Online Psychosocial Assessment Instruments
NIH / National Institute on Aging STTR
Grant Number: 1R41AG037216-01
Kinnexxus, Inc. & Carnegie Mellon University
Final Report

1. State the beginning and ending dates for the period covered by the STTR Phase I grant.

Beginning date: 9/15/2010
Ending date: 6/30/2011

2. List all key personnel who have worked on the project during that period, their titles, dates of service, and number of hours devoted to the project.

Benay Phyllis Dara-Abrams, Ph.D.
Kinnexxus CEO and Chief Gerontechnology Officer
9/15/2010 – 6/30/2011
800 hours

Joseph Alexander Dara-Abrams, M.S.
Kinnexxus Research Scientist
9/15/2010-6/30/2011
800 hours

Edwin Joseph (Ted) Selker, Ph.D.
Carnegie Mellon University Silicon Valley, Principal Investigator
9/15/2010 – 6/30/2011
180 hours

Patricia Collins, M.S.
Carnegie Mellon University Silicon Valley, Assistant Professor
9/15/2010 – 6/30/2011
180 hours

Michael C. Smith. M.S.
Carnegie Mellon University Silicon Valley, Research Scientist
9/15/2010 – 6/30/2011
180 hours

Lucas Sun
Carnegie Mellon University Silicon Valley, PhD student
9/15/2010-10/30/2010
180 hours

Rahul Rajan
Carnegie Mellon University Silicon Valley, PhD student
9/15/2010-6/30/2011
540 hours

Aretha Kebirungi
Carnegie Mellon University Silicon Valley, Master's student
9/15/2010-4/30/2011
360 hours

This project required certain team members to work many hours beyond the allocated time. What is reported above is the approximate *allocated* time.

3. Summarize the specific aims of the Phase I grant.

The study's specific objective is to evaluate the feasibility of using novel pain assessment technology and a standard, paper-based Brief Pain Inventory questionnaire [Cleeland] in order to support older adults in monitoring their pain and sharing that information with others.

4. Provide a succinct account of published and unpublished results, indicating progress toward their achievement. Summarize the importance of the findings. Discuss any changes in the specific aims since the project was initiated.

Changes in Specific Aims:

- Feasibility of a flexible and robust extension to the Kinnexxus platform: Because this was a technology feasibility study, the team believed that it was premature to integrate the proposed technologies with the prototype Kinnexxus platform. Instead, the project created and tested stand-alone prototypes that could be easily changed and evaluated independently.
- Research and development of novel pain assessment technologies: When the STTR Phase 1 application was originally submitted, the team anticipated that novel pain assessment technologies would be researched and developed before the targeted start date. However, the pre-award research that was completed held little promise. Therefore, four novel pain instruments were prototyped in support of this STTR feasibility study. The new technologies (i.e., an online version of the Cleeland Brief Pain Inventory questionnaire, a smart phone-based tremor detector, an online pain journal and a heart rate monitor) were developed during the Phase 1 project. This feasibility study includes data from experiments with those instruments.

Progress toward Aims:

- Research and develop novel pain assessment technologies:
    - Online Brief Pain Inventory: We developed a computerized version of the Cleeland Brief Pain Inventory (BPI), short form [Cleeland]. This implementation presented the entire two-page form on a single touch-sensitive screen. In the paper-based version of the BPI, subjects can mark a front/back human figure by shading all areas where the subject is experiencing pain and can use an X to mark the location with the most intense pain. The prototype of the online BPI used a different approach to marking the figure: The subject could only mark one spot to indicate the most significant pain.
    - Online Pain Journal: We analyzed the Cleeland BPI to identify pain characterizations that it uncovered. We then created a one- touch mobile phone-based diary that would cover most of what the BPI covers. This took the form of an Android-based application that presented the subject with a front/back human figure. The subject could mark as many pain points as s/he was experiencing. The duration of the touch indicated the intensity of the pain at each of the pain points. The mobile phone displayed the number corresponding to the intensity (on a scale of 1 to 10). When the subject reviews his/her pain journal history, an animated clock allows the user to see the way pain has changed over time.
    - Online Hand Tremor Monitor: Based on our past research on tremor detection, including correlation with sleep index, we hypothesized that tremor characterization might be useful as a psychosocial instrument that would correlate tremor with pain or other stress. We developed an Android-based application on a mobile phone that presented the subject with a game. The overt purpose of the game was to keep a movable ball inside a rectangle. To accomplish this, the subject was supposed to keep the mobile phone flat and steady. The degree to which the subject was able to maintain a steady grasp on the phone was intended to indicate the degree of hand tremor. The working hypothesis was that people who are in some degree of pain would have more pronounced hand tremor. We developed an analysis to determine if the frequency and standard deviation varied with the degree of reported pain.
    - Heart Rate Monitor: Using a Nonin fingertip pulse oximeter, we developed heart beat data capture and analysis software. Each measurement required a 5 minute time series of heart beat data. The working hypothesis was that people who are in pain would be experiencing more variability in heart rate. We developed an analysis to determine if this hypothesis was valid.
- Develop study protocol
    - Protocol development: The primary goals for the protocol included:
        - Gathering home health data from each of the five pain assessment instruments

    - Observing (and documenting) the behavior and comments of the subjects with regard to the use of the pain assessment instruments
    - Alternating the order of use of paper-based BPI and online instruments to minimize bias
    - Gathering supplemental contextual information to use in analyzing the pain assessment instruments data

  The protocol was reviewed by the team members and carefully analyzed by the CMU IRB team to ensure the confidentiality and privacy of the subjects, as well as to ensure that the protocol adequately supported the goals.

