Piloting the IPROACTIF Program to Preserve Functioning & Prevent Cognitive Decline

2020-1461: NCT: 04682977 Principal Investigator: Mansha Parven Mirza, PhD. Date: May 17, 2022

OFFICE OF THE VICE CHANCELLOR FOR RESEARCH

Office for the Protection of Research Subjects (OPRS)
Institutional Review Board
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Initial Review Application: Social, Behavioral, and Educational Research

Form Version # & Date: 5.2; 03/09/2020

Date application completed by the Investigator: 4.26.22

I. Research Title:

Piloting the IPROACTIF program to preserve functioning and prevent cognitive decline

II. Personnel

A. Principal Investigator (PI)

Name (Last, First)	Degree(s)	Net ID (e.g., NetID@uic.edu)
Mirza, Mansha	**PhD, OTR/L**	**mmirza2**
Department **Occupational Therapy**	College **Applied Health Sciences**	University Status ☐ Student/Fellow/Resident ☒ Faculty/Staff
Phone Number **312-35505427**	UIC E-mail Address **mmirza2@uic.edu**	

B. Faculty Sponsor – Complete only when PI is a student, fellow, or resident

Name (Last, First)	Degree(s)	Net ID (e.g., NetID@uic.edu)
Department	College	
Phone Number	UIC E-mail Address	

C. Primary Contact In Addition to PI – Complete only if the primary contact person is different than the PI

Name (Last, First)	Net ID (e.g., NetID@uic.edu)
Phone Number	UIC E-mail Address

☐ Principal Investigator grants this personnel access to OPRS Live for this protocol

D. List all co-investigators and key research personnel on Appendix P and upload with this application packet.

III. Performance Sites

Definition of a Performance Site: A performance site is a location at which the research is conducted, data is gathered from subjects and/or records, and/or subjects are consented into the research. Sites are performance sites whether the research activities there are funded or not funded.

A. Are there non-UIC performance sites?

☒ No – *Skip to Section IV.*
☐ Yes – Complete Appendix K and upload with this application packet

IV. Research Funding

A. Is this research funded?

☐ No – *Skip to Section V.*
☒ Yes
☐ Pending

***B.* Check all of the appropriate boxes for funding sources (including pending sources) for this research.** *If the study is supported by more than one funding source, complete and upload* Appendix Z *for each additional funding source.*

☒ Federal Agency Name: **National Institutes of Health**
☐ Foundation Name:
☐ State Agency Name:
☐ Department of Defense – Complete Appendix Q and upload with this application packet
☐ Sub-contract from non-UIC agency or institution: Name:
☐ Other - Name:

C. Funding Identification:

1. Institutional Proposal (IP) Number: **0045807**

2. a. Name of the PI on the grant or contract received directly from the sponsor: **Susan Hughes**

b. Is the PI of this grant or contract affiliated with UIC?

☐ No – Identify the agency or institution with which the above PI is affiliated:
Explain the relationship between that agency or institution and UIC:
☒ Yes

c. Grant, contract or sub-contract title: **Midwest Roybal Center for Health Promotion and Translation**

d. Grant, contract or sub-contract number: **5P30AG022849-17**

V. Conflict of Interest (COI)

All investigators must disclose all real, apparent, or potential Significant Financial Interest (SFI) to the IRB. For more information, see the Investigator Conflict of Interest Disclosure Policy for Human Subjects Research.

A. Disclosure

1. At present or in the 12 months prior to this disclosure, did or does any investigator or investigator's family members have a significant financial interest (SFI) with the research sponsor or any subcontract recipient; or have a SFI reasonably related to a product (e.g., drug, device, method, treatment, etc.) that is the subject of the research; or have any other relationships (e.g. fiduciary, even if uncompensated) that may present a potential conflict of interest with this research?

☒ No
☐ Yes – See Section B below.

2. Are you aware of an institutional conflict of interest with this study?

☒ No
☐ Yes – See Section B below.

B. Management

If **YES** is checked for any of these questions, complete the disclosure and management plan via START myDisclosures application (https://myresearch.uillinois.edu/myDisclosures/). Guidance can be found on the COI website under "Managing Conflicts". Final IRB approval of the research cannot be provided until a management plan is in place and is approved by the IRB. For additional assistance contact the COI Office at **(312) 996-3642 / (312) 996-4070** or email *coi@uic.edu*.

VI. Protocol Components

A. Provide a description of the background and rationale for the proposed research. Cite appropriate literature to support the relevance and importance of this research.

B. State the research objectives/hypothesis being explored by the current research. Please include primary and secondary aims.

Chronic conditions such as diabetes and heart disease entail cardiovascular risk factors which play a critical role in cognitive decline1. The majority of aging adults presenting with these conditions and associated cardiovascular risk factors such as obesity, hyperlipidemia, hypertension, and physical inactivity, are treated in primary care settings. Thus, primary care offers an opportunity to help patients manage chronic conditions, modify cardiovascular risk factors, and prevent cognitive decline2. One promising way to identify and target at-risk patients in primary care settings is through focus on activities and instrumental activities of daily living (ADLs and IADLs). Primary care patients with chronic disease(s) and cardiovascular risk factors are more likely to be in the stage of preclinical cognitive changes. Converging evidence indicates that subtle deficits in ADL and IADL performance precede clinically identifiable cognitive impairment. ADL limitations are also strong predictors of progression between normal cognition, mild cognitive impairment (MCI), and dementia3-5. Evaluation and rehabilitation of ADL/IADL performance in at-risk patients can activate a positive cycle of ADL independence, better management of chronic disease, lowering of cardiovascular risk factors, and prevention/deceleration of cognitive decline. However, there is a dearth of evidence-based interventions that focus on ADL/IADL training for at-risk aging patients in primary care.

C. Clearly describe the study design/intervention. The description should demonstrate how the stated objectives will be met.

IPROACTIF (Integrated PRimary Care and Occupational Therapy for Aging and Chronic Disease Treatment to preserve Independence and Functioning) is an intervention designed to be delivered in primary care settings by an on-site occupational therapist. Based on the premise of preventing the physical and cognitive decline that is associated with aging and chronic disease, the 12-week intervention includes a comprehensive assessment of ADL functioning and ten intervention sessions

addressing disease management, physical activity and executive functioning. The intervention is designed for adults, aged 55 and over, with a primary diagnosis of diabetes or heart disease, and pre-clinical cognitive decline. We propose a study to assess the efficacy of IPROACTIF in a pilot randomized control trial with a control group receiving usual primary care services.

The intervention comprises three components spread across 12 weekly sessions: (1) comprehensive assessment of physical and executive functioning i.e. person factors (Session 1) using the Physical Performance Test, the Dimensional Change Card Sort, and the Executive Function Performance Test, (2) assessment of home safety and accessibility i.e. environmental factors using the HOME Falls and Accidents Screening Tool (Session 2), and (3) assessment of ADL/IADL competence and performance in context i.e. occupational factors using the Performance Assessment of Self-Care Skills (Session 2). Information in these areas is used by the interventionist to collaboratively identify three patient-centered goals. To facilitate this process, we have developed an agenda mapping script and a goal planning worksheet based on principles of motivational interviewing. Goal planning is followed by 12 in-person treatment sessions. Treatment sessions focus on chronic disease education, problem solving issues related to disease management by modifying daily routines, recommendations for embedding physical activity in everyday tasks, and environmental modifications or activity adaptations to increase ADL/IADL independence. The goal planning worksheet is revisited at every session to ensure patient-centeredness. Thus, while the intervention is manualized, it also includes built in flexibility for individualized patient goals and treatment plans.

D. Describe in chronological order all the tasks/tests or procedures subjects will be asked to complete in participating in this research. Distinguish between tasks performed solely for research and those being performed for non-research purposes.

