Ambient Independence Measures for Guiding Care Transitions Study Protocol and Statistical Analysis Plan NCT02566239 11/26/2014

AMBIENT INDEPENDENCE MEASURES FOR GUIDING CARE TRANSITIONS

OBJECTIVES

Aim 1: Develop a pervasive computing system tuned to identify trends in AIMs data that are predictive of health decline. Implement a software tool for automatically generating these data on a regular basis for review by care transition teams.

Aim 2: Develop an automated system and reference platform for presenting AIMs data to care teams on an as-needed basis.

Aim 3: Assess the efficacy of using the AIMs metrics and the computer-based tool in senior community settings to improve care transition decisions.

BACKGROUND

Substantial revolutions in care were introduced in the 1990's. Changes in reimbursement schemes (explicitly paying for rehabilitation services and through home and community-based waivers), the adoption of new home-like or home-based care models (in-home care, adult foster homes and assisted living), and improved medical management of some conditions essentially averted the forecasted disaster of millions of additional nursing home residents entering care since 1994. Despite this success and evidence that rates of disability on a population basis declined from 1982 through 2004, there is concern that this trend may be reversed with large increases in the number of people with chronic conditions or poor health. As a result it has not been clear how one might build on the success of community care by increasing the capability of maintaining independence and transitions to higher levels of care.

Key to this needed innovation is the ability to proactively forestall trends and events that result in major care transitions, since once critical functional or cognitive thresholds are reached, future risk of institutional care increases substantially. The weight of evidence suggests that intervention at earlier stages of a chronic disease trajectory may help to delay nursing home entry. However, in order to provide these early interventions one needs reliable data beyond basic *static* predictors (e.g., age, gender, current health condition). Unfortunately, only rarely have *changes* in functional or health status been examined in predicting future transitions to more intense levels of care. Further, conventional static functional predictors (including impaired cognition, high medication load, and compromised ability to perform typical instrumental activities of daily living) predict long-term nursing home residence, but these higher order functional activities and behaviors are difficult to directly assess in home; frequent self-report is not feasible for most domains.

It has been suggested that continuous in-home monitoring may be better able to capture such trends. However, little longitudinal research has been done to identify what metrics are most useful and how they might best be used in real world care decisions. Prior promising studies using pervasive or continuous computing metrics have been small and developmental. The proposed research fills this gap by building on an established study of cognitive and motor change that has instrumented the homes of more than 240 individuals to gather continuous activity data as people go about their daily lives. These

data have provided us with an exceptional understanding of the types of behaviors that can be captured with a low-cost ambient sensored environment. The multi-domain nature of our technology-assisted approach, which includes health annotation by the individual on a weekly basis, improves our ability to differentiate concerning trends from normal daily variations. This technology allows identification of times of increased or decreased need for acute attention. It aids caregivers, both informal and professional, to base care decisions on objective, systematically assessed real-time data at a granularity that is impossible for current conventional practice to achieve.

The proposed study has the potential to transform current research and clinical practice paradigms of prediction and decision making about independent living. This is accomplished by shifting from reliance on episodic, self-reported or crisis event provoked data to the use of ecologically valid multidimensional and continuous physiological, activity, and behavioral data. This approach has great potential to substantially improve care need and transition decisions. In achieving this goal several innovations beyond available systems and ongoing research are notable. First, grounded by prior studies associating static clinical measures to future placement outcomes, we now contemporaneously and continuously will acquire fundamental physiological measures (weight and walking speed), activity and behavioral measures, thereby improving our ability to proactively discriminate important health and functional change in real time. Using existing in-home activity data collected longitudinally in an aging population combined with simulated data from additional new sensed measures (phone use, medication taking, body composition) we will generate derived ***novel metrics - AIMs – to provide objective dynamic measures*** of activity and behaviors that are essential to maintaining independence. These metrics will be used to develop prediction algorithms based on documented transition outcomes from the original data set to be used by care teams (Aim 1). ***Working care transition professionals*** **will be iteratively queried** for the refinement of these objective measures (Aim 2). These care providers' expertise and understanding of key changes that impact independence is invaluable to identification of ambient independence measures that matter, and lead to meaningful care implementation pathways. The efficacy of the final set of measures chosen and built into a user friendly interface for the care team to use (Aim 2) will then be tested (Aim 3) by comparing independently living seniors in one of three comparison groups: 1) installed technology, from which AIMs data will be extracted and provided to the care transition team to aid in transition decisions; 2) installed technology, from which AIMs data will be extracted but will not be available to the transition team; and 3) no technology.

