Study Protocol and Statistical Analysis Plan

E-training of Inmate Peer Caregivers for Enhancing Geriatric and End-of-life Care in Prisons Phase II

NCT05017129

April 2025

SPECIFIC AIMS

The 1,719 state and federal prisons in the United States (US) house over 2.3 million adult inmates. The prison population is rapidly aging-in-place. In 2017, 20.3% of sentenced prisoners in state or federal facilities were 50 and older.[3] While demographic shifts in age are parallel between prisons and the free world, inmates typically present with health issues common to free people who are 10-15 years their senior.[50] In 2014 , "more than half (59%) of state prisoners who died were age 55 or older"[15(p1)] and prisoners over the age of 45 have a death rate that is greater than 10 times that of prisoners aged 18-44.[15] In addition, "older prisoners disproportionately account for escalating correctional health care costs".[51(p1475)]

Prisons are facing sharply increased demands in caring for aged and dying inmates.[52] A recent systematic review revealed that inmate peer caregivers figure prominently in delivery of end-of-life (EOL) care.[24] Inmates offer an abundant human resource that is poised to contribute in important ways to augment corrections staff in meeting a growing care need in US prisons. However, a barrier to high quality caregiving is insufficient and/or inconsistent training. The degree of training received by Inmate Peer Caregivers varies widely,[29] which points to a critical need for evidence-based and readily accessible learning materials tailored for the inmate population. The proposed project focuses on research and development of computer-based learning modules for training Inmate Peer Caregivers to support their aged and dying peers. This Phase II STTR proposal originates from four of our previously funded projects including a successful Phase I study.

Our past research[24,25,28,29,31-33] suggests that inmates are engaged in supporting peers with physical and mental health needs. This led us to embark and complete our recent Phase I STTR *E-training of Inmate Peer Caregivers for Enhancing Geriatric and End-of-Life Care in Prisons* [R41 AG 057239] study. Our research revealed that inmate access to technology is continually evolving, and inmates can be successful e-learners. Through focus groups and usability testing of the three prototype modules, we learned that inmates are receptive to e-learning and that correctional settings have a model for inmates learning via computers (i.e., electronic law library). Inmate usability testers were able to successfully complete our newly developed *Inmates Care* computer-based learning (CBL) program and e-learning is a feasible approach for inmate training. Study findings also indicated that the look and feel, the interactive nature, and the vast majority of the content in the *Inmates Care* program were well received. Learner and content preferences, as well as expanded interactive functionality were gleaned as requested future modifications to existing modules. Our proposed Phase II study will address these requests and expand upon the program. Specifically, we will refine the existing modules that were usability tested in our Phase I project; develop an additional 3 modules for training inmate peer caregivers; develop an introductory module for the staff who will oversee and implement the e-learning within the state prisons; and test this new product for its fit with inmate peer caregivers within the restrictive constraints of prison.

In Phase I, we demonstrated the technical merit, feasibility, and market potential of *Inmates Care* computer-based learning. Phase II will continue research and development of the *Inmates Care* learning system with an emphasis on developing a scalable unit for commercialization and testing scale-up in a larger number of more diverse state prison contexts.

The **Specific Aims** are:

AIM 1: Develop a full scale, media-rich, interactive CBL system, *Inmates Care*, that consists of six modules aimed at augmenting the highly variable face-to-face inmate caregiving programs in state prisons with standardized, evidence-based training to prepare inmates in assisting with EOL and geriatric care; and one *Training Overview and Rollout* module that prepares staff to use *Inmates Care* as a tool for inmate peer caregiver training.

AIM 2: Conduct in-person usability testing of the full-scale *Inmates Care* program in state prisons to evaluate logistics, IT and staff impressions, as well as the user interface, ease of use, and perceived barriers in order to optimize the scalable unit for broader dissemination. In-person usability testing includes:3

2a. Small-scale usability testing in both a men's and a women's prison with front line multidisciplinary corrections staff (e.g., nursing, security, chaplaincy, education, unit management, information technology; n=10) regarding logistics, feasibility, and refinement of newly developed module *Training Overview and Rollout* staff training module.