At the beginning of the study participants will be asked to complete phone surveys and assessments in-person and by video/phone call. These activities will take place in the followingorder

- **Phone surveys – Participants will be asked to complete demographic and background surveys (including self-reported height and weight) and assessments about their health, healthcare utilization, and daily activities.**
- **In-person assessments – A week to ten days after the phone surveys, participants will be asked to visit the study occupational therapist at the faculty practice clinic at 1640 W. Roosevelt Road or in the Department of Occupational Therapy, 3rd floor, 1919 W. Taylor Street. During this visit, the therapist will assess their physical and mental functioning using a variety of standard tests. The therapist will also give each participant an accelerometer to take home and teach them how to wear it.**
- **Video/Phone call assessment – A week after the in-person visit, the therapist will make an appointment for a video/phone call with each participant. During the video/phone call, the therapistwill observe the participant performing one or two daily living tasks in their home.**
- **Wearing the accelerometer – During the week between the in-person visit and the video/phone call, we will ask participants to wear the accelerometer for at least 12 hours a dayfor 7 days. The accelerometer along with a stamped and self-addressed return envelopewill be provided to the participant at the end of their in-person visit.**

During this visit, the therapist will explain the purpose of the accelerometer and demonstrate how to wear it. The participant will be informed that a research assistant will contact them by

phone after a week to check if they are wearing the accelerometer and answer any questions. If participants have completed their 7-day data collection period, they will be asked to return the accelerometer using the envelope provided. If not, they will be instructed to start wearing the accelerometer at their earliest convenience. A research assistant will check on the participant by phone again after a week. If the participant has still not begun wearing the accelerometer they will be reminded to do so at their earliest. After another week, a final reminder call will be made, and if the participant does not intend to wear the accelerometer, they will be asked to return it using the envelope provided.

After completing surveys and assessments participants will be randomly assigned to a treatment or control group. Participants in the treatment group will participate in ten sessions with an occupational therapist. Sessions will be held via video/phone call, will take place weekly and will last 30-45 minutes. During these sessions the therapist will work with each participant to understand their strengths and challenges in doing day-to-day activities and to improve their physical fitness and mental alertness. At the beginning oftreatment, the therapist will help participants set three health-related goals.

- **Sessions 1-3: The first three sessions will focus on the first health-related goal. During Session 1, the therapist will discuss how age and chronic disease affect physical functioning. The therapist will work with each participant to develop a step-by-step plan to achieve their goal. In Session 2, the therapist will offer advice on action steps toward that goal. These steps might include physical activity and exercise, or changes to the environment so that day-to-day activities are easy and safe. In Session 3, the therapist will follow-up on progress and help problem-solve barriers.**
- **Sessions 4-6: These sessions will focus on the second health-related goal. Activities conducted during these sessions will be similar to those conducted during Sessions 1-3.**
- **Sessions 7-9: These sessions will focus on the third health-related goal. Activities conducted during these sessions will be similar to those conducted during Sessions 1-3.**
- **Session 12: During this session, the therapist will discuss the overall progress you made on your health goals. The therapist will also check with you to make sure you have gained knowledge about your health and how to improve it. The therapist will share tips to maintain the gains you have made in your physical and mental functioning.**

Participants in the control group will not receive treatment sessions with the occupational therapist. They will only receive weekly check-in phone calls from a research assistant that will last 5-10 minutes. They will have the opportunity to receive occupational therapy services after completion of the study.

Follow-up Surveys and Assessments
Twelve weeks after beginning the study, all participants will complete the same surveys and assessments completed during the beginning of the study. These surveys and assessments will be completed in the same order and using the same format as at the beginning of the study. Participants in the treatment group we will also complete a brief satisfaction survey.

In addition, we will also record blood pressure and HBA1C readings from participants' medical records AFTER we have obtained consent from participants. For participants in the treatment group, we will use readings from their last visit with the PCP before the intervention and closest visit with the PCP after the intervention. For participants in the control group, we will use the information that is available in their medical records from the last available record before the date of completing the baseline surveys and assessments, and the next available record approximately 10 weeks after the date that they complete the baseline surveys and assessments.

Two occupational therapists will also be involved in the study and will provide the aforementioned intervention sessions to all patient participants. Some of these sessions might be monitored (observed in real-time) by the PI or a research assistant as part of fidelity monitoring

The entire study will last about 12-15 weeks.

E. Describe the plans for data analysis. If applicable, include statistical considerations and justification for subject population and planned enrollment numbers.

We will use paired t-tests or Wilcoxon Signed-rank tests (nonparametric) to examine differences between pre and post-intervention scores for the two groups. Between-group differences, variability, and effect size in outcome measures will be used to project sample size for future trials. Our analytical strategy for future trials is to estimate difference between groups in change over repeated measures (i.e. "group-by-time interaction"). We will use Pearson correlation to examine association between physical functioning and executive functioning, and between ADL/IADL performance and executive functioning.

F. Is this is a clinical trial?

☐ No – *Skip to section VII*

☒ Yes - Is the research required to be registered on http://clinicaltrials.gov? *For more information, refer to the UIC HSPP policy Clinical Trials Registration*

☐ No

☒ Yes – Include the required language within the informed consent document.

VII. Research Records

A. Indicate the type(s) of data being collected and/or recorded *(check all that apply)*:

X Interviews/Questionnaires
Audio recordings
Video recordings
Photographs
School/Student records
Internet research data
Lab, pathology and/or radiology results
X University of Illinois Hospital & Health System medical records – University of Illinois Hospital & Health System medical records (only HBA1c and Systolic/Diastolic blood pressure readings from last visit with PCP before the intervention and closest visit with the PCP after the intervention – patients will NOT be asked to make an appointment just for the study. For participants in the control group, we will use the information that is available in their medical records from the

last available record before the date that that they completed the baseline surveys and assessments, and the next available record approximately 10 weeks after the date that they complete the baseline surveys and assessments. For participants in both groups these data will be abstracted AFTER consent is obtained.

Physician/clinic/hospital medical records from sources outside of UI Health System
Psychotherapy Notes
Billing records
Data previously collected for research purposes
Data containing no health information
Study-generated health information
Biological specimens
X Other. Describe: **Performance-based observations by a clinician**

No audio/video recordings will be collected during the course of the study

B. Will any of the following be banked or stored for future (planned or unplanned) analysis ***beyond the scope of the current research proposal***? *If the following will be used and/or destroyed prior to the closure of the research, they are not considered to be stored; therefore, please answer "No".*

- biological samples or specimens
- identifiable data,
- coded data where a master list to the codes exists

☒ No Study assessments are only intended to generate data that will help monitor intervention and/or test study hypotheses. These data should not be considered health information.
☐ Yes – Complete Appendix D and upload with this application packet.

Note: A plan for securely storing the data must be submitted for IRB review and approval if identifiable and/or coded data will be retained after the research has been completed. Development of a separate data/tissue repository/bank research protocol is required if the investigator will be retaining data from multiple proposals.

VIII. Research Subject Population

A. Indicate the anticipated subject enrollment number (This number cannot be exceeded without prior IRB review and approval via an amendment)**: 75**

B. Indicate which populations below are the PRIMARY FOCUS of this research. *Please refer to the UIC HSPP policies regarding the incidental enrolment of select vulnerable populations (i.e., decisionally impaired, prisoners, etc.).*

Check all that apply

☒ Adults (18 years of age and older)
☐ Minors (17 years of age and younger) – *Complete Appendix B **(required regardless of primary or incidental enrollment)** and upload with this application packet*
☐ Pregnant Women, Neonates, Fetuses/Fetal Tissue – *Complete Appendix U and upload with this application packet*
☐ Prisoners – *Complete Appendix C and upload with this application packet **- Please note that certain types of research with prisoners approvable under the federal regulations may not be allowed under Illinois state law including, but not limited to, biomedical research.***
☒ UIC Employees
☐ UIC Psychology Student Subject Pool -
- *Complete Appendix S and a debriefing document and upload with this application packet;*
- *Complete and upload Appendix B if the research will involve Pool subjects who are minors. If minors will be excluded, then a scientific justification must be provided under item VIII.D.1.b, below.*

☐ UIC Management Study Pool - *Complete Appendix S and a debriefing document and upload with this application packet*
☐ Students - *Complete Appendix S (required only if the research involves classroom activities and/or*

student records) and upload with this application packet

☐ Decisionally-Impaired - *Complete Appendix V and upload with this application packet*
☐ Economically and/or Educationally Disadvantaged
☐ Vulnerable to Coercion or Undue Influence
☐ Other: specify

C. If including economically and/or educationally disadvantaged subjects, subjects vulnerable to coercion or undue influence, UIC Employees, and/or other populations that may be considered vulnerable, provide a rationale for their inclusion and what additional safeguards, if any, are in place to protect their rights and welfare:

Two UI Health clinicians will be included in the study as the lead interventionists. They will provide data about the treatment sessions, which is necessary to monitor the fidelity of the experimental intervention. Specifically, the PI or a research assistant will attend and observe randomly selected treatment sessions and will complete a fidelity monitoring checklist based on their observations of the clinician's delivery of the session (uploaded). Clinicians will also be asked to complete case notes for each treatment session. The case notes template is embedded in the intervention manual.