The approach we propose is intentionally constrained to a well-defined research population: senior communities with care transition teams. This provides a level of control and design efficiency that facilitates our ability to demonstrate feasibility and early efficacy in this specific care setting. However, the AIMs and assessment approach developed through this research are immediately transferable and modifiable to many other populations as well, making our proposal novel in a broad sense. Although we will collect informal caregiver data in this proposal (via on-line questionnaire, email, phone use), we chose to initially focus on the professional care community at this time. Future research using our open tools will be able to address informal caregiver input as well as other stakeholders such as physicians or seniors themselves, with consideration of how these various stakeholders would best use the data in concert with each other.

INCLUSION AND EXCLUSION CRITERIA

Aim 1 Inclusion:

1. Existing, independently-living participants from the ORCATECH Life Lab (IRB#2765)
2. Participants must live alone
3. Participants must live in a partner community (Willamette View, Rose Villa, Terwilliger Plaza, Mirabella and Mary's Woods, Holladay Park Plaza)

Aim 1/Experiment 3 Inclusion:

1. Staff at partner communities who participate in the community's transition team meetings.

Aims 2&3 Transition Team Inclusion:

1. Staff at partner communities who participate in the community's transition team meetings.

Aim 3 Inclusion:

1. Age 75 or older
2. Living alone in a larger than one-room apartment
3. Not demented (CDR scale score < 0.5); Mini-Mental State Examination (MMSE) score >= 24)
4. Of average health for age. Medical illnesses that would limit physical participation (e.g., wheelchair use) or likely lead to untimely death over 36 months (such as certain cancers) are exclusions.
5. Must have a computer and a broadband internet connection

NUMBER OF SUBJECTS

Aim 1: Up to 66 participants recruited from existing ORCATECH Life Lab cohort.

Aim 1/Experiment 3: Up to 100 transition team members from partner communities.

Aims 2&3 Transition Teams: Up to 100 transition team members from partner communities.

Aim 3: 100 participants (including any continuing participants from Aim 1) will be enrolled into the technology arms. 50 additional participants for the non-technology arm of Aim 3 will be tracked through the ORCATECH repository (IRB#6845) and consented to complete occasional surveys.

RECRUITMENT METHODS

Aim 1: Current participants in Life Lab have consented to be contacted about other research opportunities. All eligible Life Lab participants will be contacted by study staff to determine if they have an interest in participating in Aim 1 of the AIMs study.

Aim 1/Experiment 3: We will contact the care team coordinator(s) at partner communities and have them bring together their transition team for a focus group session.

Aims 2&3 Transition Teams: We will contact the care team coordinator(s) at partner communities and have them provide us a list of transition team members.

Aim 3: Presentations about the project will be given at partner sites. Both potential and existing (Aim 1) participants will be invited to the presentations. Interested parties will be consented into Life Lab first and then, if they meet all eligibility criteria, consented into AIMs.

PROCEDURES INVOLVED

Aim 1: Develop a pervasive computing system tuned to identify trends in AIMs data that are predictive of health decline. Implement a software tool for automatically generating these data on a regular basis for review by care transition teams.

In this aim, we will identify AIMs data most likely to inform care transition decisions. Using data collected from the Layton Center/ORCATECH Repository IRB#6845, and working with the care transition professionals from partner communities, we will develop algorithms to derive key AIMs data from our sensor data in a form easily interpreted by transition teams.

