¡Caminamos!: A Location-Based Smartphone App for Latina Women to Connect with Nearby Walking Partners

Phase II

NCT03854916

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2. SPECIFIC AIMS

Latino women are a growing and influential segment of the population,[1] yet health disparities for Latinas remain high.[2-4] Latinas are more likely than their non-Hispanic White counterparts to be overweight, diagnosed with diabetes, and physically inactive.[1,5,6] These disparities are amplified when poverty is present, and Latinas are nearly 3 times more likely to live below the poverty threshold than non-Hispanic White females.[1] Interventions that target improving health and ameliorating chronic diseases among Latinas are of high public health significance. Regular physical activity (PA)[7-9] promotes physical and emotional well-being (e.g., lower risk of heart disease and diabetes, weight management, improved quality of life, etc.),[7,8,10-17] yet PA interventions for Latinas remain limited.[18] The available research suggests that community-focused walking interventions produce improvements in PA and are well-received by Latinas[19-25] especially when culturally important factors (e.g., community-based, social engagement, safety concerns) are addressed.[18,26-28]

Physical and social environments play a role in an individual's PA behaviors.[29-31] Common barriers reported by Latinas involve built environment and access concerns (e.g., neighborhood safety, access to facilities that enable PA).[17,32-46] Social support has been shown to be a positive influence on behavior and an important construct to use when developing PA interventions,[29,30,47] particularly with a Latino population.[20-24] Therefore, PA interventions for Latinas need to target both social and physical environments.

New technology has the ability to reach this growing population and provide Latinas with innovative ways to connect socially and increase PA. Research suggests that Latinos respond favorably to technology-based health interventions.[48-52] With over 80% of Latinos accessing the Internet via their smartphone,[53] interventions that can address Latinos' preferences regarding their physical and social environments while utilizing a preferred technology source (i.e., smartphone) could prove highly successful.

One smartphone feature that offers great potential for positive health outcomes is location-based services (LBS). LBS are a technology quickly growing in popularity for smartphone apps that uses geographic positioning to help users connect in real time to their surrounding environment and to other users. In doing so, it provides users with real-time, user-specific information. Ninety percent (90%) of adult smartphone users utilize LBS to gather information,[54] yet the application of LBS to increase PA remains untested.

In Phase I, the feasibility of the _¡Caminemos Juntas! (translated - 'Let's walk together!')_ app using LBS was established in six ways: (1) feedback from an Expert Advisory Board (EAB) on app development; (2) feedback from Latina community leaders on the app through a Community Advisory Board (CAB); (3) an online survey of a national sample of Latinas on their smartphone usage including their app use for health promotion, and interest in social networking and LBS technology features for PA; (4) iterative focus groups with Latinas age 18-45 years to guide development of app content, design, and aesthetics to develop a functioning prototype; (5) field usability testing of the prototype app with Latinas tested the app's accuracy to establish users' location, ability to connect users through the _¡Caminemos Juntas!_ system, and users' satisfaction with and use of the app; and (6) a full-scale specifications document was prepared to guide Phase II development.

In Phase II of this SBIR research, the following **Specific Aims** will be achieved:

1. To develop a full-scale, fully programmed _¡Caminemos Juntas!_ app that aims to improve physical activity among Latinas by providing opportunities to connect women within geographically proximal neighborhoods to promote walking, using user location and preferences through location-based services (LBS).
2. To determine whether the _¡Caminemos Juntas!_ app can be (a) translated and adapted to a new community environment and (b) test the performance, usage, and usability of the full-scale, fully-programmed _¡Caminemos Juntas!_ app.
3. To evaluate whether _¡Caminemos Juntas!_ increases physical activity, social support for exercise, and quality of life (QOL) in Latinas.

¡Caminemos Juntas! will be tested in a 12-week randomized comparative-effectiveness controlled trial with 200 Latinas between the ages of 18-55 years in the Denver, CO and San Jose, CA areas. Latinas will be randomized to either the _¡Caminemos Juntas!_ app or to a comparator app (_World Walking_). Phase II will be led by researchers and multimedia developers at Klein Buendel, Inc. (KB) in collaboration with Stanford University. Dr. Valerie Myers (PI) at KB and Dr. Abby King (Co-I) at Stanford University successfully collaborated in Phase I. Dr. Myers is an expert in technology-based interventions for diet and PA promotion and Dr. King is an expert in PA promotion with Latinos. The project will continue to be guided by an Expert Advisory Board (Drs. Elva Arredondo, Dr. Katherine Gregory, and Dr. Dori Pekmezi), and a Community Advisory Board consisting of Latina community leaders.