D. Eligibility Criteria

1. Provide specific details regarding the following:

a. Inclusion Criteria: **For patient participants:**

- Age 55 years or over
- Primary diagnosis of one or more of the following: diabetes ,heart disease
- Evaluated as experiencing or being at risk of functional decline OR self-identified need forsupport with chronic disease management and functional health

For clinician participants:
- A certified occupational therapist licensed to practice in the state of Illinois
- A minimum of 5 years clinical experience

b. Exclusion Criteria: **For patient participants:**

- Unable to participate in study activities due to time or other constraints
- Current/past diagnosis of stroke or dementia, or other neurological disorders
- Receiving pharmacological treatment for cognition
- Participation in other clinical trials involving a rehabilitation/functional healthmanagement component
- Non-English speaking
- Residing in a long-term care institution
- Compromised decision-making capacity (score >8 on SOMCT) - Short Orientation Memory Concentration Test (SOMCT) will be used during the screening process to ensure the participant is eligible for the study. A score of 0-8 on this test indicates normal to minimal impairment. Any one with a score>8 will be considered ineligible.
- Not an active patient at the study clinic (two years or more since last appointment)

For clinician participants:
- Unable to participate in study activities due to time or other constraints. Please note, recruitment and eligibility sections have not been completed for clinicians as the clinicians have already been selected and will serve as co-investigators on this study.

2. Explain how and by whom potential subjects will be assessed to determine their eligibility for the research: **A trained research assistant and graduate student in occupational therapy will assess potential subjects to determine eligibility using a screening questionnaire administered over the phone**

3. Explain how initial eligibility will be documented (upload any screening documents): **For patient participants: We have developed an eligibility screening form (attached) to ascertain eligibility of potential subjects. The screening form will include a standardized assessments for assessing risk**

of functional decline. Functional decline will be assessed using the Brief Risk Identification of Geriatric Health Tool (BRIGHT). Subjects will be flagged as being at risk of functional decline if they get a score of >=3 on the 11 item BRIGHT. The entire screening procedure will be completed by a trained research assistant. We will maintain an Excel spreadsheet to document eligibility. The spreadsheet will be anonymized and subjects will only be identified by a serial number. For provider participants: We will not be documenting eligibility for clinicians.

4. Explain how subjects will be monitored during the course of the research to ensure that they still meet the eligibility criteria and how their continuing eligibility will be documented:

For patient participants: Participants in the intervention group (occupational therapy) will be continuously monitored by the occupational therapist who will administer the experimental intervention. The occupational therapist will monitor patients for any worsening in cognitive functioning. Being in close contact with patients, she will also be aware of changes in residential situation (e.g. move to a nursing home) and enrollment in other studies that might render participants no longer eligible for this study. Participants in the control group will also be closely monitored by a research assistant through weekly phonecalls to monitor for changes in cognitive functioning, living arrangement (i.e. relocation to nursing home), and enrollment in other studies.

We will not be monitoring eligibility for clinician participants.

OR

☐ N/A – Assessment of continued eligibility is not required

IX. Recruitment of Subjects

A. Describe how potential subjects will be initially identified for this research study.

Potential subjects will be recruited in the following ways:

1, Potential participants will be identified by their physicians or other primary healthcare providers including nurses, pharmacists, occupational therapists, and care coordinators. We will conduct in-service trainings about the study and eligibility criteria with clinical staff at three UI Health Clinics - University of Illinois Family Medicine Center, University Village; University of Illinois Geriatric Outpatient Clinic; University of Illinois Endocrinology Outpatient Clinic. A presentation template for this purpose is attached.

A flyer advertising the study will then be disseminated via physicians, nurse practitioners, and other clinical staff working at these clinics. The flyer willinclude a phone number that patients can call or further information about the study.
Alternatively, patients can complete a brief form on the flyer with their contact information and indicating their permission to be contacted by the research team. Physicians and other staff will contact the research team to schedule a time for a research assistant to pick up completed flyers.

The research assistant will then contact eligible individuals by phone and screen them for the study's inclusion criteria. Individuals who meet inclusion criteria will be invited to enroll in the study and set up a phone appointment for completion of consent procedures and baseline data collection.

Due to the COVID-19 pandemic, some providers such as care coordinators are not seeing patients in-person. We have developed an alternative secure strategy for the providers to share the study flyer with patients and pass on completed flyers to the study team. The details are described under section IX B below. Note that care coordinators will be identifying potential patients in the same way as physicians, nurses, and pharmacists described above i.e. based on study eligibility criteria which will be shared with care coordination staff during an in-service presentation.

2. Through electronic medical records – This will be done at two of the recruitment clinics. At the U of I Family Medicine Center, this will be done in two ways: [1] a data manager (member of the health iformatics team) who has completed training in HIPPAA compliance (specifically the UI Health Learning Management System (LMS) registration course for enhancing research compliance when using EHRs**) will use electronic medical records to generate a list of individuals who meet study inclusion criteria. This individual is not a key research personnel listed in the Appendix P. This someone who works at the clinic and will only abstract the data and transfer it to the UIC Box of the researchers [2] some physicians at the U of I Family Medicine who also have health formatics training will use EMRs to identify their own patients who meet study inclusion criteria. They will then send these patients a one-time bulk message via the patient portal which will include the study flyer as an attachment (please see the next section). A spreadsheet containing names and contact information of eligible individuals identified using either of the above strategies will be uploaded to a subfolder within a secure UIC Box Health folder. This spreadsheet will also include the patient's primary diagnosis (diabetes or heart disease). Only names, contact information (specifically emails and phone numbers) and the primary diagnosis (i.e. diabetes or heart disease) will be abstracted from medical records at recruitment and prior to subjects' enrollment. Only the PI and key research personnel will have access to this spreadsheet;**

At the U of I Endocrinology Clinic, a study research assistant who has completed training in HIPAA compliance will access electronic medical records to generate a similar list as above. A spreadsheet containing names and contact information of eligible individuals from this clinic will be uploaded to the same secure UIC Box Health folder described above.

B. Describe how, where, when, and by whom subjects will be recruited for the research.

Recruitment will be conducted in four ways:

1. **Recruitment via primary care providers seeing patients in-person - Potential participants will be identified by their physicians or other primary healthcareproviders including nurses, pharmacists, occupational therapists, and care coordinators. We will conduct in-service trainings about the study and eligibility criteria with clinical staff at three UI Health Clinics - University of Illinois Family Medicine Center, University Village; University of Illinois Geriatric Outpatient Clinic; Universityof Illinois Endocrinology Outpatient Clinic. A flyer advertising the study will be disseminated via physicians, nurse practitioners, and other clinical staff working at these clinics. Providers who are seeing patients in-person will share the flyer with their patient at the end of their regular scheduled appointment. A script has been created for introducing the flyer to specify that the decision to participate in the study is voluntary, that the providers themselves are not members of the research team, and that choosing to participate or not will not affect services received at the clinic [Note that the two clinicians who will be serving as study interventionists also work at two of the recruitment clinics. A separate script has been created for them to introduce the study to patients which specifies they are research personnel associated with the study – we have also addressed this in Section IX C]. The flyer will include a phone number that patients can call or further information about the study. Alternatively, patients can complete a brief form on the flyer with their contact information and indicating their permission to be contacted by the research team. Physicians and other staff will contact the research team to schedulea time for a research assistant to pick up completed flyers.**

The research assistant will then contact eligible individuals by phone and screen them for the study's inclusion criteria. Individuals who meet inclusion criteria will be invited

to enroll in the study and set up a phone appointment for completion of consent procedures and baseline data collection.