The AIMs to be developed were chosen based on several principles: 1) the measure or a close surrogate has been shown in prior studies to predict loss of independence or institutionalization; 2) our discussions with the care providers and transition teams in our partner communities indicated that the measures would be of value to them; and 3) the continuous unobtrusive assessment of that measure can be inherently more precise than usual methods (e.g., self-report of activity vs. objective measure of activity). Based on these principles we will focus on 5 domains that tap behaviors and health changes that are known to place seniors at risk for a loss of independence: mobility, patterns of sleep, medication adherence, weight change, and socialization.

COLLECTION OF NEW DATA FOR AIM 1

Subjects enrolled in Life Lab studies and living alone will be invited to participate in the collection of additional data for up to a one-year period. All potential participants have previously signed consent forms allowing contact for additional study opportunities. For each of the enrolled subjects, we will install MedTrackers (medication adherence-tracking pill boxes), weight scales, and phone monitors (if not already installed in the home under the Life Lab protocol), which subjects will be asked to use daily. These additional data, will be used to ensure functionality of the entire system (augmented with the new measures) in conjunction with the historical data from ISAAC and Life Lab, will be used in our experiments below.

EXPERIMENT 1: MODELS FOR DERIVING NEW AIMS METRICS

In Experiment 1 we will develop models to derive metrics for the behaviors we will be tracking. We anticipate using mixture models, Support Vector Machines (SVM), and other related approaches that have been show to assist with behavior classification. Training data will come from data collected from participants consented and installed with the AIMs platform. For example, we will use number and duration of outgoing phone calls and of outings from the home, the duration of intervals between outings and phone calls as the feature space for a non-linear SVM.

EXPERIMENT 2: IDENTIFYING TRENDS IN THE DATA

The above measures will form the basis for estimating AIMs that may be of most impact to present to care transition teams. Building on our previous work and drawing on an extensive body of work in process control, we will model each individual's behavior as a number of ergodic random processes whose mean and variance may change over time. The basic approach is to (1) develop a baseline model of typical measures for each individual, over multiple-week periods; and (2) monitor these measures on a regular basis (e.g., weekly) for trends away from the norm – these trends are the AIMs.

The primary outcome of interest in Specific Aim 1 is the number of transitions to higher levels of care; secondary outcomes of interest are cognitive changes based on yearly memory testing, and the FAQ IADL score. Logistic regression will be used to determine which measures are most predictive of changes in the outcomes of interest. We will use multivariate multiple regression to look at how our continuous assessment indicators predict transitions, cognitive change, and IADL scores.

EXPERIMENT 3: IDENTIFYING USEFUL METRICS FOR CARE TRANSITION PROFESSIONALS

The first step in creating a tool to examine the AIMs data is to understand the needs of the caregivers who make transition decisions. We will work with community transition teams to preview ways of displaying our available metrics to ensure we have usable displays for feeding back the AIMs metrics to transition teams in Aim 3.

EVALUATION OF THE ACCEPTABILITY OF SHARING DATA WITH THE TRANSITION TEAM

Focus group sessions will be conducted with staff care transition teams at retirement communities to better understand the current process of making decisions about when residents need escalated care. The interview schedule will include open-ended questions followed by specific, probing questions. Focus groups will last approximately 1.5 hours each, and participants will not be paid for participation. Focus group size will vary according to the community contacted and the availability of staff. Each focus group will begin with a review of the study aims and obtaining consent from the participants. Each group will then be presented with examples of actual data to be shared with the transition teams, presented anonymously. Focus group participants will be asked (a) if the data shows information that is meaningful to them; (b) if they believe participants would be willing to have that type of data shared with the transition teams; (c) who else, if anybody, it might be helpful to share the data with; and (d) if there are other types of data they would like to see.

APPROACH FOR SPECIFIC AIM 2

Aim 2: Develop an automated system and reference platform for presenting AIMs data to care teams on an as-needed basis.

In Specific Aim 2, we create a software tool that tracks AIMs data, identifies outliers and trends requiring attention, and allows the care professionals to access expanded views of data at a variety of timescales.