2b. Small-scale usability testing with inmate end users at a men's (n=10) and a women's prison (n=10).

AIM 3: Test scale-up of the full-scale *Inmates Care* program in state prisons across the nation to evaluate knowledge acquisition outcomes, usage patterns, and commercialization opportunities (n=288).

Project Timeline. This 24-month Phase II project will refine the Phase I prototype, develop 3 additional inmate e-learning modules and one staff module, and conduct full-scale testing

Study Aims

Content Refinement, Focus Groups, and Development (AIM1). We will make needed refinements to our 3 *Inmates Care* prototype modules (i.e., *Standard Precautions; Loss and Grief;* and *Role of the Inmate Caregiver in the Final Hours*) that were developed in Phase I. This will be achieved through engaging with both Inmate Peer Caregivers and staff involved with inmate caregiver training, via FGs.[81,82] During FGs, we will: present segments of each of the 3 prototypes; gain reactions (e.g., to look-and-feel, content, learning strategies employed); and ascertain priority foci for the 4 new modules (i.e., 3 for Inmate Caregivers; 1 for prison staff). We know that a module guiding staff in the implementation of *Inmates Care* training with inmate peer caregivers is essential because inmates cannot just decide to embark on this training in the prison world—a demand must exist, vetting must be achieved, and ongoing oversight is essential. The goals of both the inmates and staff FGs are to ascertain: a) additional priority training topics for development of our new inmate modules; b) key content for the staff module being developed; and c) if what we learned in Phase I, that *Inmates Care* should be developed to supplement and facilitate, rather than replace, existing instructor-led training holds true across additional prisons outside of PA.

Field notes from the FGs (and audio-recordings if permitted by each state prison) will be transcribed verbatim, verified line-by-line for accuracy and cleaned of identifying information. Standard techniques of content and thematic analysis will be used. PI Loeb is a skilled FG researcher[83] having completed rigorous FG studies with adults age 50+ in community settings,[84,85] as well as in state prisons.[86] Phase II, Aim 1 is essential because although inmates and staff were exposed to content and prototype modules, Phase I testing was limited in scope (i.e., 2 prisons in PA) and depth due to the formative research stage. Through this planned research, we will learn if our Phase I findings hold across other state prisons. Our third source of information for the achievement of Aim 1 is via consultation with our content and implementation advisory boards.

Phase I findings, CAB and IAB expertise, and FGs with inmate peer caregivers as well as prison staff in one men's and one women's state prison not in PA will determine refinements to existing modules as well as additional modules to develop our innovative, evidence-based, and highly interactive *Inmates Care* training program. Aim 1 will consist of two stakeholder groups in two state prisons. Ten to 16 total inmate participants (n=5-8 inmates from men's prison and n=5-8 inmates from women's prison) along with 10-16 total staff participants (i.e., n= 5-8 staff at men's prison and n=5-8 staff at women's prison) will be recruited. Using recruitment methods that have been successful for well over a decade for MPI Loeb, eligible inmates (i.e., total n=10-16) will be identified as potential participants by a correction's senior official. Inmates will be contacted by the research team through Penn State University (PSU) Institutional Review Board (IRB) approved recruitment flyer in their mail drawer and those who return a tear off reply indicating they are interested in participating will be scheduled through the Superintendent's Assistant (or designee) to meet with the investigative team. Potential prison staff (n=10-16 total) participants will be similarly recruited through PSU IRB approved mail/email distributed by the same correction's senior official. Informed consent will be obtained from all participants. From our past experience we anticipate that a total of four FGs will be needed for this study (2 per stakeholder group) with 5-8 participants per FG,[81] but we will continue to conduct FGs until thematic saturation of the data is reached.[87] Inclusion criteria for inmate peer caregivers are: (a) providing geriatric and/or EOL care at participating state prison; (b) age ≥18; (c) able to speak and understand English; and (d) able to consent. Inclusion criteria for prison staff are: (a) age ≥18; (b) able to speak and understand English; (c) able to consent; and (d) have been exposed to inmate peer caregiving (e.g., through training them, oversight of a peer caregiving program, or working with inmate peer caregivers in the infirmary, personal care, or hospice area of prisons). PI Loeb will moderate the FGs and another trained research team member will co-moderate the FGs. Incentives are typically prohibited and not needed to achieve recruitment success in prisons. Instead, a Certificate of Completion will be given.

