl I. Use of the 9-item Shared Decision Making Questionnaire (SDM-Q-9 and SDM-Q-Doc) in intervention studies-A systematic review. *PLoS One.* 2017;12(3):e0173904.
96. Linder SK, Swank PR, Vernon SW, Mullen PD, Morgan RO, Volk RJ. Validity of a low literacy version of the Decisional Conflict Scale. *Patient Educ. Couns.* Dec 2011;85(3):521-524.
97. Anderson RM, Fitzgerald JT, Gruppen LD, Funnell MM, Oh MS. The Diabetes Empowerment Scale-Short Form (DES-SF). *Diabetes Care.* May 2003;26(5):1641-1642.
98. Weinger K, Butler HA, Welch GW, La Greca AM. Measuring diabetes self-care: a psychometric analysis of the Self-Care Inventory-Revised with adults. *Diabetes Care.* Jun 2005;28(6):1346-1352.
99. Washburn RA, Smith KW, Jette AM, Janney CA. The Physical Activity Scale for the Elderly (PASE): development and evaluation. *J Clin Epidemiol.* Feb 1993;46(2):153-162.
100. Li C, Friedman B, Conwell Y, Fiscella K. Validity of the Patient Health Questionnaire 2 (PHQ-2) in identifying major depression in older people. *J Am Geriatr Soc.* Apr 2007;55(4):596-602.

101. Summary of the Updated American Geriatrics Society/British Geriatrics Society clinical practice guideline for prevention of falls in older persons. *J Am Geriatr Soc.* Jan 2011;59(1):148-157.
102. Borson S, Scanlan J, Brush M, Vitaliano P, Dokmak A. The mini-cog: a cognitive 'vital signs' measure for dementia screening in multi-lingual elderly. *Int J Geriatr Psychiatry.* Nov 2000;15(11):1021-1027.
103. Morley JE, Malmstrom TK, Miller DK. A simple frailty questionnaire (FRAIL) predicts outcomes in middle aged African Americans. *J Nutr Health Aging.* Jul 2012;16(7):601-608.
104. Brown JS, Vittinghoff E, Lin F, Nyberg LM, Kusek JW, Kanaya AM. Prevalence and risk factors for urinary incontinence in women with type 2 diabetes and impaired fasting glucose: findings from the National Health and Nutrition Examination Survey (NHANES) 2001-2002. *Diabetes Care.* Jun 2006;29(6):1307-1312.
105. Katz S. Assessing self-maintenance: activities of daily living, mobility, and instrumental activities of daily living. *J Am Geriatr Soc.* Dec 1983;31(12):721-727.
106. Lawton MP, Brody EM. Assessment of older people: self-maintaining and instrumental activities of daily living. *Gerontologist.* Autumn 1969;9(3):179-186.
107. Guralnik JM, Simonsick EM, Ferrucci L, et al. A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission. *J Gerontol.* Mar 1994;49(2):M85-94.
108. Universal health outcome measures for older persons with multiple chronic conditions. *J. Am. Geriatr. Soc.* Dec 2012;60(12):2333-2341.
109. Sarkar U, Karter AJ, Liu JY, et al. The literacy divide: health literacy and the use of an internet-based patient portal in an integrated health system-results from the diabetes study of northern California (DISTANCE). *Journal of health communication.* 2010;15 Suppl 2:183-196.
110. Huizinga MM, Elasy TA, Wallston KA, et al. Development and validation of the Diabetes Numeracy Test (DNT). *BMC health services research.* May 1 2008;8:96.
111. Kasper JD, Chan KS, Freedman VA. Measuring Physical Capacity. *J. Aging Health.* Mar 2017;29(2):289-309.
112. Huque MH, Carlin JB, Simpson JA, Lee KJ. A comparison of multiple imputation methods for missing data in longitudinal studies. *BMC Med Res Methodol.* Dec 12 2018;18(1):168.
113. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation science : IS.* Aug 7 2009;4:50.
114. Erwin K, Martin MA, Flippin T, et al. Engaging stakeholders to design a comparative effectiveness trial in children with uncontrolled asthma. *J Comp Eff Res.* Jan 2016;5(1):17-30.
115. Nundy S, Mishra A, Hogan P, Lee SM, Solomon MC, Peek ME. How do mobile phone diabetes programs drive behavior change? Evidence from a mixed methods observational cohort study. *The Diabetes educator.* Nov-Dec 2014;40(6):806-819.
116. Munshi MN, Florez H, Huang ES, et al. Management of Diabetes in Long-term Care and Skilled Nursing Facilities: A Position Statement of the American Diabetes Association. *Diabetes Care.* Feb 2016;39(2):308-318.
117. Hamilton, A. Qualitative methods in rapid turn-around health services research. VA HSR&D National Cyberseminar Series: Spotlight on Women's Health (December 2013). https://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/video_archive.cfm?SessionID=780 (accessed Jan 2024).