2. **Recruitment via primary care providers seeing patients remotely – Some providers, specifically care coordinators, are only seeing patients remotely (via phone or video conferencing using the Doxy.me platform) due to the COVID19 pandemic. They will share the flyer with their patient at the end of their regular scheduled appointment. These providers will share the flyer with their patient at the end of their regular scheduled REMOTE appointment. A separate script and instructions have been created for them to introduce the study to their patient. They will also be asked to offer to read the contents of the flyer for the patient verbatim, with no deviation. If a patient has questions about the study, they will be asked to contact the research team directly using the number stated on the flyer. If a patient is willing for their contact information to be shared with the study team, the provider will ask if they can complete the brief form at the end of the flyer on the patient's behalf. Information noted in the flyer (name and phone number) will be retrieved directly from the patient and NOT from their EHR. The completed flyer will then be uploaded to a separate subfolder (different from the one described in #1 above) within the study's secure UIC Box Health folder. Patients will be informed and made aware of this procedure. Of note, care coordinators will only be granted 'uploader' access to this folder. This means that they will be unable to see completed flyers uploaded by other care coordinators.**

   The research assistant will then contact eligible individuals by phone and screen them for the study's inclusion criteria. Individuals who meet inclusion criteria will be invited to enroll in the study and set up a phone appointment for completion of consent procedures and baseline data collection.

3. **In person recruitment by a member of the research team – This will be done only at the U of I Endocrinology clinic. One or two days a week, a trained research assistant will shadow physicians and/or nurse practitioners as they consult with patients. The research assistant will not accompany the physician/NP into an exam/consultation room but will wait outside until the visit is complete. Patients who might be eligible for the study will be identified by physicians and/or nurse practitioners based on the study's inclusion criteria which they will be informed about during presentations about the study at clinical/staff meeting. Clinicians will introduce their patient to the research assistant at the end of their visit/consultation. A script has been created for this purpose. Then, the patient will have the option to meet separately with the research assistant to learn more about the study. The research assistant will then meet one-on-one with patients who express verbal interest in learning about the study. This meeting will take place in a private consultation room. The research assistant will first introduce the study using language contained in the study flyer. If the participant expresses verbal interest in learning more, she will administer the screening questionnaire during the meeting. Individuals who meet inclusion criteria will be invited to enroll in the study and either complete the consent process in person or set up a phone appointment for completion of consent procedures and baseline data collection.**

4. Outreach to individuals identified through electronic medical records - As previously described, potential participants will also be identified through electronic medical records at

the U of I Endocrinology Clinic and the U of I Family Medicine Center. Individuals thus identified will be sent an email (provided their email address is available in the EHR) by the study PI introducing the study and notifying them that a member of our research team might contact them in the next couple of weeks. Physicians with healthinformatics capability who volunteer to run an EMR search to identify eligible individuals from their existing patient caseload will have the option to send a bulk message to eligible individuals using the patient portal. A script has been created for this purpose and will include the flyer for the study as an attachment. The patient portal (labelled MyChart within Epic) is typically used by physicians to communicate with patients – no changes will be made to the portal for this study. This means that we will not need a study build within EPIC. Regardless we have completed the Epic Study Build Request to adhere with institutional procedures. The research assistant will then contact individuals identified through EMRs (in the order that they appear on the EMR list) by phone and screen them for the study's inclusion criteria. Individuals who meet inclusion criteria will be invited to enroll in the study. At this time, we will not be using the UI Health Research Registry or The New Normal for this study.

C. Explain the proposed measures to minimize the possibility of coercion or undue influence on potential subjects, particularly for subjects identified in VIII.B. as being vulnerable *(for example: how will you maximize the subject's autonomous decision-making; what if the investigator is also the participant's healthcare provider, what if the participant is enrolled in a class the investigator is teaching, what if an employer/employee relationship exists)*.

To reduce this risk, patient participants will be told that being in the study is completely voluntary. They can choose to not participate in the study and they can discontinue their participation at any time. They will be told that choosing to not be in the study will not affect their legal rights, access to health care, or the quality of health care that they receive at the study clinic. All study-related compensation ($25-$75) has been kept to a reasonable amount so as not to make patients feel compelled to participate. Efforts will be made to ensure that participants consent to becoming involved in the project only after gaining a clear understanding of the study procedures and their rights as research participants.

The clinicians who will be serving as interventionists in the study also work at two of the clinics where recruitment will be conducted. It must be noted that both clinicians are co-investigators on the study and clinical faculty in the Department of Occupational Therapy. Neither their clinical contracts nor their academic appointments are contingent on the success of this study. In other words, there is no monetary reward or incentive for recruiting patients into the study.

The following steps will also be taken to minimize coercion during patient recruitment. These steps pertain to all healthcare providers who will assist with recruitment including, but not limited to, the study interventionists:
1. Providers will be advised to bring up the topic of this research only at the end of their clinical consultation to ensure that the patient's therapeutic needs are not compromised.
2. Providers will be advised to remind patients that participation in the study is not obligated and should they decide to not participate, they will continue to receive their usual clinical care.
3. Providers will be advised to remind patients that they can take 2-3 days to reflect on the study before making their decision.
4. It must be noted that providers will only seek patient permission to introduce them to the research assistant or pass on their contact information to the research team so they can receive a call from a research assistant to explain the study in detail. The actual decision to participate or not will be made during the in-person meeting or phone follow-up which will be conducted by a research assistant not connected with the patient's clinical care

(therefore making it easier for patients to decline participation).

D. Will any identifiable data obtained at recruitment, including screening data from records, be retained without consent from subjects who failed to qualify or declined to participate?

☐ No
☒ Yes – Describe the screening data to be retained and justify the retention of such data: Names and contact information will NOT be retained. For participants found ineligible and for those who decline to be in the study, PHI (names, email addresses, diagnoses) will be deleted from the spreadsheet listing potential participants identified through electronic medical records. Recruitment fliers/permission slips containing this information will be shredded (if submitted in hard copy) or deleted (if submitted in electronic copy) as soon as a potential participant is found ineligible or declines to be in the study. However, we will retain deidentified data on reasons for ineligibility and reasons for declining as this information will assist in planning of future studies. This information will be analyzed as frequency counts e.g. x/xx individuals contacted were ineligible as they were receiving regular outpatient rehabilitation services; x/xx patients declined because they reported being not proficient with the technology that would be needed to participate This information will be critical for planning future recruitment efforts. Please note that some participants might not decline at first contact. instead they might request time to think over their decision or might be willing to be recontacted in 2-3 weeks after they have had time to consider their decision. Completed screening forms of these 'undecided' participants will be retained for 2-3 weeks until time of recontact. At that time, if they decline, the forms will be destroyed immediately.

E. **Check <u>and upload</u> all materials that will be used for recruitment.** Refer to the OPRS website for the Investigator Guidance: Recruitment Materials for additional information.

No recruitment materials will be used
X Print materials (flyer, brochure, info sheets, etc.) – Describe: **Flyer**
Ad (radio, TV, etc.) – Describe:
Letter – Describe:
Verbal script – Describe:
X Electronic materials (e.g., website, mass mailing, email notice) – Describe:
recruitment email
Social Media – Specify social media outlets:
Other – Describe:

X. Reasonably Anticipated Risks of the Research

A. Identify all of the reasonably anticipated risks or discomforts that may result from participation in this research (actual and reasonably possible, current and future) and describe the expected frequency, degree of severity, and potential reversibility of those risks (if known). *Remember that risks can be psychological, physical, social, economic, or legal.* If any portion of the research involves review of medical records, the potential for loss of privacy or confidentiality of health information should be listed as a risk.