KB has experience in developing SBIR/STTR projects. There are no currently available products that use geo-location technology dedicated to walking with a social emphasis, for any population. Thus, commercialization potential for _¡Caminemos Juntas!_ is high.

3. RESEARCH STRATEGY
3A. Significance
3A.1. *This project is significant due to its focus on ameliorating health disparities among Latinas through physical activity.* Health disparities exist with high prevalence among minorities and the socioeconomically disadvantaged.[3] Latino women are a growing, influential constituency in the U.S. Estimates suggest the Latina population will increase from 16.4% to 25.7% by 2050.[1] Some of the most important health disparities and inequalities targeted for public health intervention involve Latinas.[2,3] Over 75% of Latinas are overweight or obese compared to 60% of White women[5] and Latinas are 17 times more likely to die from diabetes than their White counterparts.[1] Only 9.5%[6] of Latinas meet federal physical activity (PA) guidelines[55] and only 6.3% of Latinas below federal poverty levels[6,56] meet PA recommendations.[5] Health interventions focused on addressing chronic disease conditions in Latinas are paramount.[4]

Research has shown many health benefits associated with regular PA.[7-9,57] Benefits include lower risk of heart disease and diabetes, weight maintenance, strengthening bones, improving balance and the reduction of other chronic diseases.[7,8,12] Walking produces the same health benefits associated with more vigorous PA[58-61] and is associated with increased quality of life and mood improvement in ethnic-minority women.[10,11,13-17] Yet, PA interventions among Latinas remain limited,[18] despite the fact that theoretically-driven PA interventions can be successful with Latinos.[18,23,26,62-66] Tailoring to the needs of the Latino culture is critical,[18,20,24,67] especially to their sense of community.[18,67] Community-based PA interventions are the most prevalent type of intervention, with 78.6% demonstrating PA improvement.[18,23-25,27,62,65,66,68-70] Considerations in tailoring interventions to Latino populations include finding innovative, community-based strategies to recruit and retain individuals[65] such as incorporating community collaboration into the intervention to improve program reach, showing community buy-in, and using existing community resources.[26-28] In addition to utilizing community factors when tailoring a PA intervention for Latinos, incorporating social support is crucial, especially for Latinas.[71] The link between social environment and health is widely recognized .[29,72-76] Social support (i.e., the extent to which a person is connected to others) has been strongly correlated with individuals' PA behaviors,[29-31,47] particularly for Latinas.[20-26,28,62,63,66-69,77-79] Increasing social support through the use of walking group interventions has shown success.[24,25,62,63,66,77-80]

Data with Latinos suggest that PA improvements occur when an intervention is easily available. Yet, most studies have not focused on addressing the factors which may increase access to PA programs. Barriers reported by Latinos vary, but common themes relate to time constraints (e.g., multiple role responsibilities) and built environment and access concerns (e.g., neighborhood safety, access to PA facilities).[17,32-46,81-89] Key motivators for PA among Latinos include the physical and psychological benefits and a desire to be healthy for the family.[67] Therefore, a PA intervention for Latinas that addresses the key factors for initiating PA (e.g., one that addresses time management and safety concerns), as well as factors which are crucial during PA engagement (e.g., social support driven; community-based), should prove highly beneficial for promoting PA.