118. Al Ozairi E, Alsaeed D, Al Roudhan D, et al. The effect of home-based resistance exercise training in people with type 2 diabetes: A randomized controlled trial. *Diabetes Metab Res Rev.* 2023;39(7):e3677.

119. Anjali M, Khapre M, Kant R, Kumar S, Pandey P. Effectiveness of Diabetes Self-Management Education on Distress and HbA1C among Indian Type 2 Diabetes Mellitus Patients: A Randomized Controlled Trial. *Indian J Community Med*. 2023;48(5):702-708.

120. Baig AA, Staab EM, Zhu M, et al. Cluster Randomized Trial of Diabetes Group Visits in Community Health Centers across the Midwest. *J Health Care Poor Underserved*. 2024;35(3S):27-46.

121. Calikoglu F, Bagdemir E, Celik S, et al. Telemedicine as a Motivational Tool to Optimize Metabolic Control in Patients with Diabetes in Turkey: A Prospective, Randomized, Controlled TeleDiab Trial. *Telemed J E Health*. 2023;29(4):518-530.

122. Feng Y, Zhao Y, Mao L, et al. The Effectiveness of an eHealth Family-Based Intervention Program in Patients With Uncontrolled Type 2 Diabetes Mellitus (T2DM) in the Community Via WeChat: Randomized Controlled Trial. *JMIR Mhealth Uhealth*. 2023;11:e40420. Published 2023 Mar 20.

123. Gerber BS, Biggers A, Tilton JJ, et al. Mobile Health Intervention in Patients With Type 2 Diabetes: A Randomized Clinical Trial. *JAMA Netw Open*. 2023;6(9):e2333629. Published 2023 Sep 5.

124. Heald AH, Roberts S, Albeda Gimeno L, et al. A Randomised Control Trial to Explore the Impact and Efficacy of the Healum Collaborative Care Planning Software and App on Condition Management in the Type 2 Diabetes Mellitus Population in NHS Primary Care. *Diabetes Ther*. 2023;14(6):977-988.

125. Ibrahim AKA, Syed Sulaiman SA, Awaisu A, Shafie AA. Impact of brief smoking cessation intervention on quitting rate and glycemic control in patients with diabetes: a randomized controlled trial. *J Int Med Res*. 2023;51(10):3000605231208598.

126. Iqbal MZ, Alqahtani SS, Mubarak N, et al. The influence of pharmacist-led collaborative care on clinical outcomes in type 2 diabetes mellitus: a multicenter randomized control trial. *Front Public Health.* 2024;12:1323102. Published 2024 Feb 27.

127. Lamptey R, Amoakoh-Coleman M, Barker MM, et al. Change in glycaemic control with structured diabetes self-management education in urban low-resource settings: multicentre randomised trial of effectiveness. *BMC Health Serv Res*. 2023;23(1):199. Published 2023 Feb 24.

128. Pardhan S, Upadhyaya T, Smith L, et al. Individual patient-centered target-driven intervention to improve clinical outcomes of diabetes, health literacy, and self-care practices in Nepal: A randomized controlled trial. *Front Endocrinol (Lausanne).* 2023;14:1076253. Published 2023 Jan 19.

129. van den Burg EL, Schoonakker MP, van Peet PG, et al. Integration of a fasting-mimicking diet programme in primary care for type 2 diabetes reduces the need for medication and improves glycaemic control: a 12-month randomised controlled trial. *Diabetologia*. 2024;67(7):1245-1259.