There are five potential risks for patient participants in this study.
1. There is a mild risk of loss of confidentiality if information about the participant inadvertently released through study reports. The likelihood of this risk is ongoing through the course of the study. This risk will be minimized through a series of measures we will undertake (see section below), however, if it occurs, it is not completely reversible.
2. There is a mild risk for loss of anonymity if patients are inadvertently identified as being study participants. The likelihood of this risk is ongoing through the course of the study. This risk will be minimized through a series of measures we will undertake (see section below), however, if it occurs, it is not completely reversible.

3. There is a potential mild risk of coercion because patients may feel that they have to participate in the study to please the clinic staff and providers. This is risk is likely only during the recruitment phase of the study and is potentially reversible by allowing participants to opt out of the study at any time.
4. There is a potential mild risk of physical and mental fatigue and some physical pain because patients may feel overwhelmed and tired from completing the battery of outcome measures and instruments. This is risk is likely only during periods when completing assessments with participants and is potentially reversible.
5. There is a potential minimal risk of emotional reactions when patients express concerns about their functional limitations during study visits. The likelihood of this risk is ongoing through the course of the study but it is potentially reversible.

We do not anticipate any risks for the clinician participants in this study other than minimal risk of losing privacy and confidentiality as they will only be providing data related to fidelity of intervention delivery.

B. Describe the measures taken to minimize the risks (other than undue influence or breaches of privacy and/or confidentiality) listed above. *Measures may include screening of subjects by qualified personnel, eligibility criteria, use of procedures already being used for clinical purposes, qualifications and experience of staff performing procedures, specialized facilities or equipment, medical or psychological services that may be required as a consequence of the research and frequency of monitoring.*

1) Measures to minimize loss of confidentiality.

We will use the HIPPA-certified version of Zoom to conduct all treatment sessions via video-conference or via phone call if the participant so prefers. Clinical case notes and assessment data will be stored only in electronic format in password-protected files or folders stored on a lab computer at 1919
W. Taylor Street, which is part of the network server of the College of Applied Health Sciences. Clinicians will be asked to complete notes using a standard template (embedded in the intervention manual). The notes will be typed into Microsoft Word using password-protected, UIC-issued laptops. Completed notes will bestored in a HIPPA-compliant UIC Box Health Folder temporarily before being transferred to a password-protected folder stored on a secure HIPPA-compliant sever maintained at UIC.

Outcomes data will be collected in RedCap. The data will be coded and identifiers removed before being exported from RedCap as a CSV or SPSS file. The coded dataset without identifiers will be stored on a lab computer at 1919 W. Taylor Street, which is part of the network server of the College of Applied Health Sciences. This is essential for data analysis as we have appropriate statistical software installed on our lab computer. If a statistician from a different UIC department is added to the research team, we will upload the coded outcomes data to our HIPAA secured UIC Box Health Folder so the statistician can access it. Our outcomes database will not include patient identifiers such as names and addresses. Each patient in the database will be identified with a unique project code. Patient names,addresses, and contact information, which will be collected for purposes of scheduling future visits, will be recorded in a separate master list. This master list will distinct fromthe screener spreadsheet. The master list will include patient information and their unique project identifiers and will be stored in a separate, password protected file, on a secure HIPPA-compliant server maintained at UIC. Only

designated research personnelwill have access to these files through individualized passwords. Once data analysis is completed the files will be destroyed.

2) Measures to minimize loss of anonymity. To reduce this risk, only the PIs and key personnel involved in data collection and patient scheduling will have access to the master file which contains patient identifiers. It is anticipated that the results of this study will appear in scientific publications and will be presented at scientific meetings and community events. The research team will ensure that dissemination products do not include any identifying information. Quantitative findings will be summarized across all patients in the study and will not be presented at the individual level.

3) Measures to minimize any risk of coercion. Patient participants will be told that being in the study is completely voluntary. They can choose to not participate in the study and they can discontinue their participation at any time. They will be told that choosing to not be in the study will not affect their legal rights, access to health care, or the quality of health care that they receive at the study clinic. All study-related compensation ($25-$75) has been kept to a reasonable amount so as not to make patients feel compelled to participate. Efforts will be made to ensure that participants consent to becoming involved in the project only after gaining a clear understanding of the study procedures and their rights as research participants.

4) Measure to minimize physical and mental fatigue and physical pain. Patients will be given rest breaks as needed during completion of rest breaks and surveys.

5) Measures to minimize emotional reactions. Patients will be free to not answer any questions that make them feel uncomfortable. Research assistants and clinicians will have the requisite training and expertise to counsel patients if they express emotional reactions.

C. Describe the process for reporting any unanticipated problems to the IRB and sponsor, as applicable.

We do not anticipate serious adverse events for participants in the proposed study. Any health-related events occurring as a result of study procedures will be considered an adverse event. Potential AEs include fatigue, mild joint pain, and mild muscle soreness. Adverse events will be will be graded according to the National Cancer Institute's Common Toxicity Criteria II (0 = No adverse event or within normal limits; 1 = Mild, not requiring treatment; 2 = Moderate, resolved with treatment; 3 = Severe, resulted in inability to carry on normal activities and required professional medical attention; 4 = Life-threatening or disabling; 5 = Fatal.

The principal investigator will use an adapted version of the NIA Adverse Event Form (https://www.nia.nih.gov/research/dgcg/clinical-research-study-investigators-toolbox/adverse events) to monitor any AEs. Such events will be reported immediately (within 24-48 hours of occurrence) to the institutional IRB and the sponsor-approved DSMB.

The Adverse Event protocol will be initiated when a potential issue is observed or identified by the investigators and/or clinicians/interventionists. Given that this study primarily focuses on encouraging participants to engage in daily living tasks in their own environment [things they are already doing to some extent in their everyday lives], we only anticipate adverse

events in the 0-1 range based on the NCI criteria described above. The remote intervention is a counseling and education-based intervention so chances of more serious risk or injury are very remote. The most likely events are fatigue, pain, and mild emotional reactions. These will be handled in the same way as they would be during in-person treatment sessions. The intervening clinicians have many years of experience working with patients with physical disabilities and are trained to identify any signs of physical fatigue. Participants demonstrating signs of fatigue will be asked to take a break before continuing with the assessment. Part of the intervention involves training participants to monitor their own levels of pain and their resting heart rate. Participants will be empowered to use these skills to monitor their own bodily reactions and rest and stretch their joints to relieve fatigue and/or mild pain. In case of emotional reactions, the intervening clinicians are licensed occupational therapists with requisite training and experience to counsel paticipants through emotional reactions.

In the rare case of a more serious adverse event (such as a fall) that occurs during a remote interaction, the intervening clinician will take the following steps:

1. Assess whether the partcipant has sustained an injury and how serious it is. This will be done by asking the patient a series of questions to assess their mental status [e.g. What is your name? What city are you in? What is today's date] and their physical status [e.g. Do you feel any pain? On a scale of 0-10 how would you rate your pain? Do you see any swelling or fresh wound? Is the wound bleeding?]

2. If the injury is deemed non-serious, the clinician will advise the participant to keep any on things, and if they feel no better/get worse in the next 24 hours, to contact their primary care provider.
3. If the injury is deemed serious, the clinician will call 911 to get the patient immediate medical assistance.
4. Report the adverse event to the principal investigator, who will inform the IRB and the DSMB.

