Fall Detection and Prevention for Memory Care through Real-time Artificial Intelligence Applied to Video

Protocol Number: SY-NIA-GX001

Clinicaltrial.gov registration number: NCT03685240

Primary Investigator:
Glen Xiong, MD; CMO Safely You

co-PI
George Netscher, CEO SafelyYou

Research Sites:
SafelyYou Office – 450 Townsend St, San Francisco, CA 94107

Purpose

The purpose of the research is to study a new safety monitoring system developed by SafelyYou to help care for a loved one with dementia. The goal is to provide better support for unwitnessed falls.

The SafelyYou Guardian system is based on AI-enabled cameras which detect fall related events and upload video only when these events are detected. The addition of a Human in the Loop (HIL) will alert the facility staff when an event is detected by the system. This would allow the facility to continue with its current safety precaution but add another level of support by using HIL's to monitor for falls in real-time and 24/7.

This process enables staff to know about falls without requiring residents wear a device and to see how falls occur for residents that cannot advocate for themselves while still protecting

resident privacy by only uploading video when safety critical events are detected. Seeing how the resident went to the ground (1) prevents the need for emergency room visits when residents intentionally moved to the ground without risk and (2) allows the care team to determine what caused an event like a fall and what changes can be made to reduce risk.

AIMS & HYPOTHESES FOR RANDOMIZED, WAITLIST-CONTROL STUDY.

Aim #1. **To assess whether *SafelyYou Guardian* + HIL will lower fall rates.** *Hypothesis 1.* Compared to standard-of-care (waitlist control group), *SafelyYou Guardian* will reduce fall rates in study participant over the study period of 6 months.

Aim #2. To assess how use of the SafelyYou Guardian affects time spent on the ground after a fall. Longer time to fall discovery is associated with higher human suffering and often leads to higher medical morbidity/mortality. *Hypothesis 2: SafelyYou Guardian + HIL* will reduce time to fall discovery (time from fall to staff notification) to under 5 minutes and reduce time spent on the ground to under 15 minutes. Since there is no way to measure control participants time spend on the ground, the aim will not have a comparison but will be descriptive.

Aim #3. To assess whether *SafelyYou* Guardian will lead to improvement in hard clinical outcomes. *Hypothesis 3: SafelyYou Guardian participants will lower ED visits and hospitalizations when compared to control.* This reduction in ED and hospitalization will correlate with reduced fall rates (aim #1) and reduced time spent on the ground (aim #2). We will review the strength of the association with aim #1 and #2 outcomes.

Design

For Aim 1, we plan to recruit 460 study participants from 19 memory care facilities. For the purpose of this study, facilities will include Skilled Nursing Facilities (SNFs), or equivalent. \Aim 1 will be a randomized controlled study using a waitlist control group. The randomization will occur at the individual (resident) level within each facility to control for variations at each facility in terms of facility size, facility administration, and staff training. During the first 6 months, n=230 will receive the intervention (SafelyYou Guardian, i.e. real-time alarms through a phone call from the HIL to the facility, front line staff intervention, and OT review), and n=230 will not receive the intervention. This design is the most rigorous way to test the intervention against the control: the randomization allows for control of confounding variables and has been previously used in the evaluation of medications, non-pharmacological, and mobile electronic interventions (where use of placebo treatment and blinding is not feasible) [87-89]. Previous work used a baseline as control, allowing possible confounding variables. As we recognize that 50% of the interested participants will not receive the intervention, those residents will be offered the intervention for a 6-month extension period (in order to accomplish Aim 2). This is the best compromise between the need for a rigorous randomized controlled trial vs. ethical responsibility to maximize benefit to each study participant.

For Aim #2, we will measure response times to each fall and the amount of time a resident spends on the ground after each fall. We intend to include all 460 participants' data from Aim #1. These will be participants who receive the initial intervention (n=230) and the additional participants who are on the waitlist control group who will receive the intervention in the second 6month period. The design for Aim #2 is observational in nature. The significance is that a large cohort of video data about the naturalistic progression of falls in residents with dementia has never been conducted to our knowledge. We will determine if the two time variables (time to fall discovery by staff and time spent on the ground after a fall, controlling

for baseline participant characteristics – i.e., demographics and medical conditions) and facility size, will predict need for ER visits or hospitalizations.