Prototype Optimization. Phase I findings and meetings with our CAB and IAB will guide the refinement of the 3 module prototypes. We will refine the interactive exercises to optimize engagement while delivering content;

obtain or produce powerful video/photographic images that are specific to the context of prison and messaging; and ensure that each module begins and ends with narration. Experts at KB will refine the technical aspects of *Inmates Care* to ensure functionality and compatibility with web-based access or installation on a Learning Management System (LMS).

Engage with a Content Advisory Board (CAB). Our interactions with multiple stakeholders during Phase I, along with parallel experiences when completing the ECAD-P study, reinforced the need for early and frequent user-focused feedback in the design and implementation phases. For Phase II, we have established a CAB comprised of 6 stakeholders representing both continuity and fresh perspectives. The CAB consists of 3 ongoing members from the Phase I study; a member who was on our ECAD-P study board (i.e., a returning citizen who served 20+ years in state prisons and now is released and living in the community); and 2 members with no past experience with our prior research (see **Letters of Support**). Within the CAB are experts in corrections health, geriatrics, EOL care, and experience with growing older in prison and seeing peers age and die in prison. This group of six content experts will ensure that the final *Inmate's Care* product's relevance and utility to the context of corrections is strong. Also, the CAB will test the usability of our prototypes. We will engage our CAB in two formal ways—a) through independent video meetings with them twice per year; along with one joint face-to-face annual meeting with the IAB at the Penn State campus. The CAB will contribute to Inmates Care via: informing selection of the new inmate-focused modules and identifying key areas of content; confirming and/or revising the planned focus of our newly conceived staff training module; developing a FG discussion guide; recommending design features; and establishing essential content based on FG findings (Aim 1); as well as determining needed revisions to content and design that are learned about through our small- and large-scale usability testing (Aims 2 & 3).

Engage with an Implementation Advisory Board (IAB). An IAB comprised of one member from our Phase I study, 2 members who were on our ECAD-P study board, 4 members who were contact people/site liaisons for our ECAD-P testing sites, and 2 members with no prior experience with our research were recruited. These experts possess experience from correctional settings and systems across the US, represent a wide array of disciplinary perspectives, and hold varied levels of authority within their prison systems. The IAB will guide us in the best approaches for operationalizing the rollout of small-scale and large-scale usability testing, promote selection and recruitment of testing sites, test the usability of our prototypes, and evaluate future commercialization. The IAB also will aid us in developing questions to guide conversations with one or more state level officials at each of the DOC systems (e.g., state level official such as Director of Health Services, Director of Research and Statistics or Risk Management, Chief of Medicine; Director of Training), and/or executive leadership team member(s) at SCIs targeted for large-scale testing. We will engage our IAB in two formal ways—a) through convening independent video meetings with them twice per year; along with an annual joint face-to-face meeting with the CAB at the Penn State campus.

Operationalizing CAB and IAB Insights. Armed with the insights gained from our CAB and IAB, the research team will employ a process that worked exceptionally well in our prior PSU and KB collaborative research. The PSU Researchers will develop content for the 4 new modules and the KB team will develop prototypes of 4 modules for usability testing. In short, we will refine and extend content that was developed and evaluated in our preliminary work to develop a 7 module *Inmates Care* product. Our comprehensive approach reflects our commitment to rapid, iterative cycles of feedback-refinement to develop and test our scalable unit.