XI. Reasonably Anticipated Benefits of the Research

A. Identify the potential for benefits to individual subjects, including those related to an experimental intervention or interaction that are available only in the context of the research. *Please note that participation in Social and Behavioral Sciences research (such as interviews, focus groups, surveys) rarely presents a direct benefit to the subject. Unless a direct benefit to subjects is anticipated (such as an educational benefit from a new curriculum, therapeutic benefit from a new service/therapy), please state that no direct benefits to subjects are anticipated.*

As part of the experimental intervention participants will receive occupational therapy services at no cost. It is anticipated that many of these individuals will have little or no access to these services outside the context of this research study. Services delivered as part of the intervention will address patients' physical functioning and occupational activities. If the intervention is effective, we anticipate that patients' functional health will improve, as will their health-related quality of life and their experience of primary care services. Improved functional health might reduce burden of care for caregivers. There are no direct benefits for clinicians in this study. However clinicians will learn about the role of occupational therapy in the management of functional health. This knowledge might have secondary benefits for other patients.

B. Indicate how the knowledge gained from the study could produce a benefit to society or to others who

share the same disorder or condition.

Evidence from the proposed project will offer new insights on the effectiveness of embedding occupational therapy services in outpatient care settings. Currently there is a lack of mechanisms to monitor and address functional health in these settings. Patients in need of this type of care may require referrals from their Primary Care Providers but may be unable to follow-through with referral advice. Embedded occupational therapy services may increase patient access to needed care, improve patients' functional abilities, and influence physicians to be more holistic in their treatment approach with patients with chronic health conditions. The benefits may be particularly significant for low income, low literacy, and underserved patient populations such as those served by the study clinic. These patients often have multiple barriers to effectively engage in recommended health and wellbeing regimens. Second, evidence from the proposed project will offer new insights on how best to introduce occupational therapy services into primary health care clinics serving vulnerable patient populations. Community clinics must balance complex scheduling issues, time limitations, high patient needs, and limited referral resources, against available space, patient no-show rates, patients who have multiple health problems requiring extensive review for a differential diagnosis, etc. Identifying ways to improve patient engagement, shared decision-making, and self-management has significant positive implications for improving clinical outcomes, patient experience of clinical care, and provider satisfaction.

XII. Privacy and Confidentiality

A. Describe the precautions taken to protect subject privacy during the initial identification of subjects, subject recruitment, and collection of data from the subjects *(for example: what precautions will be taken to protect the subject from being recognized as a research subject if recruitment or data collection occurs in a group setting or in public?)*.

1) Measures to minimize loss of confidentiality.
We will use the HIPPA-certified version of Zoom to conduct all treatment sessions via video-conference or via phone call if the participant so prefers. Clinical case notes and assessment data will be stored only in electronic format in password-protected files or folders stored on a lab computer at 1919 W. Taylor Street, which is part of the network server of the College of Applied Health Sciences. Clinician notes will be stored in a UIC Box Health Folder temporarily before being transferred to a lab computer.
Our outcomes database will not include patient identifiers such as names and addresses. Each patient in the database will be identified with a unique project code. Patient names, addresses, and contact information, which will be collected for purposes of scheduling future visits and/or mailing gift cards, will be recorded in a separate master list. This master list will distinct from the screener spreadsheet. The master list will include patient information and their unique project identifiers and will be stored in a separate, password protectedfile, on a secure HIPPA-compliant server maintained at UIC. Only designated research personnel will have access to these files through individualized passwords. Once data analysis is completed the files will be destroyed.

Outcomes data will be collected in RedCap. UIC Box is not a platform for collecting outcomes data from the standardized questionnaires and assessments that we plan to use.

The skip patterns and assessment item banks necessary for accurate data collection can only be configured in a program such as RedCap. Prior to RedCap, we would have administered via paper and pencil in hard copy. However, the paper and pencil format of data collection is obsolete and inefficient and prone to errors.
The data in RedCap will be coded i.e. subjects will be represented by a code. The coded data will be exported from RedCap as a CSV or SPSS file. The coded dataset without identifiers will be stored on a lab computer at 1919 W. Taylor Street, which is part of the network server of the College of Applied Health Sciences. This is essential for data analysis as we have appropriate statistical software installed on our lab computer. If a statistician from a different UIC department is added to the research team, we will upload the coded outcomes data to our HIPAA secured UIC Box Health Folder so the statistician can access it.

Unfortunately, data cannot be analyzed within RedCap and therefore need to be exported for analysis using statistical software such as SAS and SPSS. Data analysis involves multiple steps and cannot be completed in a single session. We anticipate that after downloading the data into a password protected folder within our secure college server, we will need to:
- **Mathematically recode variables (e.g. merging two variables into one, creating summary scores of assessments)**
- **Divide the dataset into two or more datasets for subgroup analyses (e.g. separate datasets for control and intervention participants, separate datasets for participants with heart disease and diabetes)**
- **Clean datasets by deleting outliers**
- **Run simpler analyses in SPSS and more complicated analyses in SAS**

Given the above, constantly downloading and uploading data from and into the UIC Box Health after every analysis session will not only be cumbersome (tens of files will need to be uploaded and downloaded every single time and have to re-labelled with every download and upload) but also carry the risk of losing data files reconfigured for analyses. Therefore we will download the coded dataset without identifiers to a lab computer at 1919 W. Taylor Street, which is part of the HIPAA compliant network server of the College of Applied Health Sciences.

The spreadsheet containing names and contact information of eligible individuals identified through electronic medical records will be uploaded to a secure UIC Box Health Folder. Only the PI and key research personnel will have access to this spreadsheet.

For participants recruited in person, the research assistant will meet with them separately in a private exam room or office so although others may see them together; they will not know if they agreed or not to research.

2) Measures to minimize loss of anonymity. To reduce this risk, only the PIs and key personnel involved in data collection and patient scheduling will have access to the master file which contains patient identifiers. It is anticipated that the results of this study will appear in scientific publications and will be presented at scientific meetings and community events. The research team will ensure that dissemination products do not include any identifying information. Quantitative findings will be summarized across all patients in the study and will not be presented at the individual level.

B. Data Security and Management Plan

1. Indicate the identifiable elements that will be collected and/or included in the research records.

Check all that apply

X Names	☐ Social Security Numbers*	☐ Device identifiers/Serial numbers
XPhone numbers	☐ Medical record numbers	☐ Web URLs
X Street address	☐ Health plan numbers	☐ IP address numbers
X City or state	☐ Account numbers	☐ Biometric identifiers[1]
X Zip Code	☐ Fax numbers	☐ Vehicle ID numbers
X E-mail address	☐ License/Certificate numbers	☐ Facial Photos/Images

Financial account information (including student ID)

All elements of dates (except year) for dates directly related to an individual; and all ages over 89 and all elements of dates (including year) indicative of such age

Date of Birth

Identifiable UIC Student Records[2] ☐ University Identification Number (UIN)

XAny other unique identifier - Specify: HBA1c and Systolic/Diastolic blood pressure readings AFTER obtaining consent from participants. For treatment group participants we will record these parameters from their last visit with PCP before the intervention and closest visit with the PCP after the intervention. For participants in the control group, we will use the information that is available in their medical records from the last available record before the date of completing the baseline surveys and assessments, and the next available record approximately 10 weeks after the date that they complete the baseline surveys and assessments.

None of the identifiers listed above – ***Skip to item C***

[1] Biometric Identifiers are observable biological characteristics which could be used to identify an individual, e.g., fingerprints, iris/retina patterns, and facial patterns.

[2] Documentation of approval from the Registrar must be submitted unless prospective signed consent is obtained from the student or guardian.

***NOTE:** If social security numbers will be collected, explain below why they are necessary and how they will be used:

2. Data Collection and Storage

a. Identify what methods you will use to collect and store data:

☒ Internet-based application/package – Specify:

- ☒ REDCap [define host X CCTS/IHRP ☐ Other (define):]
- ☐ UIC ACCC Qualtrics
- ☐ UIC Box
- ☒ UIC Box Health Data Folder (for research involving PHI)
- ☐ *Survey Monkey or other commercial survey service – Specify:
- ☐ *Other - A thorough description of the characteristics of the application/tool must be provided. This description should address the following elements if applicable: product/tool name, host, security measures, encryption mechanism, and how collected data is maintained and stored by the application/tool.