For aim #3, we will ascertain the occurrence of fall in the intervention group by doing follow-up case review of each detected fall. For the control group, we perform biweekly check with facility staff and family regarding knowledge and documentation of any falls. For falls in both the intervention and control group, we will additional collected data regarding occurrence of ED visit and hospitalization days. We will also include occurrence (or absence) of any operations, intensive care unit stays, and other medical procedures. We will also collect mortality data.

Participant recruitment and retention

In the Phase I project, recruitment was performed by hosting a family night with care staff from the facility. Recruitment rate among families attending family nights was 85%. Our retention over 10 months with the 11 partner facility was near 100% (no family / resident ever requested to remove the system). One resident did begin taking the sign off the door after enrolling in the study, and the system was removed with approval from the family since he may have been attempting to object to the study. We credit this high retention to the very little burden required.

The recruitment of 460 residents will happen in batches (we expect to have access to our entire cohort 6 months from the start of the project). Once the resident population is recruited, we will deploy the system and onboard the facility staff. Onboarding will be gradual over 3 months. Through randomization, the population is split in half. One half, the control group, will not receive the intervention for the first 6 months, but will get the intervention for the next 6 months. The other half, the intervention group, will be in the study for the first 6 months only and then continue for the next 6 months. In total, 12 months will be needed per cohort. Installing the system requires 1-5 days depending on the facility size to mount the SafelyYou Guardian in the electrical closet alongside the router and PoE switches required to connect and power the cameras. Installation will be provided by SafelyYou contractor.

Subject Identification, Recruitment and Consent

All consent procedures will be conducted by the research study personnel or the facility memory care representative who often has a personal relationship with residents and families. At this time, the informed consent document will be explained in detail and any questions will be answered. All participants will have a documented cognitive impairment and designated Legally Authorized Representatives. Because the designated Legally Authorized Representatives is required for the individual to live in a memory care facility, no participants will have capacity to consent independently. Legally Authorized Representatives will instead provide consent. If the individuals with dementia express any desire not to participate verbally or non-verbally to facility staff or Legally Authorized Representatives, they are instructed to alert research study personnel to remove the participate from the study.. If at any time, residents express verbal or nonverbal indication that they would like the camera removed, facility staff are instructed to place a cover over the camera and alert research study personnel at (415) 579 3630 or research@safely-you.com to remove the resident from the study. Camera covers are provided in advance with more available as needed.

Subjects will not be compensated for participation in this study.

Subjects will not be charged for any of the study activities.

Inclusion criteria: residents included for this study are residents of memory care facilities who have agreed to participate in this clinical trial. All pilots have been conducted based on study design approved by the UC Berkeley IRB and the California Department of Social

Services Community Care Licensing Division. We have not selectively recruited or excluded ethnic (or other) minorities.

Exclusion criteria: (1) residents about to be transferred to a different facility where higher level of care is needed; (2) residents unable to consent and without Legally Authorized Representatives to provide consent, and (3) residents with Legally Authorized Representatives that choose not to take part. Compensation and measures to reduced dropouts:

Drop out: We do expect some residents to move to another location or pass away and have included the expected dropout based on the Phase I project into the statistical calculations used below to determine the necessary participant number.

Study procedures

After informed consent, each participant will be randomized to either standard-of-care (wait list control) vs. intervention. We will randomize participants within each facility as they are enrolled into the study. This ensures that site differences such as size, staff training, and other confounding variables will be controlled for by having a balanced number of intervention/control participants per site. Family meetings and staff education sessions will be conducted at each site.

If Legally Authorized Representatives wish to access recorded fall videos at any time, they can do so by contacting facility staff so they can walk through recorded video for the resident at the facility. These are sensitive videos, so we require Legally Authorized Representatives to visit the facility to view the videos with facility staff.

