Using Smart Devices to Implement an Evidence-based eHealth System for Older Adults

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STUDY SUMMARY

The primary purpose of this study is to investigate whether voice-activated "smart" technology increases adoption and sustains use of an evidence-based electronic health intervention (Elder Tree, or ET) for older adults with multiple chronic conditions, and thereby improves its potential to widely enhance quality of life and health outcomes. ET is an existing intervention providing tools, motivation, and support on a computer platform to help older adults manage their health. An AHRQ-funded randomized controlled trial (RCT) found that ET improved quality of life and other factors among high users of primary care with multiple chronic conditions such as diabetes and hypertension. However, many people did not use it extensively, which is a common problem with all web apps.

ET is based on the extensively tested Comprehensive Health Enhancement Support System (CHESS).[1-7] ET is a "walled garden" free of ads, with design features based on older users' feedback as well as best-practice principles such as uncluttered screens and large type.[8] Like all CHESS systems, ET uses computers to deliver key elements of successful interventions: long duration, ongoing outreach, prompts, monitoring, cognitive reframing, action planning, problem solving, self-tailoring, and peer support.

The central question is, can the unique accessibility characteristics of smart devices substantially increase and sustain the impact of ET among older adults? Toward that end we propose a pragmatic, 3-arm RCT comparing the laptop version (ET-LT) to a smart system version (ET-SS) to Control or Usual Care (UC) with no technology. The goal is to assess whether ET-SS is better at 1) sustaining use of ET and 2) improving long-term QOL, health, and health service use (reducing readmissions) among older patients with multiple chronic conditions.[9]

1.0 BACKGROUND & SIGNIFICANCE

Multiple chronic conditions (MCCs) are costly and pervasive among older adults. MCCs account for 90% of Medicare spending, and 65% of Medicare beneficiaries have 3 or more chronic conditions; 23% have 5 or more. MCCs are often addressed in primary care, where time pressures force a focus on medication and lab results rather than self-management skills. Patients often struggle with treatment adherence and the emotional and physical burdens of self-management and health tracking.[10] Chronic conditions reduce quality of life (QOL) and increase loneliness, which exacerbate those conditions.[11-13]

ET laptop intervention. As reported in a paper under review, an earlier AHRQ-funded laptop version of ET significantly increased QOL. In a current NHLBI clinical trial, our team is testing a version of ET for patients with MCCs that adds a report to clinicians (CR) documenting changes in health status. Health-tracking data reported by patients to ET are sent to clinicians before patients' appointments to help make those visits more effective and efficient. In a lung cancer RCT of CHESS,[7] the CR reduced symptom distress by more than 50% over 12 months ($p<.001$). We added the CR to ET because of these compelling results and are testing hypotheses that patients assigned to ET, vs. an attention control, will have better QOL, fewer symptoms, and better condition-specific lab scores. The AHRQ-funded trial of our earlier ET found high and sustained engagement, relative to reports for other health apps.[14-17]In months 1-6, 89% of all participants used ET a mean of 44.84 days. However, in just 4 months, pages viewed dropped by 53%. Overcoming barriers to sustained, in-depth use is a critical challenge. Discussions with older adults found two main reasons why use dropped off: 1) The little hassles of going to and turning on the computer, remembering and entering a password, and opening a service created barriers to use. 2) Many older adults face barriers due to limitations such as arthritis and impaired vision.

Enter the "smart system." Smart speakers are voice-activated devices connected to the Internet. Because they are used by talking and listening rather than typing and reading, many barriers associated with laptop use are

avoided. One can, for example, access a smart version of ET from their easy chair. They would not need to get up and go to the computer, type, and read. And, smart systems provide easy access to other Internet services.

Smart technology makes things convenient, as well as entertaining. Smart speakers are so new there has been little study of their general use, let alone health-related effects. That said, a 6-month pilot study of the Amazon Alexa with 18 older adults in a retirement community[18]found that 100% said Alexa made their lives easier and 71% felt more connected to friends, family, and community. Uses included setting alarms and timers and listening to music, weather, news, and other information. This suggests older adults will prefer smart speakers. A small test of smart speakers with 12 veterans receiving rehabilitation services found that 100% reported the speaker "useful in their daily lives" and that they would be "very likely to continue using" it for a wide range of services, including relaxation, information, alerts and reminders, and even companionship.[19] Recent media reports indicate a groundswell in the use of speakers among the elderly and people with vision loss, tremors, mobility problems, dementia, and more.[20-24]

In fact, the acceptance of smart speakers has been nothing less than extraordinary. In the few years since its introduction, 90 million U.S. adults have placed one in their home—a faster adoption rate than TV or the Internet.[25,26] Industry estimates suggest that by 2020 over 30% of Internet browsing will occur on such devices.[27] Recently Epic, a leader in medical record software, announced that within 4 years data entry will be audio based.

We believe smart devices are ready for dissemination for behavior change. Worth noting is a study conducted by the NPR and Edison Research group in which smart speaker owners reported behavior changes in use of radio (39% said they use radio less), TV (30%), and smartphones (34%). The study also shows that 83% of smart speaker users are using that device at least as much as in the first month they bought it, with 70% using it daily.[28,29] This contrasts with dramatic *reductions* in the use of smartphone apps over time.

What makes smart speakers so innovative is their ease of use. Patients can ask questions and get answers immediately spoken back to them. They can hear and respond to messages, request audio services such as guided meditation, record health data, and more, just by talking. In theory, these capacities also exist on smartphones, but speakers have been developed for natural interactivity, incorporating chatbots that mimic conversational turn-taking. Smart speakers can be used by patients whose limited vision or dexterity makes it difficult to use a mobile phone or laptop. Improvements in artificial intelligence and voice recognition hold the promise of overcoming these difficulties more than ever before, assuming the necessary data are available.

Smart displays. Speakers do have limitations. Without a visual display, it can be hard (particularly for those with memory challenges) to recall information they have heard but not seen. A smart speaker could link users to a laptop when they want information conveyed visually, but this is inconvenient. Smart displays are specifically designed to address such issues, including screen magnification for those with partial vision.

The Center for Health Enhancement Systems Studies (CHESS). CHESS is a research center at the University of Wisconsin–Madison. CHESS, or Comprehensive Health Enhancement Support System, is also the name of the platform we developed to help people cope with life's challenges. We have conducted 16 RCTs of our eHealth CHESS systems and published more than 190 peer-reviewed works, as well as over 100 about organizational change and implementation engineering. In randomized trials, CHESS significantly improved: 1) childhood asthma control and parent coping[1]; 2) QOL and cost of care in HIV patients[2]; 3) QOL and self-efficacy in breast cancer patients, including elderly women[3]; 4) physical activity for survivors of colon cancer[30]; 5) risky drinking[6]; 6) caregiver coping for patients with dementia[31]; and 7) caregiver burden, symptom distress, and median length

of survival in lung cancer patients.[7] That experience bodes well for the success of this project.

Preliminary data. Our AHRQ-funded Center of Excellence in Active Aging developed ET to help older adults remain independent. Our completed RCT involved 310 older adults from 3 Wisconsin counties (urban, rural, and suburban).[32] Among high users of primary care, patients assigned to ET, compared to patients in the control group, experienced greater improvements in mental QOL (OR = 0.31, p = .006), social support provided (OR = 0.25, p = .002), social support received (OR = 0.16, p = .011), and depression (OR = -0.20, p = .037). These findings suggest that ET improves health when used by patients with high primary care use. The question is how to maximize ET use. In our ongoing NHLBI clinical trial (1-R01 HL134146), we are examining the impact of a laptop-delivered ET on QOL, of health, and healthcare use for older patients with 3 or more chronic conditions. Now we are planning to compare it with ET delivered by a smart display.