  The implemented protocol required each subject to engage with the five pain assessment instruments before breakfast, after breakfast, and before lunch on two days. The experimental hypothesis that required this schedule was that subjects might experience variations in pain intensity at different times of day or on different days: before breakfast (hungry, rested, with early-morning pain symptoms), after breakfast (sated and awake with possible social encounters), and before lunch (hungry, with possible changes in pain symptoms due to morning activities).

- Recruit subjects: When the STTR application for this study was submitted, the team planned to work closely with an elder care home services provider in Sacramento, two hours from the location of the research team. Upon detailing the logistics for such an approach, the team considered the long commute and the time spent driving between the homes of several subjects to set up equipment for each of them three times in a day. This led to a concern that we might be adding complexity and precariousness to the data collection process. Considerable effort was made to include a diverse subject pool. We were able to recruit participants with a wide range of health issues, spanning a wide range of ages. The 15 subjects in our formal study ranged in age from 66 to 95 and included three Caucasian males, one black female, one Asian female, and ten Caucasian females, suffering from a variety of health issues, including stroke, mobility problems, memory loss, diverticulitis, back pain, hearing loss, macular degeneration, arthritis, and osteoporosis. Some subjects came from a population of older adults who attended the Aging in America Conference in April 2011. Another group volunteered from the Los Gatos Meadows residential community in Los Gatos, California. The researchers also found a few participants from among their older acquaintances. The 30-minute protocol time commitment was a challenge for getting older adults to participate, even though the recruitment at Los Gatos Meadows was supported by the facility director and the director of activities.

- Train experimenters: We realized early on the importance of detailed protocol and instrument training for experimenters. Once the protocol had

been reviewed and refined by the team members, we piloted the use of the protocol with the seven members of the research team. This led to a further refinement and more explicit description of the tasks that the experimenter would need to carry out in order for the protocol to be administered consistently. The initial pilot experimenter then trained one of the graduate students, who carried out some of the pilot study. Prior to the field study, two other team members volunteered to conduct all of the interviews and trials with all of the identified subjects. The first pilot experimenter trained one of the volunteers, using the protocol document and walking through the entire protocol, with the instruments. The trained volunteer then trained the other volunteer before venturing to begin the field study. Both volunteers served as subjects in the pilot study before they were trained as experimenters.

- Conduct pilot study: Seven team members participated as subjects in a pilot study, using the protocol. During that time, numerous software problems were uncovered and addressed by the researchers. Among the problems uncovered by the pilot study were:

    - Heart Rate Monitor: During the pilot study, we identified two considerations: Some pilot subjects found the graphical display (a visual display of the music) distracting. They also found the yoga relaxation music distracting. Therefore, a simple solution was to remove the music and to replace the graphical display with a time-progress bar. At this time, we also discovered a Bluetooth connection reliability problem. We established some workarounds for the purposes of the field study, but we did not develop a permanent solution. Based on discussions with experienced technologists, it appears that Bluetooth technology will continue to improve, so this problem is expected to disappear over time.

    - Online Brief Pain Inventory: While older adults appreciated the ease of touching a screen rather than using a keyboard or a mouse, we found that the target area on the screen was not large enough for some of the participants, particularly those with arthritis in their hands (many of the women had severe arthritis in their hands). There were also challenges in making the prototype implementation a faithful translation of the paper-based BPI and the online version deviated from the paper-based version in that it did not support the user in marking multiple pain points and it did not include a way to enter the textual data that is requested in the paper-based BPI (e.g., listing pain medications taken). Such improvements will be included in the next version of the instrument.

- Online Pain Journal: One early problem with the pain journal application was that inadequate thought had been given to data analysis. Therefore, when the data were written out to a file, the essential information about the subject identification and the time/date were missing. Furthermore, there was no digital way to read or interpret the saved data. The initial prototype saved a representation of the bitmap of the final state of the mobile phone display, at the point when the subject selected to save the image. As a result of this, the pilot data were not analyzed and we had no indication whether the pain journal results correlated with the paper-based BPI images.

- Online Hand Tremor Monitor: Like the online pain journal, the online hand tremor monitor design did not initially take into consideration the data analysis task. The time-series data from the tri-axial accelerometers was stored on the mobile phone as a file, but the file did not contain the subject identifier or the timestamp. The identifiers were therefore lost, which precluded analyzing the tremor data against the paper-based BPI. Simple corrections in online pain journal data recording were made before the field study began.