☐ Non-internet based application (i.e. directly on a desktop/laptop).

☐ Paper

☐ Recording Media - ☐ Photo ☐ Video ☐ Audio

Specify how the data will be stored and how participants will be identified in the recordings:

☐ Subject Artifacts (such as classroom assignments, regular work products, lesson plans)

☐ Stored specimens

☐ Other:

***Note:** Any investigator who uses external survey software other than REDCap, UIC ACCC Qualtrics, or UIC Box Health Data Folder for collecting and maintaining UIC/UI Health PHI and/or personal data from individuals physically located in the European Union Economic Area (EEA) must provide evidence of a business associate agreement between the University and the external survey software provider. For more information, refer to the UIC HSPP policy Research Data Security. Please visit the OPRS website or contact OPRS at uicirb@uic.edu for more information regarding data collected in the EEA and the European Union General Data Protections Regulation (EU GDPR).

b. Describe whether and how social media platforms (e.g., Facebook, Twitter, Snapchat, etc.) will be used to collect data and/or communicate with subjects:
☒ Not applicable

3. Data Security

a. Describe how all types of data as selected above will be secured.

i. ☒ Indirectly with a code linked to the identity of the subject.
Describe the coding method, specify who will have access to the code/master key, indicate where the key is stored, and explain how it will be protected against unauthorized access: **Participants who enroll in the study will be assigned a numeric code in the outcome database in RedCap i.e. outcome data from REDCap will be identified by a code. The master list including the participants' names, contact information, and corresponding numeric codes will be stored separately from the research data. The master list will be saved as a Microsoft Excel spreadsheet on the secure network server of the College of Applied Health Sciences. The file will be password protected and only the PI, Dr. Mirza and key research personnel, will have access to the password. Hard copies of permission flyers completed by participants who are screened eligible and agree to be in the study will be stored in locked filing cabinets in the PI's locked research lab. Only the PI, Dr. Mirza and key research personnel, will have access to the cabinet.**

PHI collected post enrollment and POST CONSENT will include the following variables – BP and HBA1c reading [for treatment group participants – at last visit with PCP before the intervention and closest visit with the PCP after the intervention. For control group participants - last time tested before completing the baseline surveys and assessments, and the next available record approximately 10 weeks.] These data will be stored in the RedCap outcome database where subjects will be identified by a code. Note that dates of readings will not be recorded. We will record these variables as 'preBP', 'postBP. 'preglucose' and 'postglucose'. After data collections is completed the coded outcomes data with identifiers removed will be exported from RedCap as a CSV or SPSS file. The coded dataset without identifiers will be stored on a lab computer at 1919 W. Taylor Street, which is part of the network server of the College of Applied Health Sciences.

ii. ☐ x Directly, personal or private identifiers (identifiable elements) are maintained with thedata.
Justify the inclusion of direct subject identifiers, and indicate who will have access to the data:

PHI collected at recruitment, pre-enrollment AND BEFORE CONSENT will only include the following variables – potential subject's name, email, phone number, primary diagnosis (diabetes or heart disease). This information will be for recruitment purposes only and will be stored in the protected UIC Box health folder only. Only designated key personnel will have access to it.

☐ Limited Data Set [Protected Health Information (PHI) subject to the Privacy Rule that includes elements limited to city, state, ZIP Code, elements of date, and other numbers, characteristics, or codes not considered as direct identifiers]. *Requires a Data Use*

Agreement.

Please note:
- *Items i and ii require consent and/or authorization (if PHI is involved) from the subject or a Waiver of Consent and/or Waiver of Authorization (if PHI is involved) from the IRB.*
- *UIC and/or outside agencies may require the use of a data use/data transfer agreement that outlines the procedures necessary to protect identifiable or coded data that will be transferred or shared between agencies. You must contact the Office of Sponsored Programs (OSP) at 312-996-2862 or awards@uic.edu for additional information and direction.*

b. Indicate the method(s) used to secure each data type.

☒ Password access
☒ Portable devices – Specify encryption software (required): **Data Protection (in-built within Apple iPad)**
☐ Encryption software will be used – Specify encryption software:
☒ Secure network server will be used – Specify secure server: **College of Applied Health Sciences**
☐ Stand alone desktop/laptop computer will be used to store data
☐ Not connected to server/internet
☐ An organization outside of the UIC will store the code key.
X Locked file cabinet
☒ Locked office/lab.
☐ Locked office suite.
☐ Locked refrigerator/freezer
☐ XOther - Specify: HIPAA compliant UIC Box Health Folder

c. Indicate when **identifiers** (including the master list) will be removed or destroyed.

☐ End of data collection
☒ End of data analysis
☐ Post publication/dissertation defense
☐ Other – Specify:

4. Data Sharing

a. Will the data or specimens be shared with persons **other than** UIC investigators and research staff noted on the protocol application and Appendix P?

☒ No – *Skip to item C.1.*
☐ Yes – Specify with whom the data will be shared:

b. Indicate the manner in which the data will be shared:

☐ As a de-identified dataset – *Skip to item C.1.*
☐ With direct identifiers
☐ With indirect identifiers (i.e., coded dataset) and/or Limited Data Set
Identify who will have access to the code key or master list:

c. Specify how identifiable data will be transferred:

☐ Non-electronic transfer (hard copy or physical specimens) – Specify:
☐ Transmitted over a secure network – Specify network:
☐ Via UIC e-mail - Specify encryption:
☐ Cloud based data sharing program (*UIC Box Health Data Folder is the only approved method of sharing PHI in this manner*)
Specify:
☐ Other - Specify:

C. 1. Does the research protocol have a data and safety monitoring plan? *For more information refer to UIC OPRS HSPP policy Data and Safety Monitoring Plans (DSMPs), Data and Safety Monitoring Boards (DSMBs), and Data Monitoring Committees (DMCs).*

☐ Not Applicable. – *Skip to item D* as all of the following criteria are met:

- research is minimal risk,
- research does not involve physical or therapeutic intervention with subjects,
- subject trauma or distress is not an anticipated risk, and
- the sponsor does not require a monitoring plan.

☒ Yes – Describe the plan: **The Principal Investigator (PI) will be responsible for ensuring participants' safety on a daily basis. A local DSMB has been established. The Chair of the DSMB will serve in the capacity of Safety Officer, The Data and Safety Monitoring Board (DSMB) will act in an advisory capacity to the NIA Director to monitor participant safety, evaluate the progress of the study, to review procedures for maintaining the confidentiality of data, the quality of data collection, management, and analyses.**

A minimum of two annual meetings will be scheduled between the research team and the DSMB. Meetings will occur via teleconference, web conference or in-person per the convenience of DSMB members. The first meeting will focus on updating the DSMB about study progress and issues related to participant safety. The second meeting will focus on reviewing data quality and management. Reports summarizing safety issues, study progress, and data management will be submitted to the DSMB twice a year.

The content of the report will include projected timeline and schedule, summary of changes (if an to study protocol), enrollment status (including reasons for ineligibility and participation refusal), demographic characteristics of recruited participants, treatment adherence and completion, and incidence of adverse events and their resolution.

2. Is this a multi-center trial AND UIC is the lead site or serving as the data coordinating center?

☐ Yes – Plans for managing and communicating the unanticipated problems involving risks to subjects or others, interim results, and protocol revisions among the multiple sites are described within the uploaded protocol OR explain:

☒ No

D. Will you be applying for a Certificate of Confidentiality? *Research funded by NIH that involves sensitive, identifiable data will be automatically granted a Certificate of Confidentiality. Ensure the consent document includes the appropriate language.*

☒ No

☐ Yes – Include the required template language in the consent document and refer to the Guidance for Investigators: Certificates of Confidentiality for more information regarding the submission process and regulatory requirements.