Pilot testing the smart speaker and smart display. We placed a Google Mini speaker in the homes of 11 older adults for 5 weeks. At the end of the test, we interviewed the older adults to learn how they used and felt about the device. During that time, staff contacted them by phone to suggest something new to try (e.g. make a phone call, set up a reminder, use the Internet); no one reported trouble following through on the suggestion. All felt the Mini was easy to use, and 10 of the 11 "strongly agreed" it would improve older-adult quality of life. A common criticism of the speaker was the periodic difficulty of asking a question in a way the Mini would understand, a problem that can be addressed by a smart display showing how the question was understood. Also, reviewers felt it would help to review comments later made by the technology or read them to confirm what was heard, both of which are possible with the display.

In a separate pilot, 10 older adults were given an opportunity to observe and interact with the Lenovo smart display. All had used the Google Mini. All felt the display was a significant advance over the smart speaker and that they would find the display progressively more valuable as they aged. In particular, they noted things a speaker can't do, such as allowing the user to dig more deeply into a topic with lists of options and prompts rather than a single response. For example, if users were to ask a smart speaker about their high school, they might get a 10-second audio response, but with the display they would get that response plus options to see a picture of the school, learn about graduating class size, and more. Participants liked that the display could show printable answers, eliminating the need to take notes, and that they could go back to repeat information. In general, they felt having a visual component made many smart features easier to understand and follow. All felt the display was easier to use than a laptop computer because of its ease of access.

Innovation. ET-SS is highly innovative for the following reasons.

- *One location - wide access.* ET currently operates on a laptop because many older adults have difficulty using smartphones. Although portable, laptops tend to sit in one place for older adults. For frail older adults, even walking to the computer can be a challenge. With our proposed system, smart devices will be placed in multiple areas, giving easy, low-cost communication with ET without needing to walk to or carry the device.
- *Tactile input - two-way voice activation.* Most eHealth apps, including ET's laptop version, need patients to see content on a screen and respond by typing or touching options on-screen. Physical limitations, common with elderly (vision, motor control, hand pain), can make this difficult. Smart speakers provide bi-directional, voice-activated interactions. Patients ask out loud, listen to answers, and follow up verbally.
- *Multi-step activation – one-step activation.* Laptops require multiple steps to engage a desired feature. With a smart speaker, a patient can simply say, "Hey ET, I'll answer my health survey now." Voice authentication replaces a laptop's burdensome activation, login, and even site navigation.

- *Medical focus – whole-person focus.* All chronic diseases share certain features. Patients feel frustrated, discouraged, and lonely. They face continual, ongoing ups and downs. NIH funded us to develop one program that would address these common needs shared by all patients with MCCs. ET's focus is therefore the whole person, not the management of any particular disease. In our completed trial, ET improved QOL among those with high levels of primary care use across a wide range of conditions. Older adults in that RCT reported that ET increased happiness by being fun, not just utilitarian. In our pilot studies, all were enthusiastic about the smart system's potential, not only for health tasks (e.g. medication reminders) but also for music and social interaction. In a national survey of more than 1800 adult users,[32] top requests included jokes, games, and music, underscoring the expectation of pleasure. We predict the smart system's ease of use will increase sustained use of ET's content, prompt more overall use and higher quality of life.
- *Groundbreaking.* This will be the first large RCT of a smart system that is likely to take the health field by storm. The knowledge gained could significantly improve future designs and implementations of smart devices.

2.0 STUDY OBJECTIVES

Overview of methods. We propose a 3-arm RCT to examine whether delivering ET on the smart system (ET- SS) will increase frequency and sustainability of use and improve quality of life, when compared to ET on the laptop (ET-LT). A Control group (ET-C), which will receive no technology (smart system or laptop) or ET, will allow us to assess whether both groups that receive the ET intervention (albeit on different platforms) show equally positive effects relative to control, or whether ET delivered via one platform is more efficacious relative to the control and other intervention group. We will create ET-specific commands so that the smart system operates well with ET (e.g. "Hey Google, I'm ready to take my survey"). The RCT itself will begin by identifying eligible patients and sending them invitation letters from their primary care provider (PCP). Patients who respond will be screened and recruited into the study, baseline data will be collected, and patients will be randomly assigned to a study arm, provided with devices if applicable, and trained. The intervention will last 8 months. Data will be collected at 0, 4, and 8 months. The final months of the study will be spent analyzing and interpreting qualitative and quantitative data and disseminating results through publications, presentations, and real-world field tests.

Specific Aim 1: Enhance the smart system platform to deliver ET.

Smart system technology. Users activate a smart system with a wake phrase (e.g. "Hey, Elder Tree"). Voice authentication gives individuals exclusive access to their content. All smart systems have security measures to prevent wiretapping, and data transmitted to data centers (e.g. Google) are encrypted. ET-related requests will be saved, allowing us to measure smart system use.

ET description. ET provides tools, motivation, and social support to help patients manage chronic pain and other chronic conditions. ET is consistent with Self-Determination Theory, which asserts that satisfying 3 basic psychological needs contributes to adaptive functioning: competence (feeling effective, not overwhelmed), social relatedness (feeling connected to others, not isolated), and intrinsic motivation (feeling autonomous, not coerced).

Competence services include:

- Pain learning modules: interactive lessons that will be available to participants weekly and will focus on understanding chronic pain, learning coping skills, and suggested action steps.
- Easing distress: Tools such as cognitive reframing,[33] self-calming with games, guided progressive relaxation recordings, deep breathing, and mindfulness meditations.

- Reminders: Schedule reminders (e.g. medications, appointments, blood pressure readings). Prompts will automatically ask patients if they intend to carry out the action, a question shown to improve adherence.[34]
- Tracking: Weekly survey of health-tracking questions (e.g. sleep, mood, falls). Patients can view trend graphs over time.
- Health Library: High-quality articles and videos on topics such as exercise, pain, sleep, anxiety, falls and balance, grief and loss, nutrition, and talking with your doctor. Vetted by Dr. Mahoney.

Social relatedness services include:

- Regularly scheduled social "Meetups" with research staff and guest speakers via Google Meet.
- Community Discussion Boards: Monitored, online, anonymous discussion groups for support and engagement. Research consistently indicates that participating in social interactions on CHESS predicts positive outcomes, including quality of life.[35,36]
- Private Messages: Email-like function for ET members to communicate privately with one another.

Intrinsic motivation services include:

- Thought of the Day: Daily motivational prompts to boost happiness and resilience.
- Personal stories: Audio/video of patients' advice/experiences (e.g. what to avoid, tips for coping).
- Journal: Daily writing prompts based on positive psychology.[37]

Clinician report (CR):

- The CR displays data from patients about general health variables relevant to all chronic conditions but rarely collected in clinical medicine (e.g. sleep, relationship quality, falls, missed medication). The variables were determined by practitioners in geriatrics and family medicine in the UW Health system. Data are displayed in at-a-glance graphics based on statistical process control,[38] allowing a clinician to identify problem areas and successes worth discussing.[39] When coupled with traditional clinical data (e.g. blood pressure), the CR adds an important dimension to the data set. The CR summary of trends is sent prior to appointments, facilitating more effective visits. Our lung cancer test of the CR found that issues were addressed more quickly, reducing the need for subsequent intensive clinician involvement.[40]

Design considerations.