EXPERIMENT 4: DEVELOPING A TOOL FOR CONTINUOUS REPORTING OF AIMS DATA

The web-based reporting tool that we will develop to support care transition decisions will be designed to present the data in the formats identified as most useful in Experiment 2. Since there will be a large number of subjects for which AIMs data will be available, an important part of the tool will be to flag

those subjects whose data indicate a relevant trend, change point, or outlier (as defined by our work in Experiment 1).

We will start development with the AIMs data representations deemed most useful during Experiment 2. Once we have a working prototype which uses some real data, we will ask consented members of the partner community transition teams to test the site and provide feedback.

EXPERIMENT 5: CREATION OF THE REFERENCE PLATFORM

The current ORCATECH platform consists of equipment and software deployed to individual homes in the community. In experiment 4, we will augment this system to include the automated generation of AIMs data for assisting transition decisions. Creating a sharable tool will require additional modularization, since ORCATECH's has grown organically over the past five years. Extensive documentation of how to install, configure, and use the system will be created for new users.

PLANS FOR DISSEMINATION

Documentation for our system will be made publicly available through the ORCATECH website. We will put into place an electronic system for tracking and controlling access to the data and artifacts, where they will be shared according to the Layton Aging & Alzheimer's Disease Center and ORCATECH Research Repository Protocol. This protocol defines procedures for protecting patient and subject confidentiality in compliance with OHSU and HIPAA guidelines, for accessing limited data sets, and for protecting the integrity of original work contributed to the database.

The in-home sensor data is fully annotated with extensive clinical assessments, as well as weekly reports of health changes. We will share derived anonymized AIMs data with the appropriate research community.

APPROACH FOR SPECIFIC AIM 3

Aim 3: Validate the AIMs metrics and the computer-based tool in senior community settings.

In this aim we will gather data to determine if the proactive use of AIMs data in a senior community setting leads to changes in levels of care needed. Within each of our partner communities, there is a team of health services professionals who track the health and ability to live independently of every resident, at all levels of care. Part of their job is to determine if a resident needs additional in-home care (e.g., home care service or medication assistance), or a transfer to a higher level of care (e.g., from independent to assisted living or a nursing home setting). Thus, our outcomes of interest in this aim are:

1) The number of transfers to higher (or lower) levels of care. Levels of care to be considered will include living independently, assisted living, and skilled nursing;

2) Percentage of days for which medication assistance was provided (where staff set up medications for the resident); and

3) Number of days in which the senior received in-home care for ADL or IADL assistance, by either a professional or informal caregiver

4) Quality of life as reported by the participant, as measured by the Older People's Quality of Life (OPQOL) Questionnaire.

We hypothesize that the AIMs data will result in fewer transfers to higher levels of care, an increase in average level of home assistance (because problems are identified early), more days in which medication assistance is provided, and improved quality of life for the participant. We chose to focus our study on individuals living alone, since this group is at high risk for loss of independence.

EXPERIMENT 6: LONGITUDINAL EVALUATION OF THE USE OF AIMS IN MAKING TRANSITION DECISIONS

STUDY POPULATION

We will begin enrollment for the validation study in the second year of the award. One hundred and fifty subjects living at a partner community (Willamette View, Rose Villa, Terwilliger Plaza, Mirabella and Mary's Woods, Holladay Park Plaza) will be eligible for inclusion in Specific Aim 3. The study will use a pseudo-randomized design. The 150 subjects will be enrolled into one of three groups of 50:

1) installed technology, from which AIMs data will be extracted and provided to the transition team at the facility to aid in transition decisions;

2) installed technology, from which AIMs data will be extracted but will not be available to the transition team; and

3) no technology.

Groups 1 and 2 will be comprised of existing AIMs participants as well as new recruits from the partner communities. Participants will be randomized into the 2 technology arms.

Group 3 will come from residents at the partner communities who are already being tracked through the ORCATECH repository and will not be approached about the study, except to ask them to fill out the quarterly Older People's Quality of Life (OPQOL) Questionnaire.

Groups (2) and (3) will receive the "standard of care" at their facility – that is, transition decisions will be made without reference to AIMs data.

PROCEDURES

One hundred and fifty subjects will be followed over a thirty month period. The protocol will consist of 4 parts:

1) Subject enrollment. (see above)

2) Provide AIMs data (using the web tool from experiment 4) for the transition teams. Data will include a summary of the past week and will highlight trends over time including outliers.

3) Ongoing assessment of subjects' health status and need for assistance by the care transition team. The procedures for this are: (1) Regular meetings by the care teams (as currently are done) to review resident health status. For those subjects in group 1, this will include review of the AIMs data as well; (2) Decisions about changes in support or living status for the resident, as are

normally made in these meetings; and (3) Completion of a questionnaire by the care team about what, if any, of the AIMs data influenced their decisions. Changes in support may include increased or decreased assistance with managing medications, additional or reduced home care, and/or a transfer to a different level of assisted living. The date and outcome of each intervention made will be recorded for later analysis. Care transition team members will consent to participate in this way.

4) Annual in-person clinical assessments as per the clinical protocol, as well as quarterly Quality of Life assessments (using the Older People's Quality of Life (OPQOL) Questionnaire).

DATA AND SPECIMEN BANKING

All data created in this study will be stored in the Layton Center/ORCATECH repository (IRB #6845).

DATA MANAGEMENT

Sensor data are time-stamped and stored locally on the sensor computer in a secure, password-protected MySQL (relational) database. Data are encrypted and uploaded from the homes to the OHSU research server on a regular basis, but may also be pulled on demand. Research staff access the data from the central data server at OHSU as well as through the router directly to the sensor and user computers using secure commercial remote-connection software. The data, study cohorts, and remote installations are managed using the ORCATECH Management Console (OMC), which is a password-protected multi-tiered remote monitoring application built from Open Source tools, including Adobe Flex, PHP, and MySQL. This tool allows staff to view subject and home information, track recruitment and subject contacts, track inventory, generate alerts for upcoming scheduled visits, view the “health” of the system (e.g., outages), and look at summaries of the data over time.

WITHDRAWAL OF SUBJECTS

If participants transition into a living situation that we cannot adequately sensor, they will be withdrawn from the study.

Any participants withdrawing from the study may be asked to complete an exit survey.

RISKS TO SUBJECTS

As we share AIMs data with the transition teams, our goal is to assess if and how transition teams might naturalistically use AIMs data. We will limit who we directly share data with, but will not require the transition team to keep the AIMs data confidential among themselves (except as per each facility’s own policy protecting the private information about their residents). There is a chance that the transition team might share AIMs data with others in the course of their natural transition decision process, and as a result there is a risk that study participants may have their AIMs metrics shared with people they don’t anticipate seeing the data. This risk will be explained in the consent form. We do not know what effect (if any) sharing AIMs data with the transition team at a facility may have related to that team’s care transition decisions, and as a result it is possible some unknown risks may exist.

POTENTIAL BENEFITS TO SUBJECTS

As stated previously, we do not know what effect (if any) sharing AIMs data with the transition team at a facility will have. We believe it's possible that participants in group 1 of Aim 3 may benefit by their data being shared with the transition team at their care facility, in that they may receive additional, needed support at an earlier time point than would occur without the data, but this remains to be seen.

Other groups will not benefit from participating in this research.

CONFIDENTIALITY

All data collected from participants will be stored in locked cabinets, or if digitized, will be saved in a password-protected database, both of which will be accessible only to approved study staff with access privileges. Transition team members who are study participants will have access to the identifiable data of Aim 3 participants living in their community via a web portal, for which each team member will have his or her own secure log in. For analysis, data will be de-identified using a number code. Only approved study staff will have access to the key linking the code number to identifiable information.

Findings from the study will be completely anonymized or reported as aggregate. Data may only be shared with approved others according to the Layton Center/ORCATECH Repository protocol (OHSU IRB #6845.)

During the course of the research, results will not be shared with the study participants by the study staff. It is possible that transition teams may share the information they receive from the secure web portal in compliance with the policy at their facility – this means some information may be shared with the study participant or the participant's family member, depending on the policies of the facility which were agreed to by the elder study participant.