We also found places where the protocol description was ambiguous or insufficient to carry out a consistent experiment. The pilot experimenter kept careful notes about the needed corrections in the protocol description and made those changes before completing the field study.

- Conduct field study: We conducted the interview and measurement sessions with 15 adults over a period of six weeks. Almost all subjects were extremely cooperative in completing the protocol. They completed all forms to the best of their ability, used each pain assessment instrument, and shared their observations with the two experimenters.

- Archive data: Various questionnaires gave contextual information to support interpretation of instrument data. These data were collected from the field study forms and were manually entered into a spreadsheet. For each subject this included a demographic questionnaire, a pain history questionnaire, six pre-test questionnaires before the six trials, and a final post-test questionnaire capturing each subject's experiences with the various instruments. This contextual data, plus the data from the pain assessment instruments were uploaded to a shared repository. All of the data in the repository are organized by subject identifier (0000 – 0025), ensuring the anonymity of the pilot and field subjects. Note that a single researcher provided the transcription of marked pain points on the human figure into standard nomenclature for those parts of the body (e.g., clavicle, lumbar spine, nose). This was done to establish consistency in transcription.

- Evaluate novel pain assessment technologies

    - Online BPI: The primary question with the online BPI was whether the subjects' answers would correlate well with their answers on Cleeland's paper-based BPI, which we used as ground truth. To accomplish this evaluation, a simple correlation metric was employed to detect differences between the paper-based BPI data and the online BPI data.

    - Online Pain Journal: The primary question with the online pain journal was whether the subjects' depiction of their pain areas and intensities would correlate well with the depiction on the paper-based BPI. A visual inspection of the pain journal images and the paper-based BPI markings on the human figure was completed. This led to results that are described below.

    - Online Hand Tremor Monitor: The hypothesis for this instrument was that tremor intensity and variability would correlate with the current reported pain levels in the paper-based BPI (question #6). Therefore, the data were analyzed with these two variables and simple correlation statistics were run against the reported pain level question.

    - Heart Rate Monitor: The hypothesis for this instrument was that heart rate variability would correlate with the reported pain levels in the paper-based BPI (question #6). Therefore, the data were analyzed with heart rate variability vs. reported pain level.

- Interview selected subjects: While forming initial thoughts regarding results, the team realized that it had additional questions. For example, it appeared that even when trained and prompted to do so, subjects did not distinguish between the front and back human figures on the online pain journal. The user interface depiction of the body included a face, hair, knee and foot features to distinguish front from back. The upper left of the screen included a "mirror image" to support front/back selection (figure below). It is possible that an even more realistic front and back depiction could have caused subjects to indicate pain more accurately. Another UI difficulty is that the online hand tremor monitor appeared to cause people to move their hand, rather than encouraging them to make the hand steady. We thought we had overcome earlier UI research challenges, in which we had eliminated feedback on detected tremor, because the lack of feedback might have resulted in a pointless movement game. We had theories about the subjects' interpretation of the user interface, but we wanted to hear directly from subjects about their understanding of the instruments. At this point, we created a new questionnaire to be used in posing open-ended questions with previous subjects.

Results:

- Paper-based Brief Pain Inventory: The Cleeland Brief Pain Inventory short form is a standard for communication about pain between the patient and the pain management specialist.[Cleeland] Nevertheless, the older adults in the field study had numerous difficulties in filling out the form, especially the first time.The most common problem was that the BPI is primarily intended for use by those with a noticeable pain for which they are under treatment. Subjects who had minor pain or multiple pains struggled with completing the 11 point scale in the Cleeland questionnaire, which seemed to assume that the subject had at least one noticeable pain. The form also asks the subject to list treatment undertaken for the pain and the amount of relief that the treatment provides. For those not undergoing pain treatment, these items on the form were often either skipped or answered with question marks. Once the subject indicated that s/he was not undergoing pain treatment, the following question (how much relief results from the treatment) made no sense.

  All but one subject described the paper-based form as easy to use. (That one subject had macular degeneration and needed assistance to read and complete the form.) Any literate person is very likely to be familiar with survey-style, paper-based forms. Older adults are quite familiar with the use of a pencil and eraser to complete such forms. Perhaps not surprising is that many of the subjects did not follow the instructions. For example, the instructions for marking the human figure state, “On the diagram, shade the areas where you feel pain. Put an X on the area that hurts the most.” Instead, many subjects chose to mark each pain with an X and few used the shading technique at all.

  The findings include anecdotal evidence that the Cleeland Brief Pain Inventory is not intuitive for some subjects. Some older adults in this study expressed frustration that pain experience is quite subjective, and yet they were given an apparently objective scale (0 to 10) for characterizing their pain. They assumed that in order for the characterization to be useful, there would need to be some standard interpretation of each number on the scale.

  Another anecdotal finding was that some of the subjects struggled with left-right identification. One subject was observed touching parts of her body, then relating that to the front-back human figure in the BPI form. Comparisons with other of the pain assessment instruments suggest that left-right discrimination may be confused by some older adults.

- Online Brief Pain Inventory: Because the online BPI attempts to mimic the paper-based BPI, it has some of the same strengths and weaknesses. For subjects who only suffer “everyday” pain or minimal pain, most of the questions seemed irrelevant to them. And as with the paper-based BPI, the online BPI’s numeric scale of choices for characterizing pain left some

subjects musing about the subjective nature of pain experience and the implicit objectivity of the scale.

The online BPI allowed the subject to select only one pain point. Subjects who experienced multiple comparable pains and those whose pain covered large regions of their bodies had no way to indicate this.

The detailed touchscreen interface posed problems to some participants while others found it very straightforward and easy to use. Some subjects experimented with different parts of their fingertips to try to get the mark at a point on the figure that they felt corresponded accurately with the center of their pain. Other subjects gave up easily and just accepted where the mark was placed, whether or not it was an accurate depiction of their primary pain point.

This same touchscreen challenge arose as subjects attempted to make a numeric selection for each item in the survey. The design and layout of the online BPI provided only a small piece of real estate for the subject to touch. Therefore, the subjects sometimes thought their selections had registered when they had not, but once they saw that the selections weren't showing up on the screen, they quickly touched their selections again. Participants learned from experience, and the next time, they were usually able to make their selections without any problem Though we made an explicit design decision to put the two pages of the BPI onto a single screen, this design decision will be revisited. Since a two-screen layout would allow for larger text and larger touch area, we feel that older adults will find the information more readable and the boxes easier to select by touch.

For the most part, subjects were conscious of making an effort to maintain consistency between their answers for the online BPI and paper-based BPI, no matter in which order they completed those two tasks. Nevertheless, some inconsistencies between the online BPI and paper-based BPI must be noted. The most noticeable difference was in the marking of the figure. Because the subjects generally did not follow the instructions for marking the worst pain with an X and all other pain with shading, it was later not possible to determine which pain point hurt the most. However, because the online BPI only supported making one mark on the figure, the mark could unambiguously be identified as the point that hurt the most. (Further discussion of marking a figure with pain points can be found in the Online Pain Journal results, below.)

Online Pain Journal: Many of the older adults had never held a smart phone before and were unfamiliar with touchscreen technology for "telephones."

Nevertheless, they approached the task with interest.. As mentioned in the above section, left to right and front to back were not reliably indicated. Nevertheless, some interesting qualitative conclusions can be drawn.

Some of the subjects found the online pain journal to be better for expressing their pain experience than the paper-based or online BPI instruments. Because the online pain journal deals exclusively with the current experience, users did not have to remember past pain experience and did not have to make comparisons between the current experience and past experiences. The journal maintains a history of in-the-moment assessments and, therefore, acts as an accurate memory for the older adult.

Out of all field study subjects, not one person ever marked both the front and back of the human figure during a single session. Yet we know from the paper-based BPI form that was filled out during the same session that the subjects were experiencing pain on the front and back of their bodies. Despite the fact that a face was drawn on the front of our human figure, it appears that subjects treated the human shape as a transparent cookie-cutter form, marking both front and back pain on the same figure. This was certainly an unexpected finding, one that leads us to conclude that older adults need to see front and back images simultaneously and that each figure needs “landmarks” that clearly distinguish front from back and specific regions of the body.

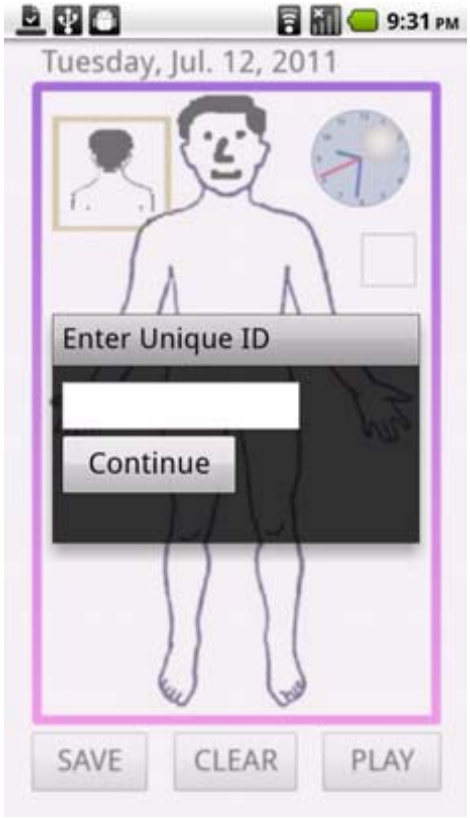

Figure 1: Online Pain Journal Login Screen

Some subjects noticed that the touch mechanism on the smart phone was different from that on the touchscreen computer kiosk. A subset found the difference

confusing and had difficulty adjusting to whichever device they used later. I.e., once they had learned one interface, they tried to apply the same touch technique for using the other interface.

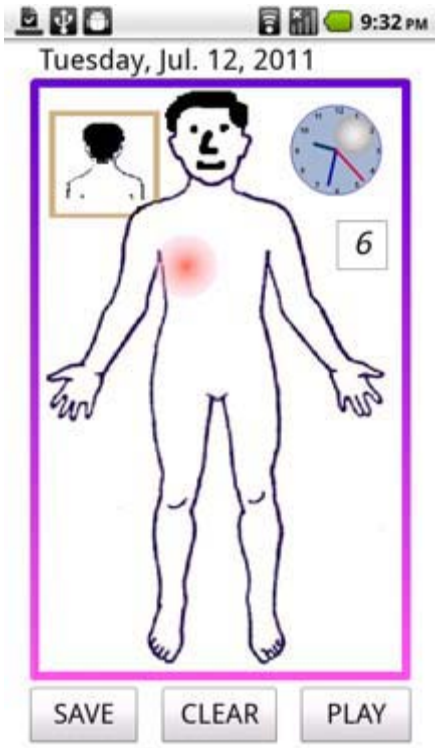

Figure 2: Online Pain Journal, Single Right Chest Pain Point at Intensity 6

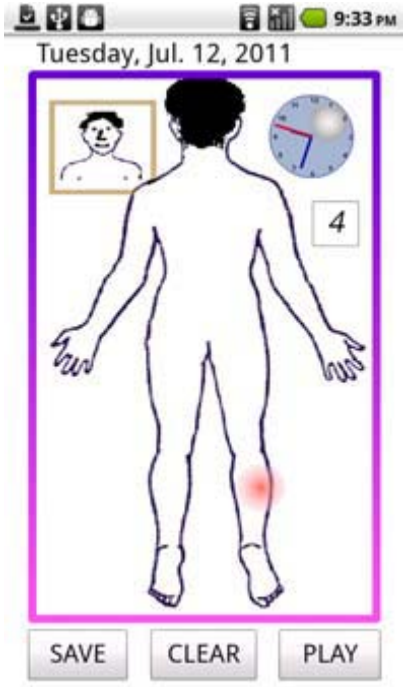

Figure 3: Online Pain Journal, Single Right Calf Pain Point at Intensity 4

Another result was that some subjects made many more marks on the pain journal figure than they made on the paper-based BPI figures. In one case, we know that the subject was trying to simulate a pain that went all around her head by marking a series of spots in the head area, whereas she did not use that technique (or shading) on the paper-based BPI. Another subject made approximately seven spots across the waist and onto the right arm. If taken literally, the interpretation could be that the subject had left, middle, and right waist pain as well as right elbow pain. However, the more likely interpretation is that the subject was attempting to show a continuous region of pain and had difficulty precisely marking the endpoints of the pain on the small figure. At another time, this same subject marked only the front figure, with pain spots across the chest, waist and left elbow. This same subject marked right shin pain in the first session and left calf pain for the next session. Since it is unlikely that there was a dramatic shift in pain location over the course of the hour between the first and second session, the more likely explanation (as stated above) is that the subject did not pay attention to the front vs. back figures, instead using them interchangeably. This is confirmed by looking at the paper-based BPI figure markings.

Each subject was instructed to touch a representation of a pain spot, with longer touch corresponding to higher pain levels which created a larger pain halo and corresponding pain value on the user interface. Although each subject was instructed in the use of these techniques, they did not seem to apply the instructions. The feedback from the user interface was possibly not clear enough to ensure reliable pain intensity data from the subjects. The online pain journal used a scale of 1 to 10 for characterizing pain at each point. The longer the subject touched a single spot, the higher the reported pain. The user interface displayed the pain intensity number next to the body and a pain/intensity halo size around the spot was meant to indicate the pain intensity.

One thing to keep in mind is that the online pain journal was based on a Motorola Droid mobile phone that lacked a high-contrast screen. It's quite possible that a mobile phone with a higher fidelity touchscreen, combined with other recommended changes, would have supported the subject's efforts at pain intensity discrimination.

- Online Hand Tremor Monitor: Subjects were able to understand the goal of the tremor instrument quickly. They were patient with this "game" and completed their trials successfully every time. The questions for this instrument fall into two categories: (1) Does hand tremor amplitude, frequency, or standard deviation correspond to degree of reported pain? (2) Does the prototyped game reveal pain-induced hand tremor? During subjects' use of the game, we observed them moving the mobile phone con-

tinually in order to attempt to keep the ball inside the rectangle, while the actual goal was to keep the ring inside the circle. Therefore, the game introduced noise into the tremor signal.
Our previous research results [Selker et al] demonstrate that tremor can correlate with certain psychosocial phenomena such as sleep patterns. However, in the current feasibility study, we were unable to establish a "ground truth," probably due to subject misunderstanding of the goal (i.e., to hold the smart phone as steadily and stably as possible). Ideally, we would have been able to establish intra-subject variations in reported pain, in order to establish whether amplitude, frequency, or standard deviation correlated with these variations. However, we did not induce pain in the subjects in order to get these data, so we are unable to answer the first question.

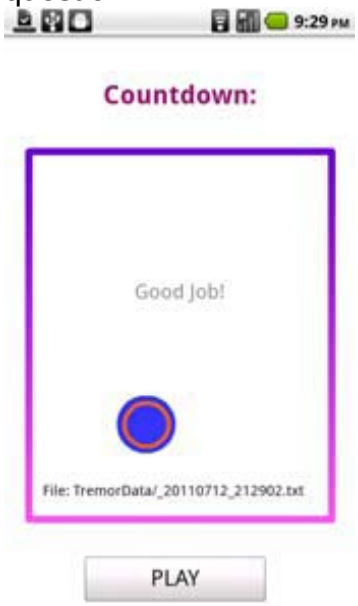

Figure 4: Hand Tremor Results Screen

The literature suggests that hand tremor is typically at or below 12 Hz, with some kinds of commonly occurring hand tremor found at 4-6 Hz. The data sampling rate was 25 Hz, but the signal was processed with a low pass filter cutting off at 5 Hz for the first few subjects. In any case the tremor instrument did not have consistent readings for pilot subjects or field study subjects. What we do know is that there was no correlation between amplitude, frequency, or standard deviation and the degree of reported pain. We expect that a new UI and protocol can allow us to get the stable ground truth and signal that we achieved in previous tremor experiments [Selker et al]. We still believe that the tremor instrument holds promise and that the necessary improvements are easy to implement for future quantitative studies.

As a side note: The earlier hand tremor study was conducted at CMUSV, using no significant user interface, with verbal instructions to hold the phone steady at arm's distance. In that study, data were sampled at 39 Hz, with no UI to distract the subject. In this earlier experiment, there was a clear inverse correlation between standard deviation and diagnosed hand tremor—i.e., those with diagnosed tremor have a more regular frequency of motion. To a lesser extent, frequency was also inversely correlated with diagnosed hand tremor—i.e., those with diagnosed tremor have lower frequency of motion. [Interact2011] In that set of experiments, subjects followed a protocol that was quite similar to the one used by neurologists in diagnosing hand tremor: The subjects extended one arm at shoulder height so that the hand tremor (if it existed) would be easy to observe.

Heart Rate Monitor: The question for this instrument is whether variability in heart rate correlates well with the reported pain levels in the paper-based BPI (question #6). We used the Nonin fingertip pulse oximeter to capture a 5-minute time series of plethysmographic data with a sample rate of 75 Hz. Each time series was subjected to an analysis to determine heart rate variability, expressed by the standard deviation of heartbeats per minute. Due to Bluetooth unreliability and scheduling problems, we were only able to collect 69 of the 90 scheduled measurements from the 15 subjects in the field study. The data collected shows a significant range in both heart rate variability (min = 1.7 BPM, max = 40 BPM) and reported pain level (min = 0, max = 7). However, there is a poor correlation between the two metrics (N = 69, R = 0.07).

Initially, the research team had reservations about the willingness of the test subjects to sit quietly for the 5-minute test measurements. As the field study was performed, however, we found that the subjects were in fact quite willing to comply with 5-minute measurement requirement. In fact, some subjects were surprised to learn that they had sat quietly for that long a time; the time passed quickly for them.

Importance of Findings:

- Paper-based Brief Pain Inventory: The difficulty in accurately following the instructions for the paper-based BPI made it an unreliable instrument in our field study with older adults. Furthermore, the questionnaire does not adequately accommodate the variety of potential responses. For example, if someone claims to have only everyday pain, they might be instructed to skip specific questions that are not relevant for someone who does not have exceptional pain. While other studies in the literature have validated the use of the BPI for cancer patients and chronic non-cancer pain [Tan et al], we can find no study of the usability of the BPI for older adults. Our findings suggest that the BPI is not a reliable instrument for older adults using the instrument on their own. Older adults may need to use the BPI in conjunction with someone who can ensure that they are following the in-

structions correctly and who can clarify their questions/confusions. On the other hand we are not enthusiastic about creating scenarios in which a person is answering more than a dozen questions several times a day.

- Online Brief Pain Inventory: The current implementation of the touch screen kiosk with online BPI can be enhanced by providing a context-based sequence of items and feedback to the older adult. These are important advances that might be considered for future development and testing of the instrument. It is an important finding that older adults struggled as much with the kiosk touchscreen as with the online pain journal interface that was also sensitive to the dynamics of touch and required an understanding of parallax effects. Future versions of the online BPI will account for these implied usability requirements, at which time we can further validate these hypotheses.

- Online Pain Journal: The online pain journal revealed a significant challenge for older adults (which may also be a problem for younger people): representational figures need an unambiguous way of coding right/left and front/back distinctions. This may be as simple as including the words (right/left, front/back) in the diagram, or showing front and back simultaneously. One idea for identifying part of the body would be to touch the body part directly or photograph it with a camera-equipped phone. Once the subject had marked the location and intensity of a pain, reducing the pain indication was not an option. This was especially problematic because all users had difficulty controlling how much pain they were indicating. A future version will make the indication of pain level adjustable.

- Online Hand Tremor Monitor: The online hand tremor monitor provided a game interface that appealed to the older adults in the study. They believed (right or wrong) that they intuitively understood the goal of the game. The game, however, seems to have introduced motion noise into the tremor signal for those subjects who assumed that the goal of the game was to keep moving the mobile phone in order to keep the “ball” inside the “rectangle.” The signal analysis developed for this hand tremor monitor revealed that the data were not as reliable or consistent within or between subjects as was found with a simpler tremor instrument. We expect that eliminating the game/interface aspect would produce better data. Findings included verification that detection of hand tremor requires at least a 25 Hz data sampling rate and at least a 12 Hz low-pass filtering of the data; filtering below 12 Hz removes potentially important signal components.

- Heart Rate Monitor: Due to the inconsistency of heart rate within subject and poor correlation of heart rate variability and reported pain levels, we concluded that variability in a subject’s heart rate cannot be used to infer

pain levels experienced or reported by the subject. This heart rate monitor is not an appropriate substitute for the self-reporting provided by the BPI.

5. List titles and complete references to publications, and manuscripts accepted for publication, if any, that resulted from the project's effort. Submit five copies of such items, except patent and invention reports, as an Appendix.

Presentations at the 2011 Aging in America conference in San Francisco, CA:

- *How E-Health Technologies Support Patient Engagement and Reduce Health Care Costs*, April 26, 2011.

- *Embedding Personal Health in a Social Context,* April 30, 2011.

6. List patents, copyrights, trademarks, invention reports and other printed materials, if any, that resulted from the project or describe patent status, trade secrets or other demonstration of IP protection.

Before the grant was initiated, Kinnexxus, Inc. had already applied for a patent for the collaborative gerontechnology apparatus and method that provides the foundation for the Elder Social Support Platform. No new patents, trade secrets or other intellectual property were developed as part of the Phase I feasibility study of older adults' usage of online pain assessment instruments.

Printed materials include two progress reports in October, 2010 and January, 2011, and slides and handouts for the Aging in America conference sessions.

7. Describe the technology developed from this STTR, its intended use and who will use it.

- Online Brief Pain Inventory: This instrument is implemented on the Kinnexxus Kiosk, using Adobe Flash with Adobe Air on Windows XP. The implementation includes a single screen that presents the information on the paper-based BPI [Cleeland]. The proof-of-concept implementation allows the subject to touch a selection to indicate where he/she is experiencing pain and to answer questions about this pain. The intended use of this instrument is to enable older adults to maintain online data about their pain experience, using a standardized tool. This information about the older adult's pain experience can be shared with members of their support network, including family caregivers and professional care providers. A further enhancement would be to track a time-series of answers to the questionnaire to be shared with family caregivers and professional care providers.

- Online Pain Journal: The instrument consists of an Adobe AIR application with a Flex framework on an Android platform. The user interface allows the older adult to select front and back images separately, marking as many pain points as they choose. Each pain point has an associated intensity and timestamp. The front and back images with markings are stored separately and can be reviewed by the older adult as a time sequence. The intended use is for journaling about pain experience, with the target user being older adults, especially those with chronic pain conditions. The older adult can share the journal entries with a medical professional or with a trusted caregiver or family member.

- Online Hand Tremor Monitor: The instrument consists of an Adobe AIR application on an Android platform. The UI presents a rectangular frame with a solid circle and a ring in the form of a game. The goal is for the user to keep the ring within the solid circle (indicating fine hand stability), with the solid circle remaining inside the rectangle (indicating coarse motor stability). After maintaining this coarse and fine stability for 8 seconds, the game terminates and the user sees a text message, “Good job!” The intended use is for monitoring pain-induced tremor, although all forms of tremor will be detected. The target user is older adults with pain-induced tremor. The current implementation does not support medical professionals’ review of the historic data, though this is an obvious use of the information.
- Heart Rate Monitor: A Nonin Onyx II 9560 BT fingertip pulse oximeter is used to generate a plethysmographic time series, reflecting how the capillaries in the subject’s finger fill and drain of blood with each heartbeat. The time series data is transmitted via a Bluetooth connection to a custom application running on nearby computer. The resulting data series is written to a disc file in a “comma separated values” (CSV) format. The time series data is processed by another custom application to identify the peak values, each representing a heartbeat, and the time interval between successive heartbeats. The standard deviation is computed and the output, consisting of the subject identifier, the measurement’s ending timestamp, the reported pain level (supplied as a separate input) and the standard deviation is written, again in CSV format to another disc file. This process is repeated for each time series measurement, with the output being appended to a single CSV file. This file is then processed by a spreadsheet application to determine the correlation coefficient.

8. Describe the current status of the product (e.g., under development, commercialized, in use, discontinued).

An initial study has been conducted with older adults, ranging in age from 66 to 95, who were presented with a set of online pain assessment instruments to use during six sessions. Through observations of the participants using the instruments and from further interviews with some of the study participants, the researchers have been able to identify specific ways to improve the usability of the instruments. Understanding how to improve these instruments constitutes a key element in the formative evaluation process.

Formative evaluation is the evaluation of a working prototype or, in some cases, a rough draft of a system [Tessmer 1996]. The objective of the formative evaluation stage is for participants to use the prototype system and provide feedback in order to improve the usability of the system [Tessmer 1996]. Figure 5 illustrates the iterative process of feedback and revisions to the prototype during each step of the formative evaluation and improvement process [Tessmer 1993]. Figure 6 shows the general sequence of formative evaluation types of participant groups.

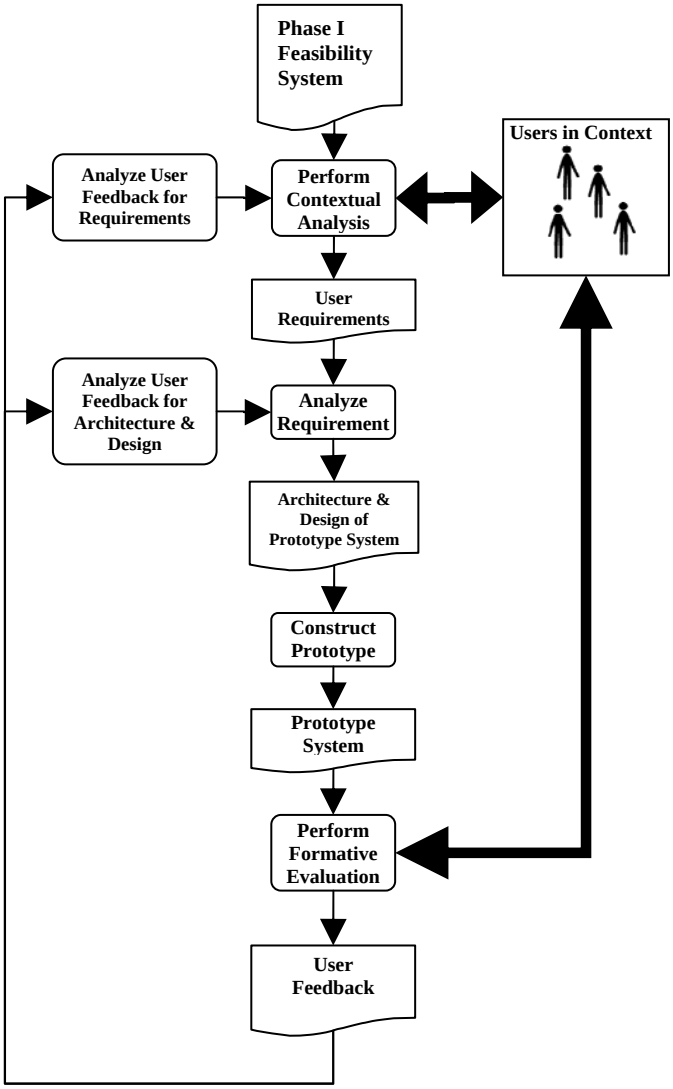

Figure 5 Cyclic prototype evaluation & improvement process

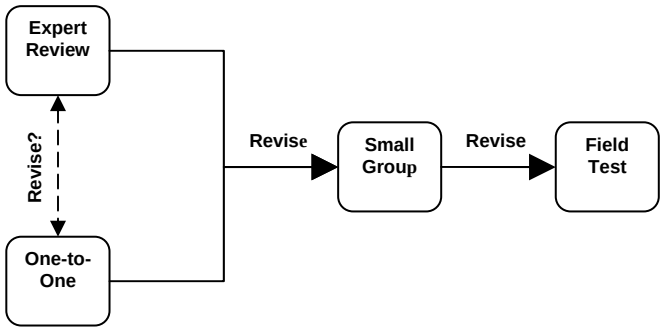

Figure 6 General sequence of formative evaluation types

9. If applicable, describe the status of FDA approval for your product, process, or service (e.g., continuing pre-IND studies, filed an IND, in Phase I (or II or III) clinical trials, applied for approval, review ongoing, approved, not approved).

Not applicable -- The Elder Social Support platform acts as a pipe, transmitting information between older adults and family members. Such information may include that derived from online pain assessment instruments. We have been informed by an FDA consultant that this use of the platform will not require approval.

10. Describe how your company has benefited from the program and/or the technology developed (e.g., firm's growth, follow-on funding, increased technical expertise, licensing agreements, spin-off companies, public offering [include stock exchange and symbol]).

The company benefited from the program by gaining the following:

- Experience and guidance in developing human subject protocols
- Assistance in developing action scripts for kiosk-based instruments
- Assistance in coding data from instrument protocols
- Exposure to design processes for smart phone interfaces and instruments
- Assistance setting up and using home health instruments, such as the pulse oximeter
- Understanding of limitations of the proposed technologies for pain assessment

11. List of the generic and/or commercial name of product, process, or service, if any, that resulted from STTR funding. If applicable, indicate the number of products sold.

The Phase I grant demonstrated the feasibility of and the challenges in using online pain assessment instruments with older adults. The next step will be to implement the improvements suggested by the findings in our study of older adults.

12. Provide the current number of employees (total full time equivalents [FTEs]).

Two FTEs

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