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Original Study

Randomized Trial of Intelligent Sensor System for Early Illness Alerts in Senior Housing

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A B S T R A C T

Objectives: Measure the clinical effectiveness and cost effectiveness of using sensor data from an environmentally embedded sensor system for early illness recognition. This sensor system has demonstrated in pilot studies to detect changes in function and in chronic diseases or acute illnesses on average 10 days to 2 weeks before usual assessment methods or self-reports of illness.
Design: Prospective intervention study in 13 assisted living (AL) communities of 171 residents randomly assigned to intervention (n=86) or comparison group (n=85) receiving usual care.
Methods: Intervention participants lived with the sensor system an average of one year.
Measurements: Continuous data collected 24 hours/7 days a week from motion sensors to measure overall activity, an under mattress bed sensor to capture respiration, pulse, and restlessness as people sleep, and a gait sensor that continuously measures gait speed, stride length and time, and automatically assess for increasing fall risk as the person walks around the apartment. Continuously running computer algorithms are applied to the sensor data and send health alerts to staff when there are changes in sensor data patterns.
Results: The randomized comparison group functionally declined more rapidly than the intervention group. Walking speed and several measures from GaitRite, velocity, step length left and right, stride length left and right, and the fall risk measure of functional ambulation profile (FAP) all had clinically significant changes. The walking speed increase (worse) and velocity decline (worse) of 0.073 m/s for comparison group exceeded 0.05 m/s, a value considered to be a minimum clinically important difference. No differences were measured in health care costs.
Conclusions: These findings demonstrate that sensor data with health alerts and fall alerts sent to AL nursing staff can be an effective strategy to detect and intervene in early signs of illness or functional decline.

Chronic disease management is the biggest health care problem facing the United States today. In 2012, nearly 1 in 2 Americans (117 million) had at least 1 chronic condition[1] and 26% of the population had multiple chronic conditions. These numbers are expected to steadily increase over the next 30 years.[2] Chronic diseases especially affect older adults[3] in whom it is widely recognized that

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exacerbations result in dramatic changes and decline in health status, hospitalization, complex treatment interventions, and high cost.[4] Recognition of small changes in health conditions are essential for early interventions when treatment is most effective, prevention of dramatic decline is still possible, and costs can be controlled. Early illness recognition and early treatment is not only a key to improving health status with rapid recovery after an exacerbation of a chronic illness or acute illness but also a key to reducing morbidity and mortality in older adults.[5–8]

This randomized prospective intervention study was conducted to measure the clinical effectiveness and cost effectiveness of using sensor data from an environmentally embedded sensor system for early illness recognition. This sensor system has demonstrated in pilot studies to measure functional ability in older adults and *actually detected changes* in chronic diseases or acute illnesses *on average 10 days to 2 weeks before* usual assessment methods or self-reports of illness.[9,10] Inexpensive sensors are embedded in the environment, so subjects *do not* "have to use" any equipment or "wear" any devices. Motion sensors monitor subjects continuously while they go about daily activities in their homes. Unobtrusive bed sensors collect data about the subjects' pulse, breathing, and restlessness while they sleep. A gait sensor monitors increasing fall risk and alerts when people fall within the view of the sensor. The sensor system automatically detects changes in functional activities, normal sleeping patterns, and walking to alert health care providers of potential health problems.[9,10] The purpose of this prospective intervention study was to measure the clinical and cost effectiveness of using sensor data to detect early signs of illness or functional decline in a randomized sample of older adults (n = 87) living in assisted living (AL) communities as compared to usual health assessment methods of older adults living in those same AL communities (n = 85).

Design and Methods

A prospective intervention study of AL residents randomly assigned to intervention or control groups was conducted. Based on the data from pilot work, minimum sample size for 80% power and 0.7 effect size was calculated to be 55 older adults; 65 per group was our initial target. We planned for rolling enrollment into both groups over 2.5 years to accomplish adequate numbers of participants. We were able to increase numbers into both groups to ensure exposure to the intervention as we experienced sensor data transmission interruptions due to network infrastructure problems within the AL communities. This enabled each participant 1 year of experience living with the sensor system, which we estimated in the study plan was an adequate minimum duration of the intervention based on our prior work.[9] Inclusion criteria included the ability to walk a minimum of 20 feet without staff assistance, although using a cane or walker was permissible; ability to grip with hands (as grip strength was a measure collected); willing to have sensor systems installed in apartments; willing to participate in baseline and quarterly data collections lasting a few minutes; sensor data transmission for an average of 1 year for intervention participants as well as continuous enrollment for control group for an average of 1 year.

Theoretical Model

Figure 1 is our theoretical model of early detection guiding the sensor system development and outcomes expected from its use. The outcome logic is that if changes in function/health status are detected earlier using the sensor information, like bed restlessness and vital signs, then they are managed at an earlier stage, thereby preventing emergency room (ER) visits, hospitalizations, and nursing home admissions. We have successfully measured most components in the Early Detection Model in prior work.[9,11,12]

Sample

Thirteen AL communities were recruited from a large and reputable long-term care corporation located in Missouri. Sites were selected based on driving radius of about 100 miles of the research team conducting the study. Facilities ranged in size from 16 to 68 residents; most of the study participants lived in private rooms with private baths. Facilities were located in both urban and rural areas.

Subjects were recruited from all 13 AL communities. A total of 171 people were enrolled and then randomly assigned to the intervention or control group. During the rolling enrollment, 86 were assigned to the intervention group and 85 to the control. It was necessary to continue enrollment beyond targeted numbers to reach the duration for sensor data transmission defined for exposure to the intervention for the intervention subjects. Demographic descriptors are displayed in Table 1.

Figure 2 displays the dose of the study in months (intervention group on the left and control group on the right), and Table 2 displays the dose of the intervention in days. Intervention group was living with the sensors and control group was exposed to usual health assessment methods.

Intervention

The sensor system deployed in this intervention consists of a "standard" suite of environmentally embedded (nonwearable) sensors to unobtrusively and automatically monitor functional status of older adults, detect potential changes in health or functional status, and send early alerts to health care providers.[10] Sensors include motion sensors to measure overall activity, an under mattress bed sensor to capture respiration, pulse, and restlessness as people sleep, and a gait sensor. The gait sensor is a small-depth image sensor that uses nonidentifiable, shadowlike images to continuously measure gait speed, stride length and time, and automatically assess for increasing fall risk. Continuously running computer algorithms are applied to the sensor data and send alerts to staff at the time changes in sensor data patterns are detected, which may be days or weeks before typical signs or symptoms are recognized by the study participant, family members, or providers. Health alerts are sent to AL nurses via email, and each alert contains an electronic hyperlink that displays the content of the health alert in the web-based sensor data interface. The AL nurses would then determine, based on their knowledge of the resident and his or her current health conditions, if further assessment was necessary. In this way, the sensor system is designed to serve

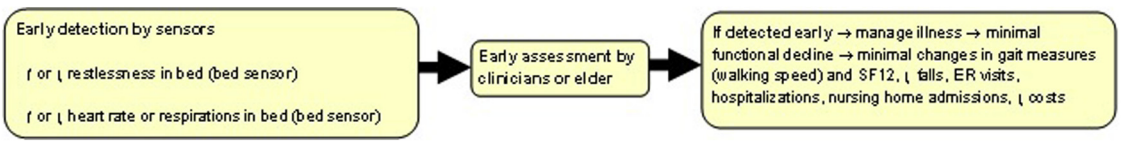

Fig. 1. Early detection with technology theoretical model.