Privacy and security safeguards. Privacy: A common concern with any video-based monitoring system is privacy. Through the series of pilots discussed previously and shown in Fig. 3, we have systematically validated the privacy/safety tradeoffs for residents, families, staff, owners, and operators of memory care facilities. Pilot 2 demonstrated at small scale (one facility, 10 residents) that the industry would be receptive to video-based fall detection and prevention. Pilots 3 and 4 confirmed the approach with 11 facilities and 87 residents while demonstrating significant positive outcomes including 37% reduction in use of EMS for falls and 38% reduction in total falls. We now have paid commitments for 480 beds and ongoing discussions regarding expansion within the networks from the Phase I facilities, validating the benefits outweigh potential privacy and legal concerns for a number of families and providers. The combined benefits of (1) reduced time on the ground due to real-time intervention of front line staff, (2) immediate assessment of severity when a resident is found on the ground without witness, and (3) reduced likelihood of future falls through intervention of OT make our commercial approach viable. The key point is that as dementia progresses, the need to keep a loved one safe often surpasses concerns regarding their privacy. The benefits provided by SafelyYou in terms of reduced falls and ED visits have surpassed the concerns for the majority in memory care facilities where 85%-90% opt-in for the system. For more information from families and care staff validating these numbers and sentiments, please see letters from Fanning, Obenauer, Bigelow, Kimokeo, and video:

https://youtu.be/ThUsBVOAJ3A. This video was made with explicit permission from all residents/families for the purposes of promoting our work and supporting further recruitment. During pilots 2, 3 and 4, no live video was available and video was recorded whenever motion was detected. For new customers signing up for the system and for the Phase II clinical trial, no live video access is available and videos that do not contain a detected fall are not kept after 60 seconds as enabled by the highly accurate fall detection system developed in Phase I. We have never placed video cameras in bathrooms and will not for the Phase II clinical trial. In our 11 partner facilities, the Phase I showed that only 5-10% of

falls occur in the bathroom, and there is much good that can be done without needing the system in the bathroom. All study protocols have been approved by the UC Berkeley Committee for the Protection of Human Subjects. In all studies, privacy guidelines published by the California (CA) Department of Social Services (DSS) for video recording in private rooms

(http://ccld.ca.gov/res/pdf/OfficeFunctions.pdf) have been followed including signs on all doors to inform visitors and staff of video recording, no audio recording to avoid accidentally recording someone in a room which did not consent to recording, and signed privacy waivers are required from legal representatives. Care staff were further instructed to take down cameras if residents ever appeared to object. In a recent presentation of the Phase I results to California DSS which included the Deputy Director of the Department, explicit approval was granted by DSS to expand our operations in California. One representative from DSS commented that this should be required for dementia care; another confirmed that we are the only company operating this type of technology in California currently (since this was the first approval of this type given by DSS). We thus take several steps to provide privacy safeguards and believe that SafelyYou meets a critical unmet need for ADRD care where safety concerns often surpass privacy concerns.

Security: SafelyYou relies on HIPAA compliant, state-of-the-art cybersecurity software and software architectures that protect against attacks/failures. AWS Cloud Security and local data encryption in motion and at-rest are used to prevent video being available to unauthorized users. See data management plan for details.

Recording: The recording process for the video proceeds as follows. A small, password-protected computer is placed in the facility and connected to each camera. Video will be recorded and stored on this small computer in an encrypted format. Recordings will be sent directly to SafelyYou through an encrypted channel after an event is detected and available to the facility staff through a password protected website hosted on Amazon Web Services.

Event Detection: As videos are recorded at the facility, the computer located in the facility will analyze the video streams and keep a buffer of 10 minutes of prior video from each camera. If a resident is detected on the ground or a resident is detected going from a laying position to a sitting position in bed, an alert will automatically be sent to the Magellan team, and the 10-minutes of buffer video will be uploaded. They will confirm a resident is on the ground by viewing a blurred version of the video as described above and reach out to the facility staff by phone or e-call system to inform them of the situation. The 10 minutes of video after a resident on the ground is confirmed will also be uploaded, enabling 20-minute window into how the fall occurred with minimal burden on the frontline care team. As long as an event such as a resident on the ground is detected, the system will continue to upload video in this way.

Abuse Reporting: Abuse reporting will be conducted following the requirements of the Welfare and Institutions (WIC) code. If any potential evidence of abuse is discovered, facility management will be immediately alerted. Note that evidence of abuse may be missed by the SafelyYou system since only video of detected events is uploaded. The SafelyYou system is not meant to be a system for reporting abuse; it is meant to be a system for improving fall prevention practices in memory care. The research system is not intended to screen for abuse or theft suspicions. As discussed below, only video of detected events are available. It is thus very possible that incidents of abuse or theft are never uploaded for viewing by facility personnel.

Confidentiality: Study data will be handled as confidentially as possible. If results of this study are published or presented, individual names and other personally identifiable

information will not be used unless you give explicit permission for this in the separate media release form.

To minimize the risks to confidentiality, we will do the following:

- During data collection, all data will be transmitted over a secure channel.
- Research records, including video recordings and computer-based data, will be stored in an encrypted format, on a password-protected computer in a physically secure room.
- Study data will be kept confidential, unless it is certain information that it must be reported for legal or ethical reasons, such as child abuse, elder abuse, intent to hurt self or others. We use the term elder abuse as defined by California Law in the Welfare and Institutions (WIC) code.

The research data will be maintained for possible use in future research. We will retain this data for up to 5 years after the study is over at which point it will be deleted. It is retained for 5 years to ensure sufficient time is given to study the content within the data and publish the results. It will not be used for any purpose beyond what is described here without explicit approval. Use of the study data will be restricted to SafelyYou research study personnel and their collaborators. For instance, if medically relevant information is observed such as significant patterns in fall behavior, we may ask primary care physician or medical collaborators from the UCSF Memory and Aging Center to provide additional clinical consultation. The same measures described above will be taken to protect confidentiality of this study data.

Data collection:

Demographic and clinical data set: We collect demographic data including age, gender, race/ethnicity, primary clinical diagnoses for SNF stay with specific focus on dementia subtype, most recent orthopedic surgery (<3 months) or reason for hospitalization, chronic medical conditions (top 3), and baseline medications (number of medications). Beyond the data collected from the video, data specific to the falls is collected either by direct extraction from the platform or from incident reports kept by facilities as (State regulations require facility track and file incident reports for all known falls). For the control population, the time of unwitnessed falls is unknown, but the number of falls and ER visits is collected from the existing facility incident reports. For the population equipped with SafelyYou Guardian, we will have direct access to the time of the fall, the time it took the HIL to verify the fall and call the facility, and the time on the ground. Note that for the residents with SafelyYou Guardian, we expect these values to be in increments of minutes.

Clinical outcomes.

For Aim #1, the primary outcomes are the number of falls detected by facilities using the adverse incident reporting system as per routine facility protocol. While use of video detected falls will be used in the intervention group to assist with prevention of future falls, we will not use this as the actual outcome measure: is not the standard-of-care, and the control group will not have video recorded outcomes. There is a bias for detecting falls using video since existing fall reporting systems do not capture falls which staff do not know about (e.g., when a resident is able to get back in bed after a fall). Staff-detected falls which automatically trigger adverse incident reporting is the “real-world” outcome measure and current stand-of-care. Thus, outcomes will differ by facility (each facility has different adverse incident reporting operations and implementation, hence the randomization at each facility will adjust for such variables).

Aim #2 will be a naturalistic observation of SafelyYou Guardian with HIL for 6 months. Specifically, for all the facilities, the use of the SafelyYou Guardian enables direct notification of falls to front-line staff in the facilities, by intervention of the HIL. We can directly measure time on the ground for the residents as follows: (1) The time of the fall is recorded by

SafelyYou Guardian (which detected it); (2) The time of intervention of the front-line staff is logged by the staff after finding the residents on the ground. This means that for the population with treatment, we can directly measure the time of fall discovery (successful call leading to front line staff intervention), and time on the ground (since time of the intervention is logged by the facility). This is because time on the ground for monitored residents can be measured precisely by video recording. Reduction of the time on the ground can be computed given the difference between the two.

Aim #3 will include number of ER visits and number of hospitalizations. We will obtain information about resident demographics, medical comorbidities, emergency room visits, and hospitalization data by asking the study participant legal representatives. In addition, we will have participant / participant Durable Power of Attorney complete HIPAA consent forms for release of medical records when indicated if the details of data are not available.

Data analysis: For aims 1, statistical analyses to address baseline comparison: Subjects' baseline characteristics (demographics and medical conditions) will be compared between the intervention and control groups using 2-sample t-tests (or appropriate nonparametric tests if the assumption of normality appears to be violated) and chi-square tests for continuous and categorical variables. Descriptive statistics will be used (means, frequencies, standard deviations, 95% confidence intervals) for all variables. We will examine the Aim #1a outcomes using a Poisson mixed-effects model to account for the nesting of outcomes within centers. We will account for baseline measures of resident activation and health status and resident demographics to statistically adjust for baseline imbalances, reduce residual intra-cluster correlation and improve the precision of estimated effects. Power analyses were performed via a simulation study in R version 3.4. and the lme4 package. We used 3 months of pilot data to guide and set assumptions for the data generating process. Based off initial data, we assumed centers ranged in size from 25-45 participants, and that roughly 30% of participants at each site would consent to the trial. Of those who consent, 50% will be randomized to the intervention. We fit the pilot data to a Poisson mixed effects model to obtain an estimate of the average monthly fall rate (0.49) as well as the between cluster variation in log fall rate ($\sigma btwn = 0.467$). We generated 1000 sample data sets assuming different effect sizes (40%, 30%, 25% reduction in falls) and calculated the power obtained to detect this improvement due to intervention, as a function of the number of centers.

Following the sample size for a time-averaged response methodology laid out in Fitzmaurice et al., we adjusted the total number of centers needed by a factor related to the number of observed months, anticipated participants per center (30% of 35 participants per center with 10% dropout) and the correlation between measurement months. The dropout rate was roughly at ~1% per month so a 10% dropout over 6 months is a conservative estimate. We assumed an extremely conservative estimate of the correlation between time points (months) of 0.8 and 6 months of follow-up. Reproducible R code is available at https://github.com/Teresa1207/. We estimate that a total sample size of 460 (n=230/arm) out of 19 facilities will be needed for a power of 80% to detect a 30% reduction in falls in the intervention group vs. control. Our approach of focusing on estimation and uncertainty and accepting the sample size collected for the main study, is congruent with experts' recommendations stating that the purpose of economic evaluation is not hypothesis testing; given there is no hypothesis testing, there is no requirement for a separate sample size calculation. For Aim 2, we will use similar descriptive statistics as described in Aim 1. For Aim 3, We will use a multivariate regression model to examine predictors of the main outcome, ER visits and hospitalizations (binary variable), using time to fall discovery by staff and time spent on the ground as the main predictors while controlling for baseline participant characteristics and facility characteristics.

Risk/Benefit Assessment

Minimal risk for study participants is expected as the system does not physically interact with study participants in any way and only provides supplementary support while all existing safety protocols in the facility remain in place.

Risks and/or discomforts include loss of privacy by placing a camera in the private room. Although the system is designed to keep video only when a fall is detected, false alarms do occur which can cause video to be uploaded at any time. If subjects feel uncomfortable about privacy once the cameras are installed, they may withdraw from the study at any time.

The research study personnel take several steps to protect the privacy of each participant. The recorded video does not have audio capability in order to protect private communication of residents and their visitors. Physical signs are posted visibly at the entrance to all private rooms containing cameras. The signs state that video recording is in progress to ensure all visitors and staff entering the room are aware of the camera. Cameras are placed in the private bedroom only, not in the private bathroom. Cameras record video only when an event is detected. Video (with no audio) will be reviewed by the research study personnel after collection. If more than one resident occupies a room, all roommates must provide informed consent for any to participate. All data is encrypted in transit and at rest.

Installation of the wall-mounted cameras will require inserting screws into the wall in the corner of the room adjacent to the ceiling and installing cabling which may be visible. No other risk of property damage is expected.

The ongoing safety procedures at the facility will remain in place.

The SafelyYou system has demonstrated reduced fall risk and unnecessary emergency room visits for those using it in previous studies with under 100 residents enrolled and hundreds more that have used it as a commercial product. We believe the system will provide significant benefits through faster response times to safety-critical situations, help staff make informed decisions about the need for transfer to the emergency room following unwitnessed falls, and reduce the overall frequency of falls through improved root cause analysis to minimize the risk of repeat falls, but this is active research, and we do not know if any of these benefits will occur for certain.

In the long-term, we hope that the information gained from the study will help produce a robust safety system to improve the quality and reduce the cost of dementia care.

Alternatives to participation are to not enroll in the system and continue to receive standard dementia care are the participating facility.