E. Is this research being funded by the National Institute of Justice?

☒ No

☐ Yes **–** The investigator is responsible for the following:

- Uploading the NIJ Privacy Certificate
- Ensuring the proposal indicates that a copy of all data must be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the consent document, data collection instruments, surveys, or other relevant research materials

- Ensuring the Informed Consent Document(s) include:
  - NIJ approved Privacy Certificate language
  - De-identifiable information will be sent to the National Archives of Criminal Justice Data
  - A statement indicating that if a subject is a danger to themselves or others, it will be reported to the authorities
  - A statement indicating that communicable diseases (TB, HIV) will be reported to the state and/or federal public health authorities
  - Statement that current or past domestic, child, or elder abuse is not reportable

Refer to the Additional Informed Consent Template Language and the Guidance for Investigators Informed Consent for additional information.

XIII. Compensation & Costs

Payment in exchange for referrals of potential participants (finder's fee) and payments designed to encourage or accelerate recruitment by being tied to the rate or timing of enrollment (bonus payment) are generally unacceptable.

A. **1.** Will subjects receive any compensation (for example: money, gifts, or gift certificates) directly related to research participation? *If subjects will be entered into a lottery, select "No" and skip to item B.*

☐ No – *Skip to item B.*
☒ Yes - Indicate the type of compensation.
☒ Monetary (total amount: $**90**)
☐ Non-Monetary
☐ Both

2. Describe in detail:

a) How compensation will be prorated (e.g., $x for each visit, $y for subjects who do not qualify after screening visit, etc.): **Participants will receive a Target gift card worth $30 for completing all surveys and assessments at the beginning of the study and a Target gift card worth $40 for completing all follow-up surveys and assessments. This amounts to a total of $70 for completing the study. Participants who do not complete the study will be compensated for the portion they have completed. In addition, participants will received $10 to offsetparking and transportation costs for attending the two in-person sessions. No identifiable subject contact information will have to be shared with the 3rd party for payment processing**

b) When compensation will be provided (e.g., after each visit, at the completion of all visits, 6-8 weeks after the completion of all visits due to processing of check, etc.) **and** in what format (e.g., cash, check, VISA gift card, etc.): **We will send the first $30 gift card by postal mail within approximately one week after each participant completes all surveys andassessments at the beginning of the study. We will send the second $40 gift card by postal mail within approximately one week after the participant completes all surveys and assessments at the end of the study. Participants will be paid for transportation/parking in cash at the end of the in-person visit.**

B. Will subjects be entered into a lottery for compensation (for example: money, gifts, or gift certificates) before, during, or after participation in the study?

☒ No
☐

Yes -

a. Provide a justification for conducting a lottery rather than compensation per subject:

b. Indicate the type of compensation:

c. Indicate the odds of winning the lottery:

d. Indicate when the winner will be notified and receive the compensation:

C. Does this study provide payments in exchange for referrals of potential participants (finder's fees) or payments designed to encourage or accelerate recruitment by being tied to the rate or timing of enrollment (bonus payment)?

☒ No

☐ Yes – Describe:

D. Are subjects or their insurance/third-party payer responsible for any research-related costs?

☒ No

☐ Yes – Complete items a and b:

a. List the procedures/expenses:

b. Provide a justification as to why research-related expenses are not being covered by the research.

XIV. Procedures to Obtain Informed Consent/Assent

A. Indicate the type(s) of consent you will obtain:

☐ Written

☒ Verbal

☒ Waiver of Informed Consent and/or Waiver of Signed Consent

B. Indicate who will obtain informed consent from potential subjects.

☐ PI

☐ Co-investigators

☒ Research coordinators/Others as delegated

C. Indicate where and when informed consent will be obtained from potential subjects.

We are requesting a waiver of consent for recruitment purposes. We will secure written, signed consent before study enrollment The research assistant will be trained by the PI with special attention to assessing participants' capacity for consent. An assessment script has been developed for this purpose. Duringthe consent process, potential participants will be periodically asked questions to ascertain their capacity for consent (e.g. In your own words, can you describe the risks of participating in this study? What happens if you change your mind about participating?). If the participant answers accurately, the research assistant will continue with the consent process. If answers are inaccurate, the participant will be deemed ineligible for the study. In addition, the Short Orientation Memory Concentration Test (SOMCT) will be used during the screening process to ensure the participant is eligible for the study. A score of 0-8 on this test indicates normal to minimal impairment. Any one with a score>8 will be considered ineligible.

Informed consent will be obtained both in person and remotely. Participants who are recruited in person at one of the study clinics will be asked if they have time to complete the screening questionnaire and the consent process rightaway. Participants will be given one signed hard copy of the form for their records while the research assistant will retain

the second copy, which will be later (after the clinic schedule is over and on the same day) stored in a locked cabinet in the PI's research laboratory.

For participants who are recruited remotely and screened by phone, the research assistant will ask if they are willing to complete the consent process during the same phonecall or if they'd like to schedule a separate phonecall for explaining the consent form by phone before baseline data collection begins. Either way, the research assistant will explain the consent form in detail and explain that they can sign the form on a separate and secure platform. We will use UIC REDCap hosted by CCTS/IHRP fpr this purpose. We will set up an e-consent survey in RedCap. The e-consent survey form will be sent to each participant by email using a unique survey link so that the response status and follow-up can be done using the individually linked information. This email will be sent by the research assistant through an encrypted email via Microsoft Outlook. When the participant clicks on the link, they will be asked to authenticate themselves using a pre-agreed password. The password will be agreed upon by the research assistant and participant over the phone right before the email link is sent. When the e-consent framework is setup, at the end of consent form participant will be asked to certify the information before clicking 'submit' under this statement - "I understand that clicking submit will electronically sign the form ad signing this form electronically is the equivalent of signing a physical form." They will also be able to download a PDF copy of the form.

D. Does the potential exist for enrolling subjects (or subjects' LARs) who do not understand English?

☒ No

☐ Yes – Describe how the consent process will be conducted (e.g., who will convey information to the subject or LAR in a language they understand, whether the consent will be documented using a translated consent form or short form).

For information about the involvement of non-English speaking subjects in research, including use of the short form, please refer to the Guidance: Involvement of Non-English Speaking Subjects in Research at the University of Illinois at Chicago.

E. Will any portion of the research involve deception?

☒ No

☐ Yes - Upload Appendix J and a debriefing statement with this application.

XV. HIPAA Compliance

A. Does your research use and/or disclose Protected Health Information (PHI)*?

☐ No – *Skip this section.*

X Yes

**Data is considered to represent PHI when an individual's health information, including billing records, contains or is linked to one of the identifiers listed in #XII.B.1. For example, health-related information is considered PHI if any of the following are true:*

- *The researcher obtains the information directly from a provider, billing records, health plan, health clearinghouse or employer (other than records relating solely to employment status);*
- *The records were created by any of the entities listed above and the researcher obtains the records from an intermediate source which is NOT a school record or an employer record related solely to employment status; OR*
- *The researcher obtains it directly from the study subject in the course of providing treatment to the subject.*

Health-related information is not considered PHI if the researcher obtains it from:

- *Student records maintained by a school;*

- *Employee records maintained by an employer related to employment status; OR*
- *The research subject directly, if the research does NOT involve treatment.*

B. Will PHI be used for the purposes of identifying and/or recruiting potential subjects for the research?

No
X Yes

C. Will subjects be selected from records outside the UI Health System?

☒ No
☐ Yes – Indicate who gave approval for the use of the records:

- Upload the protocol, consent documents, letters, etc., for securing consent of the subjects for the use of the records if the records are "private" medical or student records.
- Upload written documentation for cooperation/permission from the institutional holder or custodian of the records.

D. Will any research related information be put into the health information records or any other permanent record of the subject?

☒ No Clinical case notes, blood pressure readings, and HBA1c readings are the only PHI that will be used in this study. These case notes willbe collected solely for monitoring fidelity of the intervention. These notes will NOT be put into the health information records or any other permanent record of the subject. Blood pressure and HBA1c readings will be retrieved from EHRs, AFTER obtaining consent from patients; no information will be added to patient records.

☐ Yes - Explain: