Official Study Title: My Diabetes, My Community

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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 600 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. 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 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 second 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
	Hypoglycemia (self-reported)[81-83]	Survey
	Hypoglycemia requiring medical assistance	EHR
	Geriatric syndromes 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

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.

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 a secure file transfer protocol (sFTP) 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.

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 SFTP Server

NowPow will transfer files to the research team by uploading them via Secure File Transfer Protocol (SFTP) to a dedicated location on a secure server; the files will then be retrieved by the UC research team. All files will be end-to-end encrypted using a public RSA key generated by the research team.

The SFTP server is maintained by the Research Computing Group in the Department of Public Health Sciences (Ryan Carter, Systems Administrator). It is located in a secure server room within the Billings Hospital building. The room is a dedicated server room with raised floor, redundant cooling and appropriate power and fire suppression systems. Access to the room is controlled and monitored via keycard, and a video surveillance system is used to continuously monitor access from within. In addition to machines belonging to Public Health Sciences, the room also houses systems belonging to the fMRI Unit and the Cancer Center. Only systems administrators from these three groups have access.

The SFTP server is located on a dedicated machine running only the SFTP service. All remote access to the SFTP server (both user and administrator access) requires key-based authentication (password authentication is disabled). The server is configured to place all users in their own “chrooted jail” upon login which strongly limits their access to a single root directory (i.e., the system can no longer reference paths outside that directory). In this case, this will be a dedicated directory created for use by NowPow and the Lindau Lab. Backups are encrypted and stored in a secure, physically separate location within the hospital. Backups are transferred to that location electronically. At no time are backups stored on portable media (e.g., tape or USB drives) or taken off-site.

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 612 patients (12 in the pilot, 600 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).

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 are 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.

M. Informed Consent

Until we are able to recruit in-person, we 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 emailed, 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.

No surveys 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 a secure file transfer protocol (SFTP); 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.

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.

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.

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