How ET-SS will protect privacy. We created several ways to protect the privacy of older adults and families and to alert when our system is recording. We will help users understand:

- *When recording is happening, and when it is off.* ET-SS will not record during initial interactions or after users have indicated they are done. We will add a highly visible indicator light that turns on during audio recording. Users can turn off our program at any time. These features have been well received during past studies. Users are comfortable with the recording process, the indicator light, the transparency of our procedures, and the ability to control when recording ishappening.
- *How recorded data will be used.* Audio recordings will be copied and stored on a secure server that only the research team can access. Researchers may use the speech data in publications only if all identifiable information has been removed and will quote users only with their permission. Audio recordings not related to the study will be deleted. Participants can review what was recorded and consent to whether the recording can be used in research. These statements require additional initials on the consent form.
- *What happens if someone leaves the recording on?* ET-SS will automatically shut down due to inactivity. After 3 minutes, it asks if the user is "still there." If no response within 30 seconds, the audio recorder is disabled. Users can pause audio recording by pressing a dedicated "pause"button.

Potential negative impacts and how are they addressed. A potential negative is that older adults may disengage because the novelty has worn off. ET-SS will use two designs to promote long-term interaction: 1)

using information from past interactions during current dialogue[41] and 2) revealing a personality.[42] To do so, it will keep track of previous sessions. Each session starts with ET-SS reminding users of their previous activity. Also, over time, the system will reveal details of its own fictional personality during reading sessions (e.g. its favorite color is blue). These personal comments are designed to help build rapport during human–computer interactions.[43] Some older adults are ambivalent about artificial characters building an emotional connection. There is some research on how social robots should deliver on their social interaction potential.[44,45] We are exploring ways in which ET-SS could serve as a facilitator to engage family and friends.[46,47]

Design decisions already made to limit frustration with technical problems during long-term in-home use. 1) ET-SS is modeled after typical human behaviors that can help older adults interact with the system in socially positive ways.[46,48] 2) We will closely monitor and act on problems with ET-SS. This monitoring will include regular email check-ins with users to conduct routine maintenance checks. We will also coach users on simple procedures for resetting the system as needed. 3) We will include proven ways to mitigate the impact of breakdowns[49] including recovery strategies and expectation setting.

Dealing with ways ET-SS might interfere with older adults' lives. Co-designing with older adults will help us anticipate problems and design preventive solutions. Current designs include features that prevent interference with daily life, e.g. an automated option to avoid quiet time disturbances.[43,50] To ensure that privacy is respected, we provide, as noted above, a clear indication of when the device is recording and the opportunity to stop it at any time. We also use information about the user to personalize interactions but only with their knowledge and consent.[51] Concerns have been raised about using a device that is always listening. While microphones are always on, smart systems do not retain data until the wake word is used. Recordings will be stored on a distant server. We will periodically (or when requested) offer to delete those data.[52]

Ensuring patient safety. Mental health professionals are not allowed to break confidentiality except when there is imminent danger. In non-emergency situations patients will be encouraged to call their doctor or a trusted colleague. If we find that a patient is facing an emergency, we will inform the primary care team, following the treatment program's standard operating procedures for serious clinical situations.

Specific Aim 2: Conduct a randomized clinical trial to test the following hypotheses.
Figure 1 describes the 3-arm RCT. Baseline covariates include race/ethnicity, education, baseline outcomes, life stresses, health service use, and technology use.

1. Primary outcomes: For those in ET-SS (vs. ET-LT vs. Control): pain interference will decrease and psychosocial quality of life will increase.
2. Secondary outcomes: ET-SS (vs. ET-LT vs. Control) will increase ET use at 8 months, increase physical quality of life, well-being, and communication with doctor. Pain intensity, 30-day hospital readmission rates, health distress, loneliness, and

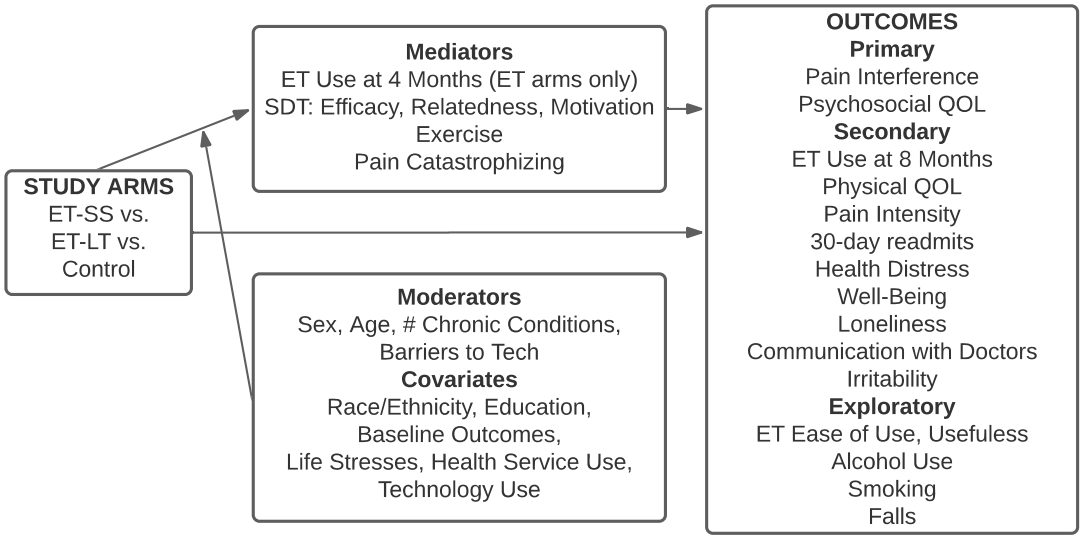

Figure 1. Logic Diagram

irritability will decrease. We also plan to compare ET-LT to the UC control, given the unique focus of chronic pain in this study.
3. Mediators: Self-Determination Theory constructs of competence, social relatedness, and intrinsic motivation, together with exercise and pain catastrophizing, will mediate the effects of study arms on outcomes. Additionally, use of ET at 4 months will mediate effects of study arms (ET-LT vs. ET-SS) on 8-month ET use.
4. Moderators: ET-SS (vs. ET-LT vs. Control) will show greater improvements for a) women (vs. men), b) patients with more (vs. fewer) chronic conditions, and c) patients with fewer barriers to using technology for the primary and secondary outcomes.
5. Exploratory analyses: We will measure level of use of each ET service, how it differs between the two ET arms, and perceptions of Elder Tree and the Clinician Report. We will also measure alcohol use, smoking, and falls.

ET implementation and operation.
Our Center developed the NIATx change model, which has been used by more than 3,000 behavioral health treatment agencies.[53] NIATx led to our extensive research on models to predict and explain implementation success,[54] ingredients of successful change,[55] and diffusion of innovations.[56] We will use this research to guide the implementation and operation of this study.

Initiate. Physician change leaders and clinic administrators have already been appointed in the 6 UW clinics we propose to use: 20 S. Park, 884 eligible patients; Yahara, 602 eligible patients; Odana, 485 eligible patients; Northeast,181 eligible patients; UW East, 376 eligible patients; Sun Prairie, 117 eligible patients. We have active collaborations with those clinics. In fact, we recently completed recruitment of 346 subjects from UW clinics to an RCT four months ahead of schedule. The clinic administrators are familiar with our research team and UW Health clinic operations and have a strong relationship with clinical staff. Our research staff has engaged clinic staff to understand the clinic flow and refine our implementation process. We will regularly follow-up with clinic leaders, using the 15-item Organizational Change Manager,[57] to measure and monitor implementation fidelity.

Prepare the environment. Clinic staff and patients will be asked to advise on SS design (already done for the LT) and implementation. We have personally experienced what it is like to be a patient at these clinics. This "walk- through"[58] helps us tailor LT and SS operations to each clinic. Clinic staff will specify how operations will be handled to minimize frustration (e.g. in a given clinic we may decide to deliver the CR by fax, not email, 3 days before a scheduled patient visit). Clinic staff will help finalize processes for patient recruitment, data collection, and feedback about the study. We are experienced in community-based participatory research, most recently via our Center of Excellence in Active Aging, where we engaged 53 of 72 Wisconsin counties and hundreds of volunteers to implement the first version of ET.[32] We will use the British NHS Sustainability Index (which we developed) at baseline and every 4 months to identify and reduce barriers to sustainability.[59]

Refine systems. In the first 12 months, our team of clinicians, engineers, and scientists will make design modifications to integrate the smart display and associated smart speaker. Our information technology team is already addressing those issues, building on our previous experience with digital assistants and wireless devices. Dr. Mahoney will guide creation of symptom management tips, health trackers, and self-management materials. Some of the data collected by our technologies will be used for just-in-time tailoring of resources to participants., including 1) modifications to data entered at setup, 2) health behaviors, and 3) health status data.

Make ET easy to use. We'll do this by 1) designing interactions with the SS so they require no training (e.g. assessments/alerts) and 2) continuing our commitment to a simple, intuitive interface for ET.

Initiatives to sustain ET use. 1) *Monitors* (lay people selected for communication skills and empathy) will keep ET appealing by removing inappropriate posts and calming any conflict that may occur. Our project director will be the lead monitor, reviewing use data and sending encouraging notes. 2) *Ice breakers* will encourage use, e.g., by asking people to find common points in their background ("Where were you on the day of the first moon landing?"). *3) Refreshers* will encourage patients to rate, comment on, and suggest ways to improve ET. 4) Under guidance of Dr. Mahoney, we will update ET as new information about relevant conditions becomes available. 5) We avoid using unsustainable financial incentives.

Training and support. To support adoption of ET, we will adapt the experience of Front Porch Communities and Services in their 2017 test of Amazon Echo.[18]Our adaptation will include bimonthly phone-based workshops to cover use of devices, answer questions, and address technical support issues. The workshops will differ by whether the participant has ET-LT or ET-SS. Family members will be encouraged to join in to build enthusiasm. Topics include: 1) overview and setting up ET, and using our help line; 2) ET features; 3) open call-in times to answer questions; 4) linking to high quality resources outside of ET via the Internet; 5) accessing audiobooks; 6) trying a new ET feature; 7) setting reminders; 8) discussion groups and weekly health-tracking questionnaires (for the CR); and 9) making calls and connecting with friends. While there will be some overlap on topics, the Front Porch participants welcomed that duplication. We will also check in with participants during the first 3 weeks and send out a monthly newsletter to participants.

3.0 SELECTION OF SUBJECTS

Patient eligibility/inclusion criteria. Eligible patients will:

1. Be ≥60 years old;
2. Have been treated in UW Health clinics in the last 12 months, with no plans to leave during the study period (only relevant for UW Health patients, not patients recruited from the community); 3. Have a chronic pain diagnosis AND a medical diagnoses of <u>three</u> or more of the following common chronic conditions: COPD, asthma, diabetes, hyperlipidemia, hypertension, ischemic heart disease, atrial fibrillation, heart failure, stroke, BMI 30+, cancer, chronic kidney disease, depression, osteoporosis, arthritis, or dizziness/falls/loss of vestibular function;
4. Be willing to share healthcare use (e.g. 30-day readmissions) in EHRs (only relevant for UW Health patients, not patients recruited from the community); and
5. Allow researchers to share information about a patient's health status with their PCP.

Patient exclusion criteria. Patients are not eligible if they:

1. Require an interpreter
2. Have a medical diagnosis of any of the following:
    - Alzheimer's
    - Schizophrenia/other psychotic disorder
    - Dementia
    - Autism spectrum disorder
    - Known terminal illness with less than 6 months to live
    - Acute medical problem requiring immediate hospitalization

Recruitment process.

<u>UW Health Family Medicine and General Internal Medicine Clinics:</u> UW's Clinical and Health Informatics Institute (CHI2) will use clinic records to identify patients meeting the eligibility criteria described above and send eligible patient data (including first and last name, address, birth date, age, UW clinic location, and primary care doctor) to the UW Office of Clinical Trials (OCT) via REDCap. Potential participants will receive an opt-in letter describing

the study and consent form from the OCT, plus a stamped return letter inviting contact from the study team.

Community Recruitment: We will supplement recruitment at UW Health with community efforts to increase the racial diversity of our patient population. Through collaborations with the African American Health Network (AAHN), Rebalanced-Life Wellness Association, African American Opioid Coalition (AAOC), and the Community-Academic Aging Research Network (CAARN) we plan to reach out to black churches, community centers, fraternity and sorority health service programs, and other organizations in the Madison and Beloit areas. We will distribute a recruitment flyer and consent with a return card/opt-in and conduct Zoom and in-person community sessions when possible to introduce the study and invite participation.

Access Community Health Centers (ACHC): In addition to our community recruitment efforts, working with ACHC, will help us reach a larger number African Americans and other participants of color, as well as expand our reach to underserved patients. We will work directly with ACHC staff to disseminate the recruitment flyer, consent, and return card/opt-in to potentially eligible patients.

Regardless of recruitment method, when a return card/opt-in is received, study staff will call and assess eligibility; provide a study overview that includes potential benefits and risks, study procedures, and compensation; thoroughly walk through informed consent; and address questions. The baseline survey will be mailed. Patients will be given adequate time to make the decision whether or not to participate and in some cases a follow up phone call will be scheduled after the patient has time to review the survey and consent form.

Once a patient verbally confirms they want to participate, a home visit will be scheduled to collect the baseline survey, randomize, set up equipment, and train. Note that all study staff that conduct home visits will be fully vaccinated for Covid-19, will wear face masks, and socially distance as much as possible while in the patient's home. If no visit is desired, once the completed baseline is received via mail, equipment will be shipped, and technology setup and training will be conducted by phone. The baseline survey should take 20-30 minutes. Measures will be the same in all three arms to avoid differential drop-out. We will document those who choose not to participate and why, following CONSORT standards.

4.0 METHODS

Development Phase Usability Testing

The development phase will involve 16 adults age 60 or over with little to no experience using a smart system who are willing to participate in a 10-day usability test of the smart system. Feedback from the usability testing will help inform final development and refinements of the system before the RCT begins. Specific goals include:

- How to make system set up easy for the user
- How new users learn to use the system
- What may go wrong in the users' interaction with the system
- Overall perceptions of ElderTree features (e.g. are they helpful, easy to use)
- How "politeness" prompts in the system affect use (e.g. "It's time to do the survey" or "Let's do something together")

Usability subjects will be recruited via word of mouth by our research team and community partners – research staff will reach out to past study participants that indicated interest in further opportunities, the CAARN group led by Co-I Dr Jane Mahoney will spread the word through their networks – they will provide basic info (can text or

email info sheet and consent with permission) and invite those interested to call the study team. A consent and info sheet will be mailed, texted, or emailed (with subject permission) and a second phone call will be scheduled to go through informed consent.

Usability subjects will be randomized to receive:

1. ET-SS: Subjects will receive a smart system, internet hotspot, and access to ElderTree
2. ET-SS + "Politeness" Prompts: Subject will receive a smart system, internet hotspot, and access to ElderTree with "politeness prompts designed to help guide user interactions.

Regardless of group, subjects participating in the usability testing will be asked to:

- Complete an intake visit or phone call. If in person, research staff will deliver and set up the smart system, train you how to use it, and explain the "tasks" you will be asked to complete during the testing period. If via phone, the smart system will be mailed to you and research staff will talk you through set up and training over the phone. The intake visit or phone call will take about an hour and will be audio-recorded. The recording will then be transcribed, removing all personal identifying information (e.g. name) and the recording will be destroyed.
- Complete recommended "tasks" and engage with ElderTree on the smart system during the 10-day testing period. Tasks include completing the ElderTree weekly survey, posting a message in the discussion group, writing a journal entry, and viewing a lesson on chronic pain.
- Allow the research team to collect information on how you use ElderTree. This will be collected automatically on the smart system and will include what services you used, when, and for how long, what prompts you say to trigger the services, and any system failures.
- Complete survey questions and an exit interview with research staff over the phone at the end of the testing period to collect your feedback on the system. The survey questions and exit interview will take about an hour and will be audio-taped for transcription as described above.

Potential Risks are similar to those for the RCT and include:

- There could be a breach of confidentiality that could result in disclosure of research data outside of the study team. To prevent this, only limited research staff will have access to subject names, addresses, phone numbers, and other identifiable information. All data will be stored securely and de-identified for analysis. Transcripts from the audio-recordings will not contain identifiable information and the recordings will be destroyed.
- The potential for subjects to receive and act on bad information or misinterpret accurate information. To mitigate the risk of providing inaccurate or harmful information to patients, all ET content will be screened by Dr. Mahoney. ET information will be accessible by individuals who have low literacy skills to reduce the risk of misinterpretation. Additionally, messages exchanged within the ET discussion groups will be monitored to make sure the information is accurate and that study participants are using the system for its intended purpose.
- During study activities we may discover behavior that raises concern about elder abuse, harm to self or others. If we see anything that suggests that patient subjects or others face imminent risk of harm, we will contact appropriate others to intervene (e.g., community mental health resources and/or police).

There is no cost to usability subjects to participate. If subjects complete the 10-day testing period and the final survey and exit interview, they will be paid $25.

Research staff will collect the smart system and internet hotspot at the end of the 10-day testing period.

RCT Patient Recruitment

The RCT will involve 291 patients age 60 and older, recruited over 18 months, and randomized into three groups:

1. ET-SS: Patients will receive treatment as usual (TAU) + Smart System + Internet access + ElderTree
2. ET-LT: Patients will receive TAU + laptop + Internet access + ElderTree
3. Control: Patient will receive TAU

Patient Screening

For patients recruited via UW Health: Research staff will call UW Health patients that return the opt-in letter and ask the following screening questions to confirm eligibility:

Vision, hearing, motor impairment	Do you have a vision, hearing, or motor impairment that would make it hard for you to use a computer or a voice-activated system?	"No" = eligible
UW Health	Do you have any plans to change your healthcare from UW Health to another provider in the next 8 months?	"No" = eligible
Pain DURATION	Have you had pain on some or most days, that has lasted at least 12 weeks?	"Yes" = eligible
Pain FREQUENCY	In the past 3 months, how often did you have pain? *Never Some days Most days Every day*	Never = *not* eligible
Pain INTENSITY	In the past 7 days how would you rate your pain on average? *0 = No pain – 10 = Worst imaginable pain*	3 - 10 = eligible

For patients recruited via the community: Research staff will call patients that return the community flyer return card/opt-in and ask the following screening questions to confirm eligibility:

Assess eligibility via self-report – inclusion criteria:

1. Are you ≥60 years old?
2. Have you had a chronic pain diagnosis in the last 6 months AND a medical diagnoses of three or more of the following common chronic conditions: COPD, asthma, diabetes, hyperlipidemia, hypertension, ischemic heart disease, atrial fibrillation, heart failure, stroke, BMI 30+, cancer, chronic kidney disease, depression, osteoporosis, arthritis, or dizziness/falls/loss of vestibular function;
3. Would you be willing to allow us to share information about your health status with your PCP?

Patient exclusion criteria.

4. Do you require an interpreter?
5. Do you have a medical diagnosis of any of the following: Alzheimer's, Schizophrenia/other psychotic disorder, Dementia, Autism spectrum disorder, Known terminal illness with less than 6 months to live, Acute medical problem requiring immediate hospitalization?

Additional Screening Questions:

Vision, hearing, motor impairment	Do you have a vision, hearing or motor impairment that would make it hard for you to use a computer or a voice-activated system?	"No" = eligible
Pain DURATION	Have you had pain on some or most days, that has lasted at least 12 weeks?	"Yes" = eligible
Pain FREQUENCY	In the past 3 months, how often did you have pain? *Never Some days Most days Every day*	Never = *not* eligible
Pain INTENSITY	In the past 7 days how would you rate your pain on average? *0 = No pain – 10 = Worst imaginable pain*	3 - 10 = eligible

Patient Consent

Patients must agree to allow monitoring of their ElderTree use and for data to be collected from their EHR (UW Health patients only), as detailed below. The patient will be given the right not to share specific information and will retain the right to revoke their permission at any point.

The consent process will inform potential subjects of:

(1) the nature and purpose of the study

(2) the types of data that will be collected from the EHR (by the CHI2 – UW Health patients only)

- Chronic conditions
- health care utilization: hospitalizations (admission and discharge), number of ER visits, urgent care visits, PC visits, specialty care visits, long-term care visits, and rehab visits

(3) the types of data that will be collected from ElderTree

- Weekly survey data (missed medications, falls, thinking and memory, mood, healthy meals/snacks/drinks, physical activity, quality time with others, sleep, pain, and balance)
- Use data

(4) the types of data that will be shared with their primary care physician - a graph that charts weekly scores related to the quality of sleep, nutrition, physical activity, memory, falls, moods, balance, pain, medication adherence and quality time spent with others- for UW Health patients only.

(5) study risks and measures taken to mitigate

(6) their right to leave the study at any time

(7) the timeline of the study

Verbal consent will be documented on the recruitment form and in REDCap and a copy of the IRB-approved consent form will be mailed to participants for their records. All study data outside of REDCap will be stored in a locked cabinet at the Center for Health Enhancement Systems Studies at the UW.

The research team will always have a member available during standard operating hours for participants to contact with questions or issues. If a patient declines to participate, a research team member will determine reasons for non-participation so we can examine how patients who opt out differ from those who choose to participate.

Patient Randomization
Once informed consent and baseline measures have been obtained from patients, they will be randomized to ET + SS, ET + LT, or the Control group, stratified on gender, site (UW clinic vs community), and number of chronic conditions (4-5 vs. 6+).

Setup and Training. Researchers will introduce patients in each arm to their technology and place the laptop or smart display in the preferred location. After explaining the implications, the smart display will go where patients least want a camera. Patients will play a 5-minute introductory video/audio recording that explains ET-LT or ET-SS. During setup, information is entered to tailor ET, such as medications, contacts, and activities of interest. During training, all patients add a post to the discussion group. A week later, they are encouraged to play the intro again and select another ET service to learn. Thus, patients can gradually increase the services they use. If necessary, UW staff will text or email patients to encourage them and resolve issues. Periodically, thereafter, a brief intervention will feature a different service, based on past use ("we see that you have not used the XXX service. We believe it is worth a try because…").

Costs to participants = $0. Patients in the ET-LT and ET-SS groups will get technology (laptop or smart system respectively), and Internet service (hot spot) for 8 months, and will be paid $10 to complete each of the three surveys ($30 total). Patients in the Control group will be paid $30 to complete each of the three surveys ($90 total).

Privacy and Confidentiality
To mitigate the risk of patient breaches of confidentiality, all subjects will be assigned a unique code number. Subject code numbers and all study data will be maintained by the UW project director and stored in UW ICTR Research Electronic Data Capture (REDCap). Members of the research team will be able to view de-identified individual and clinic-level aggregations of variables. When all study activities are complete identifiable information will be destroyed. De-identified study data will be stored on the secure servers for potential future unspecified research for which new IRB submissions will be initiated.

Potential Risks
The principal risks to participants include:

- The potential for subjects to receive and act on bad information or misinterpret accurate information. To mitigate the risk of providing inaccurate or harmful information to patients, all ET content will be screened by Dr. Mahoney. ET information will be accessible by individuals who have low literacy skills to reduce the risk of misinterpretation. Additionally, messages exchanged within the ET discussion groups will be monitored to make sure the information is accurate and that study participants are using the system for its intended purpose.
- There is a risk that information provided in ET will be used to the detriment of the subjects. All participants will receive information and guidelines on Internet safety and security during initial training in both the ET-LT and ET-SS group.
- If participants engage in the social components of ET (e.g. discussion group, live Meetups), they could get upset with opinions or comments from other participants. Research staff monitor discussions daily and facilitate live meet-ups. Appropriate action will be taken if questionable posts/comments occur. Participants may choose not to participate in social components on ElderTree if they wish.

- There could be a breach of confidentiality that could result in disclosure of research data outside of the study team. To prevent this, all subjects will be assigned a blind code number. Data collected from clinic records will have the name removed and a code number attached. Project staff who have access to the data will not have access to subject names. ET will automatically collect data on how often and for how long participants use the specific services within ET. This information will be collected by subjects' ET code number only and will not be attached to real names or identities.
- Internet service will be stopped after 8 months. Subjects may feel some loss when they no longer have this service. Participants will receive notice in advance of internet termination, but will be allowed to keep their equipment in case they acquire internet service on their own.
- On surveys participants will be asked personal questions related to past or current behaviors and experiences, such as struggles with health issues, depression, etc. that could produce anxiety, distress, embarrassment, or feelings of sadness. Participants can opt not to answer certain questions if they choose.
- During study activities we may discover behavior that raises concern about elder abuse, harm to self or others. If we see anything that suggests that patient subjects or others face imminent risk of harm, we will contact appropriate others to intervene (e.g., State authorities, clinic, and/or police).

Unanticipated Events
Should any unanticipated problems arise the UW research team will work with the Health Sciences IRB and the ICTR Data Monitoring Committee to immediately address the problem (see Appendix A for detailed Data and Safety Monitoring Plan).

Inappropriate use of ElderTree
It is anticipated that ElderTree could be used inappropriately. A research staff member will review and delete any messages deemed inappropriate (i.e nudity, threats, racism, bigotry). A research staff member will then follow up with the author of the inappropriate content. Discussion group guidelines have been developed and will be reviewed with participants as part of training.

Reasons for removing a subject from study
The PIs have discretion to remove a subject from the study for any reason that is in the best interest of the individual as well as others on the study. Possible reasons for removal may include:

- Inappropriate use of ElderTree as discussed above.
- Repeated loss or destruction of laptop or smart system.
- Inability to use the technology. In some cases, despite repeated technical support, the use of the laptop or smart system by the participant may not be possible and has the potential to cause distress. In these cases, the technology will be removed and the participant offered the option of completing the mailed surveys only for the duration of the study.

5.0 MEASURES AND DATA COLLECTION

Participants will be tracked for a total of 8 months. Data will be collected from: electronic health records (EHR), participant surveys (at months 0, 4, and 8 months), qualitative interviews, and ElderTree use data. Table 2 lists quantitative and qualitative measures, data sources, psychometrics, and references to validation studies.

Quantitative. Surveys conducted at months 0, 4, and 8 are expected to take 20-30 minutes and will assess psychosocial and physical QOL, pain, 30-day readmits, health distress, well-being, loneliness, communication with doctors, irritability, alcohol use, smoking, falls, and hypothesized mediators of competence, relatedness, motivation, exercise, and pain catastrophizing. Surveys will be mailed to patients with a self-addressed stamped envelope. Patients will be phoned if they do not respond after 2 weeks. Patients can contact study staff for more detail if questions arise. Contact with patients can be requested by staff if data integrity or compliance issues are detected in ongoing data review. Survey data will be entered into REDCap.

Table 2. Measures Used to Evaluate ET-SS vs. ET-LT vs. Control

Endpoint	Measure	# Qs	Source	Psychometrics
Primary Outcomes				
Pain Interference	Promis-29 v2.1	4	Patient	α range = .88 - .97[60]
Psychosocial QOL	Promis-29 v2.1	12	Patient	N/A
Secondary Outcomes				
ET use @ 8 mos.	# logons	N/A	ET	N/A
Physical QOL	Promis-29 v2.1 & Late Life Function and Disability Instrument	53	Patient	N/A
Pain Intensity	Promis-29 v2.1 & Lorig	3	Patient	N/A
30 day readmits	Admissions	1	Patient	N/A
Health distress	Lorig Health Distress Scale	4	Patient	α = .87[61]
Well-being	WHO Well-Being Index	5	Patient	α = .93[62]
Loneliness	NIH Toolbox	5	Patient	α = .93[63]
Comm w/doctors	Lorig Comm w. Physicians	3	Patient	α = .89[61]
Irritability	Brief Irritability Test (BITe)	5	Patient	α > .88[64]
Mediator Candidates				
ET use @ 4 mos.	# page views w/o nav.	N/A	ET	N/A
Competence	Disease Self-Efficacy	6	Patient	α = .91[65]
Relatedness	Bonding	5	Patient	α = .85[66]
Motivation	Tx Self-Regulation subset	4	Patient	N/A
Exercise	Scale created for study	4	Patient	N/A
Pain Catastroph.	Pain Catastrophizing Scale	13	Patient	α = .87
Moderator Candidates				
Sex	Baseline survey	1	Patient	N/A
Chronic conditions	Total #	N/A	EHR	N/A
Barriers to tech	Created for study	2	Patient	N/A
Exploratory Questions				
ET use by service	# pageviews per service	N/A	ET	N/A
ET/CR perception	Interviews; Scale created for study	9	Pt/cl staff	N/A
Medication	ET Weekly Survey: ET arms	1	ET	N/A
Alcohol use	AUDIT-C	3	Patient	α = .91[67]
Smoking	# per day	1	Patient	NA
Falls	# past 6 months	2	Patient	NA
Other Measures				
Demographics	Race/ethnicity, education	2	Patient	N/A

For ET use outcomes, keystrokes (for ET-LT), voice commands (for ET- SS), and time on system will be collected continuously. Data about ET use in both arms will be collected in time-stamped log files. The primary measure of use will be logons per week. Additional use measures will be: number of ET services used, pages viewed, messages posted, and weekly surveys completed.

Data about healthcare use and number of chronic conditions will come from patient EHRs. Medication adherence will come from patients' responses to the weekly health survey on ET.

Qualitative. Interviews will be conducted from prepared scripts by people unaffiliated with the study, trained and monitored by Prof. Mares. Data will be gathered from 32 patients, 16 in each arm, balanced by sex and number of chronic conditions (4-5 vs. 6+). Half of each group will be interviewed at 4 months, the other half at 8 months. This balances the need for insight into patient experience with the need to avoid confounding effects of interviews with ET effects. They will be asked about insights critical to ultimate ET dissemination: barriers to use,

technical issues that arose, whether and how ET fit into their day, what could be done to make ET better, reactions to the device(s), and how ET came up in appointments with their doctor. Clinicians will encounter ET only through the CR. We will record and analyze clinicians' comments and questions during meetings where we introduce the study and the CR to the clinics, and we will ask about anticipated barriers and benefits. We will document the protocols that clinics use to receive and disseminate the CR to clinicians. We will interview 5 clinicians at the end of data collection about their experiences with and perceptions of the CR. We will compare the qualitative and quantitative results to obtain further insights. If we find QOL improvements in the ET-SS quantitative results, for example, we will frame our qualitative interviews of both patients and providers at 8 months to help us understand why and how the effects occurred.

Data quality. Weiskopf et al.[68] offer quality assessment guidelines for using EHRs based on data correctness, completeness, and currency, which we will follow in assessing our data. We will use data related to diabetes, obesity, kidney function, lung function, hyperlipidemia, and hypertension found in Epic's EHR (Table 2). We believe these data are fit for use because: 1) it is usual at UW Health to measure blood pressure in older patients with at least two consecutive readings at the clinical visit[69] (otherwise, we will take the average of the last two measures, an approach recommended in national guidelines[70]) and 2) BMI will be taken from older adults with MCCs, a population whose BMI data typically have high levels of completeness[71] (weight measured at each visit; height measured annually). The opportunity for human error in recorded lab scores is very low because lab test data are automatically entered into the EHR by the lab. The data come from patients who are currently in treatment, thus current. Hence, we believe our data can be treated as complete and correct.

6.0 STATISTICAL CONSIDERATIONS

Power for primary outcome. Our primary outcome that we are using to power the study is reduction in pain interference. Based on PROMIS validation studies with chronic pain samples, a difference of 3 points or more between study arms was considered to indicate a clinically meaningful difference[72]. The PROMIS website also gives the mean and standard deviation of the T-score metric (M = 50, SD = 10). We powered the analysis to be able to detect a 3-point difference (an effect size of d = .30) between control and ET-LT, and then the same magnitude of effect between ET-LT and ET-SS (an effect size of d = .60 for control versus ET-SS). Across 10,000 LMEM simulations, a post-attrition-N = 255, we would have power >80% to detect the study arm X time interaction.

Missingness*.* Data are likely to be missing not-at-random. This may lead to biased parameter estimates. Pattern-mixture modeling will test the sensitivity of our intervention analysis to missing data assumptions,[73,74] by conducting sensitivity analyses after imputing missing data with a range of clinically plausible values using assumptions for missing data (e.g. best or worst case, with and without multiple imputation).[75,76] With regard to survey data, in the previous ET trial, 353 of 390 participants (90.51%) completed the 6-month survey and 310 of 390 (79.49%) completed the 12-month survey. In completed surveys, data were missing on about 2% of core items. We expect similar rates in this study, that is, about 87% survey completion at 8 months. Thus, we increased the total sample size after attrition to 291 to increase the likelihood of detecting effects on the outcomes with 2 moderators: sex and number of chronic conditions.

Quantitative analysis plan. Intention-to-treat will be the data primary analyses.

Assumptions and randomization effect. We will report descriptive statistics for all demographic and clinical variables in both arms to ensure that randomization produced comparable groups; if not, variables with significant differences will be included as covariates in a sensitivity analysis. Sensitivity analyses (with and without covariate adjustment) will determine the robustness of covariate-related error control. All outcome variables will be examined using standard summary statistics, visualizations, and tests for normality and

homoscedasticity. Data will be transformed for continuous outcomes that do not meet the assumptions of a normally distributed outcome. We will test for a main effect of clinic site. If significant, we will add clinic site to our models to control for its variance.

Effectiveness of control vs. ET-LT vs. ET-SS. Linear mixed effects models (LMEM)—which account for dependence among successive observations for the same participant and can address incomplete data—will be used to examine effects of study arm (ET-SS vs. ET-LT vs. control, a between-subjects factor) on our outcomes over time. We will conduct specific treatment X time contrasts both between, and within, groups to test time-based effects. For binary, count, and other non-normal data, generalized mixed effects models will be used.

Mediation and moderation effects. Structural equation modeling (SEM) will explore the effects of mediation on the relation between study arms and our two primary outcomes. We anticipate that the impact of study arm on pain interference and psychological QOL will be mediated by SDT (competence, relatedness, and motivation), exercise, and pain catastrophizing at 4 months. SEMs involving ET use will be run separately for just the ET-SS and ET-LT arms. 2) We anticipate that sex, number of chronic conditions, and barriers to technology will moderate the indirect paths of the mediation models (see Figure 1, logic diagram).

Impact of interim analyses on Type 1 error for whole sample analysis. Findings that are significant in the interim but not the final analyses will be treated as non-significant. The final analysis will examine all data over time. For analyses that address the same hypothesis a Holm-Bonferroni correction will be applied.

Qualitative analyses*.* For each data set, a coding scheme of key themes will be constructed, based on the research questions (perceived benefits, barriers to use) and examination of the data. Each scheme will be pilot tested, then 2 trained coders will code an overlapping subsample of 20% of content. Once reliability is established (minimum Krippendorff's alpha of .80 per category), the coders will work independently in NVivo.

7.0 RECORDS TO BE KEPT

- Subject Intake
- Subject Demographics
- Subject Consent Forms
- HIPAA Authorization Form
- Baseline and follow up survey data
- Coded ET use data
- Coded patient health care utilization
- Coded transcripts from interviews with patients

Appendix A

CENTER FOR HEALTH ENHANCEMENT SYSTEMS STUDIES

Data and Safety Monitoring Plan

Data and Safety Monitoring Committee

The Center uses the Data Monitoring Committee (DMC) located in the University of Wisconsin's Institute for Clinical and Translational Research (ICTR). The ICTR DMC will provide services to ensure appropriate measures are in place to promote subject safety, research integrity and compliance with federal regulations and local policies. The DMC members will review protocol-specific reports created by statisticians using data pulled from the Research Electronic Data Capture (REDCap) data management tool. These standard reports will include an overview of study objectives, a review of actual and projected accrual rates, an evaluation of patient demographics for balance of randomization, and a summary of the number and seriousness of adverse events. An interim analysis of study results may be performed and source documents may be reviewed to allow the board to independently judge whether the overall integrity and conduct of the protocol remain acceptable based on data provided and reported by the Principal Investigators. The board will make recommendations to the Principal Investigator that could include actions of continuation, modification, suspension, or termination.

In providing oversight for the conduct of this study, the ICTR DMC will meet annually during the 5-year study. Additional meetings may be scheduled as determined by the DMC or as requested by the PIs.

The predefined stopping points for this study will include excess rates of hospital re-admissions or quality of life determinates, exceeding 30% of pre-test values in both cases. We will record events that are deemed to be 'possibly, probably, or definitely' related to the study intervention, and communicate to the AHRQ, DMC and UW IRB in accordance with the following guideline.

What Event is Reported	When is Event Reported	By Whom is Event Reported	To Whom is Event Reported
Fatal or life-threatening unexpected, suspected serious adverse reactions	Within **7 calendar days** of initial receipt of information	Investigator	Internal IRBs NHLBI and/or DMC
		Sponsor or designee	FDA (if IND study)
Non-fatal, non-life-threatening unexpected, suspected serious adverse reactions	Within **15 calendar days** of initial receipt of information	Investigator	Internal IRBs/ Institutional Officials NHLBI and/or DMC
		Sponsor or designee	FDA All participating investigators
Unanticipated adverse device effects	Within **10** working days of investigator first learning of effect	Investigator	Internal IRBs NHLBI and/or DMC
		Sponsor or designee	FDA (if IDE study)
Unanticipated Problem that is not an SAE	Within **14 days** of the investigator becoming aware of the problem	Investigator	Internal IRBs/Institutional Officials, NHLBI and/or DMC
All Unanticipated Problems[2]	Within **30 days** of the IRB's receipt of the report of the UP from the	IRB	OHRP
		Investigator	Internal IRBs and DMC

	investigator.		

Data Security and Privacy Monitoring Plan

In accordance with the Health Insurance Portability and Accountability Act (HIPAA), CHESS has adopted the following Data Security and Privacy Monitoring Plan.

I. Appointment of Center Data Security Officers.

A. Gina Landucci and Matt Wright are the security officers for the Center.

B. Responsibilities of the security officers include:

- Developing information technology (IT) security policies
- Increasing security awareness and providing training for all Center faculty and Team Members
- Providing virus protection for IT resources
- Maintaining security patches on computing equipment
- Developing and implementing back up procedures
- Performing periodic vulnerability scanning on computers
- Reviewing and updating firewall strategies and policies
- Enhancing the physical security of IT resources
- Performing annual review of staff policies and procedures contained in this document
- Conducting formal HIPAA Risk Assessment Inventory per requirements of the UW HIPAA Office; last review completed summer 2018.

II. Policy for Orientation and Training

A. All Center students, faculty, and staff are required to complete the UW-Madison **2019-20 HIPAA Privacy & Security Training** course online which is offered in Canvas at https://canvas.wisc.edu/courses/173269. Contact Judy Ganch if you do not have the HIPAA training on your Canvas dashboard. Please email Judy when you have completed the training. You will need to retake this course annually.

B. All Center students, faculty, and staff that are involved in human subjects research are required to complete the UW-Madison CITI Human Subjects training online at https://my.gradsch.wisc.edu/citi/index.php. Register with your NetID. Select the training for the **UW Social & Behavioral Course.** Please email Judy Ganch when you have completed the training. You will need to take a refresher course every three years.

C. All Center students, faculty, and staff that are involved in human subjects research are required to complete the UW-Madison CITI Human Subjects training online at https://my.gradsch.wisc.edu/citi/index.php. Register with your NetID. Select the training for the **GCP—Social and Behavioral Research Best Practices for Clinical Research.** Please email Judy Ganch when you have completed the training. You will need to take a refresher course every three years.

D. Successful completion of the CITI and HIPAA training is required before any team member is allowed access to Protected Health Information (PHI) or Research Data.

E. All Center Team Members are required to complete training with Judy Ganch on Center security procedures and policies.

F. Sign (on the last page) the "Center Data Security Policy and Privacy Monitoring Plan" upon completion of this training and return to Judy Ganch.

III. Workstation Policy

A. All workstations will require login with a unique user name and password.

B. All workstations are required to be joined to the ENGR domain under the control of the College of Engineering. Access to specific folders on the Center network will be approved by the Center Management team or the study Project Director.
C. All workstations are required to use anti-virus software that can be remotely administered from the College of Engineering domain.
D. Users will log-out from or lock workstations when leaving them unattended.
E. Screen savers will be configured to require a password and to activate after ten minutes of workstation inactivity.
F. Users requiring remote access to the Center network will only do so with computers specifically certified by a Center Data Security Officer.
G. Study coordinators or support personnel using desktops in private or public areas must have screens adjusted so that visitors cannot read the screen upon entering the space in case PHI or other confidential information is displayed.
H. Access to the network or center work stations along with any on-line systems will be terminated immediately following an employee's last day of work at the Center.

IV. Password Policy

A. Users will require a password to access any computer connecting to the Center network.
B. Passwords must meet the requirements of the Computer Aided Engineering department (CAE). CAE password construction help can be found here: https://kb.wisc.edu/cae/page.php?id=8143.
C. Ideally the best practice is to re-set your password on a semi-annual basis.
D. Passwords may not be stored in proximity to the workstation and may not be shared by others.

V. Policy for the Use of Email

A. Patient Identifiable, Confidential, or Personnel Data may only be included in an encrypted attachment and should never be sent in the body or subject line of an email message.
B. Team Members who need to send encrypted attachments should contact a Center Data Security Officer to schedule a training session.

VI. Policy for Storage, Retrieval, and Disposal of Protected Information

A. Effective 1/1/14 any new studies must use the REDCap environment for study participant information. Contact Matt for start-up and access information.
B. Any Patient Identifiable, Confidential, or Personnel Data in electronic form will be stored on secure servers only and **may not** be stored on individual workstations, laptops, or any other endpoint devices. Currently, the only place such information can be stored is the R: Drive for studies prior to 1/1/14 or REDCap.
C. Study coordinators will have printers in their office for printing any materials that include PHI and/or names of study participants.
D. All paper-based files will be stored in locked rooms inside locked file cabinets with limited access.
E. Any offices that contain PHI must be locked when leaving a room.
F. Servers containing Patient Identifiable, Confidential or Personnel Data must be located within physically secured server rooms which can only be accessed by authorized personnel.
G. The Center Data Security Officers will be responsible for assigning and restricting access to shared resources on Center servers.
H. Patient Identifiable, Confidential, and Personnel Data as a general rule may not be copied to or stored on the Center's publicly accessible servers at any time. However, in some studies, patient's name, disease state, and physician are stored within Center applications only accessible via a

secure connection using a codename/password.

I. Remote access to files on secure Center servers will be provided in a very limited case only through a connection from a certified Center Workstation (see Center Workstation policy above for details).
J. Storage media containing Patient Identifiable, Confidential or Personnel Data will be rendered unusable before disposal.
K. All back up media will be stored in locked rooms with limited access.

VII. Policy for the Use of Endpoints (e.g. Workstation Smartphone, Laptop, Thumb Drive, External Hard Drive) Accessing Patient Identifiable, Confidential, and Personnel Data

A. Staff are not allowed to access or store any PHI data on any endpoint unless the endpoint is provided by a Center Data Security Officer ensuring that the endpoint is protected and secured. In addition, any PHI data residing on an endpoint must also be encrypted with the oversight of a Center Data Security Officer.
B. All endpoints accessing PHI must be owned and provisioned by the Center.
C. Patient Identifiable, Confidential, and Personnel Data files may not be transported from the Center unless the device/medium is monitored for physical security at all times and the data is encrypted on the mobile device.
D. Remote access to PHI data must be conducted using a secure encrypted end-to-end connection implementing modern security best practices either over HTTPS or using the WiscVPN connection.

VIII. Policy Governing the Storage and Use of Audiovisual Materials

A. Audiovisual media containing Patient Identifiable, Confidential, and Personnel Data are governed by the same policies and procedures that apply to handling and use of computerized data, including disposal, storage and access to media.
B. Such audiovisual media may not be transported from the Center unless the material is monitored for physical security at all times.

IX. Policy Governing the Transmission of Information via Fax

A. All outgoing correspondence via fax must be stripped of confidential information.
B. Before confidential information is transmitted to the Center via fax, sender must notify the appropriate Center Team Member to ensure the recipient is available to pick up the fax document.

X. Field Hardware Policy

A. Device provided for study participants will require log-in information to access the device.
B. Upon their return, all Center study computers, smartphones, or other devices that have been used in the field will have all data wiped from the hard drive in compliance with DOD standards.
C. Field computers will be stored at the Center in a wiped state.

XI. Study Participant Information

A. Center Team Members will not share or talk about confidential information regarding the CHESS study participant with anyone who is not directly involved in the management of the CHESS Project.
B. Confidential or other sensitive information regarding the study participant cannot be left in an unsecured place where others may see it.
C. Copies of written correspondence about the study participants with anyone other than CHESS management cannot be provided, unless specifically authorized to do so by the Project Director.
D. Access to study participant's PHI will be approved by the Project Director in coordination with the PI for the project. As noted in Section VI, studies beginning after 1/1/14 must use REDCap

to enter participant information electronically.

XII. User Responsibilities

A. All Center Team Members are responsible for adhering to the Center Data Security and Privacy Monitoring Plan Policies at all times. In addition, all Center Team Members are responsible for adhering to the UW-Madison IT policies detailed at https://it.wisc.edu/about/office-of-the-cio/it- policies/ at all times as well.
B. All Center Team Members will be given a comprehensive briefing session upon hire.
C. Usernames and passwords are not to be shared with others.
D. No equipment may be connected to the Center network without specific prior certification by a Center Security Officer.
E. Specifically, no wireless access points may be deployed or connected to the network under any circumstances.
F. The Center Data Security Officers will maintain records to insure that all Center Team Members have been briefed.
G. The Center Data Security Officers will provide periodic refresher sessions to all Center Team Members.

XIII. In case of a PHI breach, Center Security Officer and/or PI reports incident to UW HIPAA Security Office, the UW Health Sciences IRB or other IRB of record, the ICTR Data Monitoring Committee, and sponsor as required.

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