Production Procedures and Module Development. Program development will be performed by KB following standard production steps. The investigative team in consultation with the advisory boards will develop goals, instructional and behavioral objectives, and content based on expert consensus and Phase I prototype platforms. Interface design ideas will be created in written form, combined with scripts, flowcharts and storyboards, and reviewed by investigators before creating the actual images and authoring web elements. KB programmers will produce the program and beta test it in-house for stability and code errors, test it for usability, and revise it following KB's iterative design process. Where required, the functionality will conform to Section 508 standards for accessible information technology, allowing greater access for those with disabilities. CAB and IAB members also will be engaged in previewing/testing new module protypes for look and feel, content, and functionality.

The next phase of development will be usability testing (i.e., Aim 2) to validate each design approach and to

identify and correct usability problems. The process includes overall planning for each round of testing; reviewing the program and writing test scenarios for each round. After each testing session is complete, an informal report will be generated including the development of wireframes to illustrate recommendations. Iterative usability testing is highly effective to test app usability. Identifying problems in a round of testing, generating design fixes, and validating those fixes in the next round of testing provides an opportunity to determine whether solutions are sound and to generate additional ideas for improvement.

The program will be accessible from desktop computers, and iOS and Android tablets. Using programming approaches from Phase I, *Inmates Care* will be built on a full stack web application using HTML/JavaScript as its main interface. JavaScript libraries, such as jQuery and CreateJS, will be used to build the front end and interactive components. Animations will be performed using GreenSock Animation Platform. Videos will be edited using Adobe Premiere and Adobe After Effects, compressed with Adobe Media Encoder, and delivered via progressing download. Look and feel will be designed with Adobe Illustrator and be developed using CSS 3.0 with HTML elements plus SVG, PNG, and JPG images and graphics. C#, ASP.NET, and Microsoft SQL will be used on the server side to handle registration, user profile, log in, user progress, and storage of data in the database. The application will be hosted on a remote server provided by Klein Buendel with the following infrastructure profile: All Internet information must travel through KB's Sonicwall TZ600 firewall. Traffic then moves to KB's web server. This server is a Dell Power Edge T-430 with 128 GB of RAM, 4.5 TB available disk space on a RAID 5 redundant drive system using Windows HyperV Operating System. The virtual web server uses Windows 2012 IIS Web server software. Servers are kept in a locked room on site.

Six potential topics under consideration for module development for inmate training are: 1) *Activities of Daily Living and Instrumental Activities of Daily Living;* 2) *Being/Becoming a Successful Inmate Caregiver;* 3) *Body Mechanics;* 4) *Communicating with Care Recipients and Their Families;* 5) *Comfort Care & Non-Pharmacological Pain Management;* and 6) *Common Chronic Conditions* (e.g., Dementia, Diabetes, Heart & Lung Disease, Liver Disease). None of these have been developed and each one would make important contributions to enhancing the care provided to inmates with dementia—an exceptionally vulnerable group of older people in prison[88] and in need of Peer Support.[89]

Cognitive Interview/Small-scale Usability Testing (AIM 2). Small-scale usability will be directed by MPI Myers and carried out by at least one Key Personnel (i.e., Myers, Loeb, and/or Kitt-Lewis) along with either a second Key Personnel, a project coordinator, or another trained assistant (e.g., graduate-level nursing student research assistant). There will be a minimum of 2 research team members present at each data collection session in order to meet longstanding safety practices of MPI Loeb, as well as the typical state prison protocols/practices. We will follow protocols that we used in our past research with peer caregivers and staff. Team members will meet face-to-face at the participating women's and men's prisons so that one team member independently enrolls participants, while a second who is trained and skilled in usability testing independently conducts the face-to-face testing. SUS[77] will be the primary outcome measure of usability, along with 6 qualitative questions to glean rich data (this has proven helpful in prior research). Both inmates and staff will undergo small-scale usability testing. Regardless of participant group the goals will be to evaluate the user interface, ease of use, and perceived barriers.

Cognitive interviewing and small-scale usability testing of the refined LMS will be conducted in two rounds to permit iterative refinement. In Round 1, Inmate Peer Caregivers from one men's (n=5) and one women's state prison (n=5) as well as prison staff with experience in training and/or overseeing inmate peer caregivers (n=5) will be recruited for the study (n=10 inmates; n=5 staff). Round 1 testing will focus on the 3 newly developed inmate focused modules and the 1 staff focused module. Rapid refinement of the new modules will proceed based on the team's observations, cognitive interview, and usability findings. Round 2 testing will be an alpha test of the scalable unit of *Inmates Care* (i.e., 3 refined prototypes; 4 new modules; integrated outcomes measures). Rapid refinement will follow, with special attention to outcome measures. Round 2 testing will involve 5 male and 5 female inmate peer caregivers and 5 multidisciplinary staff (n=10 inmates; n=5 staff). Sites will be determined in collaboration with the IAB. Participant identification, inclusion criteria, and recruitment will mirror the processes for the FG described in Aim 1. Since the use of monetary incentives are prohibited, all 30 participants enrolled in either Round 1 or 2 for Aim 2 will receive a Certificate of Completion.

Testing the Full-scale Unit (AIM 3). For Aim 3 our focus is scalability, that is, a systematic investigation of the scalable unit (i.e., outcomes); adoption mechanisms (i.e., contextual influences); and support systems (i.e., infrastructure characteristics). The research approach adopted for Phase II is an exploratory descriptive study. This comprehensive product evaluation is essential to planning commercialization of the *Inmates Care* e-learning system.

Following small-scale usability testing, iterative refinement of the product will be completed. The refined full-scale learning system (6 learning modules for inmates; 1 learning module for staff) will then be tested in 12 state prison settings across the US. The selection of test sites will be based on consultation with our IAB and CAB. Although women constituted only 7% of US prison inmates at the end of 2017, trends in incarceration for women are variable with 25 states showing increases (e.g., Tennessee and Indiana had the steepest increases) and 25 states showing decreases (e.g., Texas and Illinois demonstrated the steepest decreases).[3] Because of this variability and the fact that women's prisons often have fewer training and programming opportunities relative to men's prisons,[27] we will oversample women's prisons, with 25% of the SCIs being women's facilities (i.e., 3 of our 12 state prisons).

We plan to use a pragmatic approach. The investigative team will ascertain via a telephone meeting with a decision-making administrative leader(s) which of two implementation approaches to launching the testing is feasible at their site. The first option is for the team to bring computer tablets that are pre-programmed with the training and stay on site to describe the study and obtain signed informed consent from each participant and embark on the testing over the course of several days—all while being true to large-scale testing by avoiding interference with participants' independent completion of the training. The second option is that the investigative team visits the site to work with staff for planning staff release of training on each prison's in house computers (and or inmates' tablets) providing links to the training that may be shared through each prison's intranet to both the inmates for their testing (e.g., training modules inclusive of electronic informed consent with explanation of study, consent document with radio button for agreeing or denying consent, and pre-and post-tests) and a similar process with staff.

Pragmatic approaches are essential for success in recruitment of inmates to a study where technology is involved. Although e-learning via computer (e.g., electronic law library) and tablet computer access by inmates are phenomena that have emerged and are steadily growing—there is indeed variability both in terms of resources (e.g., available equipment) and policies across state systems (and perhaps individual prisons), as well as administrative leadership philosophy (e.g., more treatment focused versus more security focused), which influences prison culture. Therefore, our approach to Aim 3 is to meet prisons where they are—allowing for tailored options for rollout. What will remain consistent is that each site will be provided with digital access to the *Inmates Care* learning system for implementation as part of each target audience's training.

Targeted participants to test the 6 inmate-focused modules will be current inmate peer caregivers and inmates who are naïve to the caregiving role in prison. Staff participants test the staff-focused module include, but are not limited to security, chaplaincy, medical services, psychology/counselling, and administrative leaders. The number of user-participants is dependent on the institution's size, but our target is to recruit 12 sites (3 of which will be women's prisons) and an average of 20 inmates per site (n=240 inmates) to test the 6 modules that are developed for inmates and an average of 4 prison staff per site (n=48) to test the 1 module for staff. Certificates of completion will be provided. The inclusion criterion for user-participants is: they must be either an inmate in or employed by a state prison. This criterion ensures that no employee participants will be under the age of 18 and all will be English-speaking. For inmates, we will ensure that no juveniles living in adult facilities are recruited to this study and that all participants read, write, and understand English via our on-site presence during rollout of the testing. In addition, in our prior experience, the administrative officials who we typically work with to plan for onsite data collection in prison are most often in a Superintendent's Assistant role and as such have ready access to information on inmate literacy, so can prospectively invite only inmates who are English language readers and speakers.

MPI Myers will direct the large-scale usability testing. At least one key team member (i.e., MPI Loeb, Myers, or Co-I Kitt-Lewis) will be on-site to facilitate the launch of the full-scale testing and will be accompanied either by another key team member or trained project staff. Unlike in the small-scale usability in Aim 2, in large-scale usability testing the research team will not guide participants through the training; however, two or more team members will be on site at launch to facilitate recruitment and problem-solve any technical concerns that may arise. Our primary outcome measure will be the pre-test/post-test scores for knowledge acquisition. The SUS[77]

also will be used to provide a quantitative score of program acceptability and feasibility. Follow-up qualitative interviews will be conducted with one or more senior officials who were directly involved with the investigative team during rollout of large-scale testing. At this time, barriers and facilitators in their facility would be gleaned as well as insights on what needs to be modified to aid us in moving forward. In addition, several global ratings of the program and experience will be done at the close of the interview.

Evaluation of scalable unit. In the testing scale-up phase, we will evaluate the effectiveness of the LMS on knowledge acquisition (i.e., the primary outcome). Pre-training outcome measures will launch first, followed by the learning modules with embedded short quizzes/summaries, and then outcome measures.

Knowledge Acquisition. Knowledge acquisition for *inmate participants* includes knowledge of both care needs and supportive care strategies that they may engage in to assist prison staff in the delivery of care to their aged and dying inmate peers. Knowledge acquisition for prison *staff participants* includes knowledge of the focus of the *Inmates Care* training, strategies for facilitating use of *Inmates Care,* and how best to roll out and integrate *Inmates Care* in order to supplement and facilitate their face-to-face and hands on training that they will continue to deliver to inmate caregivers. Regardless of participant group, outcomes will be measured by pre-and post-tests integrated into the learning system. This primary outcome measure will be developed in collaboration with our advisory boards. Pilot testing will be completed by the Board Members and Round 2 usability testing sites. We plan to design 1-2 questions per objective to comprehensively evaluate the effect of comprehensive training on knowledge. We hypothesize that knowledge regarding the content that is included in the six peer caregiver modules and single prison staff module will increase significantly for inmates and respectively from T1 (pre-test) to T2 (post-test).

There are no existing measures to evaluate improvements in knowledge among inmates for geriatric and EOL care of peers, nor to evaluate improvements of knowledge among prison staff for the focus of the *Inmates Care*, the e-learning strategies employed for *Inmates Care*, nor the best approaches for rolling out and integrating *Inmates Care* with their face-to-face and hands on training. Therefore, the primary outcome measure will be developed for this project. In our ECAD-P project, we successfully developed the primary outcome measure and will employ a similar strategy for this project. Psychometric properties will be evaluated (e.g., content-validity, criterion-related validity, construct validity, and internal consistency) using a 3-step scale development process: (1) domain identification and item generation; (2) content expert validation, and (3) pilot test.[90] The team will generate items using a sorting process that encompasses themes/construct elements noted in the aging and dying literature (Step 1). Items will then be subjected to expert validation by the advisory boards (Step 2)[90] who will identify and delete theoretically incoherent items thus ensuring that the items in the instrument demonstrate content validity. Specifically, the advisory boards will sort the items by "how much" each item measures its targeted construct. The comprehensiveness of the entire instrument will be evaluated by identifying items which the boards perceive to be incongruent with its nominated domain. The advisory boards will be asked to identify the clarity of each item's construction and wording to ensure that there are no ambiguous and poorly written items. The Lawshe's Content Validity Ratio (CVR)[91] will assess the content expert judgment; a minimum CVR value of 0.49 will be required for retention in the scale.[91] Step 3, usability testers (see AIM 2) will be asked to complete the measure to guide initial psychometric evidence and allow for revision of the instrument prior to full-scale usability launch. Reporting of internal consistency reliability is a necessary part of scale development,[92] and Cronbach's α of 0.70 is the suggested minimum.[93] Factor intercorrelations will be calculated and should be < 1.00 to be conceptually distinct.

Functionality will be evaluated via backend data analytics and the objective SUS measure. This approach will permit comparative analysis of user ratings across all phases of development. We hypothesize that user ratings of the aesthetic appeal/functionality of the full-scale *Inmates Care* unit will meet or exceed ratings obtained during small-scale usability testing.

Evaluation of adoption mechanisms. Environmental or contextual influences may constrain or facilitate the uptake of the adoption of the *Inmates Care* learning system. To obtain such data a qualitative telephone interview will be conducted with a key official in each site that participated in the large-scale usability testing. These interviews will be conducted by PI Loeb, as she has in successfully accessed such leaders for follow-up and conducted interviews in such a manner to elicit rich data.

Data Collection, Management, and Security. Following similar procedures of Phase I, KB will cede to Penn State's IRB for Human Subjects' Approval.

    Data Collection and Management: Penn State and KB data management staff have considerable experience in maintaining large databases and ensuring high-quality data. KB will modify its existing data software to be customizable to the study's needs. Study questionnaires will be programmed using software to ensure a structured approach and reduce errors and missing values to improve data quality and transferred to KB on a secure web server. All data will be uploaded in real-time using KB's secured network, de-identified and stored in KB's secured database. Established KB protocols for quality assurance will ensure high quality data. Data will be entered into a secure database using established protocols. SAS will be used for analysis. The data team will assure the data quality and compile master data files. Real-time editing and coding will be used (valid ranges; internal consistency checks, etc.). Missing data should be limited since data is recorded electronically. Staff will review the data, identify missing responses, and check that entries were not intentionally skipped. While unlikely, data may not be missing at random (NMAR). We will assign all lost responses to extreme category and perform multiple imputation procedures that can handle various amounts of missing data and use covariates and propensity scores.

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Statistical Analysis Plan

Sample Size, Statistical Power Calculations, and Analysis:

Usability testing. The Aim 2 goal is to conduct small-scale usability testing to evaluate the user interface, ease of use, and perceived barriers to optimize the program prior to large-scale evaluation (n=30). Data on applied formative research suggests that 5 users is sufficient to identify likes/dislikes and potential errors; thus, the power to detect Level 1 severity usability errors should be more than sufficient.[81] Research suggests that 10 users are needed to capture most lower severity usability problems.[94-96] Therefore we plan to recruit 10 staff to be testers. To identify any problems that impact ≥15% of users at a 95% chance of detection (log(1-.95)/log(1-.15)), 18 users are needed.[97,98] Therefore, we plan to recruit n=20 inmates. Similar to Phase I, usability outcomes will also include testers' ratings of satisfaction with the program with regards to design, appeal, and functionality. Each concept will be rated on a 5-point Likert scale. Means of the Likert-response items will be calculated and an average of 67% or higher will be considered acceptable. The SUS will serve as the primary outcome measure for usability. A SUS score of 68 is considered above average and will serve as the criterion for measuring usability.[77-79] Additional analyses will mostly be descriptive; simple t-tests will be used to make comparisons in the first versus second round of usability testing and comparisons between the men's and women's prison settings. We do not expect differences between correctional settings but will assess the level of consistency between these sites. We will examine usability scores by examining mean scores, changes in mean scores, and the variation within settings. Further, we will look for outliers to assess if there may be specific characteristics of users who have or develop problems as the processes evolve.

Sample Size and Power. The Aim 3 goal is to conduct large-scale testing of the program. The primary outcome is detecting a positive change score on the composite educational comprehension indicative of training. We propose to enroll two different populations of users (correctional staff and inmates). Twelve prisons (in 6 states) will be recruited. Three of the 12 recruited sites will be women's prisons. For the inmate training, 20 participants will be recruited in each of the 12 prisons (N=240; 60 women; 180 men). For the staff training, 4 prison staff per site will be recruited (N=48; 12 from a women's prison; 36 from a men's prison). Based on our previous research and to be conservative, we will assume that 80% of those offered the program will complete the training and have pre-test and post-test results. While we believe it will be higher, from a sample size perspective we want to be conservative. Thus, we will have 192 completed results for inmates and 38 for staff. We will assume that learning is demonstrated when the proportion of users who improve their scores over baseline is greater than 50%. Using 192 inmate participants and testing this proportion, the power is 87.5% if the number exhibiting training is 60% or higher using a one-sided test and assuming no intraclass correlation (ICC) within prison, which for individual behaviors may be reasonable. If the ICC is 0.01, the required sample size for the same power would be about 20% higher. We will have an estimate of the ICC from our Phase II results, and we can adjust the numbers, although increasing the sample size within a prison does not have much impact on the ICC adjusted sample size. Using 38 staff participants, the power is 34% for obtaining a 60% or higher response and 80% for a 70% success rate. The post-test also can be used to compare differences between men's and women's prisons and as well as regional/state differences. Whereas the power is not large, given the large number of prisons, we will look for consistency of the differences. We will assess how many prisons meet the majority reaching >50% and count the proportion of prisons that meet the goal. The figure below shows the power for differences assuming the men's prisons (P2) has success rates ranging from 50% to 70% and the higher rates for the women's prisons are shown as a ratio of P1/P2 = R1 on the x-axis – When there is no training effect in the men's prisons (50% red line), a significant difference for the women's prisons is detected with 80% power when R1 > 1.7 or 85% (note here we use a 2 sided test as we are interested in either direction); when the men's prisons achieve 60% success (blue line), the women's are detectable with 80% when they achieve approximately 90% success.

Analysis. Analyses will consist of descriptive statistics, means, proportions and 95% confidence intervals for the overall training effect measured as a proportion with learning demonstrated pre to post; as well as the average increase in number of items correct and the percentage of the baseline errors reduced by the training program. To examine the overall results, testing will follow the sample size calculations above and for sensitivity analyses

regression analyses of the post-test adjusted for the pre-test with covariates of the participants included in the model (biologic sex [both staff and inmates], age [both staff and inmates], years of service [staff], years of incarceration [inmates], years of experience in a peer caregiver role [inmates]; years of education [both staff and inmates], men's or women's prison, and state/region) will be conducted. Comparisons will be made using contrasts (i.e., men's versus women's prison, etc.).

Design Strengths, Potential Limitations, and Overall Impact. This Phase II project focuses on developing a scalable product designed for the *correct* users accessing the *correct* learning strategies in the *correct* setting—inmates who currently serve as peer-caregivers, inmates who are naïve to the caregiving role in prison, as well as prison staff who oversee inmate peer caregiver training. We have shown proof of concept and demonstrated the feasibility of this approach in our Phase I project. This Phase II application proposes continued research and development of the *Inmates Care* e-learning system with an emphasis on developing a scalable unit for commercialization and testing scale-up in a larger number of more diverse contexts.