3A.2. *Use of well-established theories elevates significance.* A socio-ecological framework will be used which takes into account multiple levels of influence (e.g., built environment at community and societal levels; personal attitudes and experiences) on an individual's health behaviors and decision-making.[90,91] This framework helps to understand factors affecting behavior and provides guidance for developing interventions through social environments. The socio-ecological framework emphasizes multiple levels of influence (e.g., individual, interpersonal, community, etc.) and is consistent with multiple behavior change theories which can be used to drive the behavioral content development.[92] Two theoretical approaches will drive *iCaminemos Juntas!* development: (1) User-centered Design Theory (UCD)[90,93] and (2) Social Cognitive Theory (SCT).[94] Both of these theories will be guided by the socio-ecological framework. UCD will be the technology development theory used to build the *iCaminemos Juntas!* app. UCD solicits user input through iterative cycles. Adjustments are made based on feedback,[95] resulting in greater user experiences, and more reliable and effective results.[93,96] The behavioral content of the app will be based in SCT which describes learning as an interrelationship between behavior, environment, and personal factors. SCT has been applied to health behavior,[97] and is a commonly used paradigm in exercise interventions[98-101] including ones with Latinos.[23,26,60,61,64,102,103] Research has shown that technology can be an appropriate observational model to elicit change[104-107] and that Latinos respond favorably to SCT-based technological approaches to improve health promotion.[48-52] Observational learning, social support, self-efficacy, outcome expectations, and self-regulation are key SCT constructs that will be addressed by[94,108] *iCaminemos Juntas!* by using social networking/social support engagement to increase walking behavior that connects Latinas who are previously "unconnected". Social support is a strong factor for increasing PA levels for Latinas, and *iCaminemos Juntas!* will develop this construct to impact other key SCT constructs such as increasing self-efficacy and self-regulatory behavior, and goal expectation (e.g., personalized walking goals).[109,110]

3A.3. *¡Caminemos Juntas!* is significant, because it will address key factors to initiating and engaging in physical activity using location-based decision support technology. Ninety-five percent of Americans own a cellphone, 77% of which are smartphone users.[111] Latinos are more likely than their White counterparts to possess a smartphone and to go online using a mobile device.[112,113] Over 80% of Latinos report accessing the internet via a mobile device (94% for those 18-29 years old and 89% for those 30-49 years old[53]). Smartphone features create enormous potential for health interventions, because they: (1) are compact, portable, normally "on", and readily available to the user; (2) allow "24/7" on-demand online access; and (3) are affordable and user-friendly, and offer advanced functionality.[114-121] A smartphone feature that offers great potential health promotion benefit is location-based services (LBS). LBS is an information service that uses the geographical position of the mobile device to guide the user on a number of services (e.g., identifying the location of a place, whereabouts of a friend, tracking of behaviors, mobile commerce, etc.) in relation to where the user is located. LBS is commonly used by smartphone users with 90% employing LBS functionality to get directions or other information.[54]

The application of LBS to promote PA is unstudied. There are no studies of LBS-focused smartphone interventions to promote PA specifically to Latinos. There are ongoing NIH studies using smartphones for weight reduction and/or PA (e.g., HL129012; NR014911; DP004995[122]; HL075451[123]). However, these studies are not in combination (1) examining PA as the main outcome; (2) using LBS; or (3) targeting Latinas.

3B. Innovation

¡Caminemos Juntas! is a highly significant and innovative project. (1) *¡Caminemos Juntas!* will be the first smartphone app that uses location-based social networking to promote PA promotion. The increased pervasiveness of cellphone ownership among U.S. adults and the growing use of smartphone technology are a successful and cost-efficient method for reaching target populations.[124] Nearly all smartphone users (90%) request "just in time" (i.e., LBS) information via their smartphone with 41% using their phones' LBS to meet up with others.[54,125] Ninety percent of smartphone owners use their phones to get real-time, location-based information.[54] *¡Caminemos Juntas!* uses LBS technology, thus giving it the potential to reach a large population and connect people in real-time conditions. LBS could be a useful delivery technique to provide users with individualized, time-specific health information. *¡Caminemos Juntas!* combines LBS with the goal of health behavior improvement among a population (i.e., Latinas) known to use mobile phones more than any other U.S. racial or ethnic group; and (2) *¡Caminemos Juntas!* will improve upon previous PA interventions with Latinas by addressing the key motivators and barriers which affect both PA initiation and engagement. The app will reduce barriers such as time management and safety concerns as well as increase social support and community-engagement (crucial factors affecting Latina PA promotion) by providing the ability to request group walking in real-time and provide safe walking locations near the app users via LBS technology.

3B.1. Market Potential. Latinos are a strong influence on the U.S. economy with a buying power of $1.2 trillion.[126-128] The Latina population is growing, and 86% drive their household purchasing decisions. [126] Latinas spend more on health and wellness and beauty products, [129] and their smartphone use continues to soar faster than the general marketplace.[130] Yet, a large gap between Latino engagement and brand support through apps exists.[131] Latinos desire apps that are culturally tailored (e.g., bilingual, social in nature), yet this demand is unmet.[131,132] *¡Caminemos Juntas!* will have strong commercial viability. It will (1) be delivered on a platform that Latinas would likely use and (2) it addresses a deficiency in health-related apps using features they value.
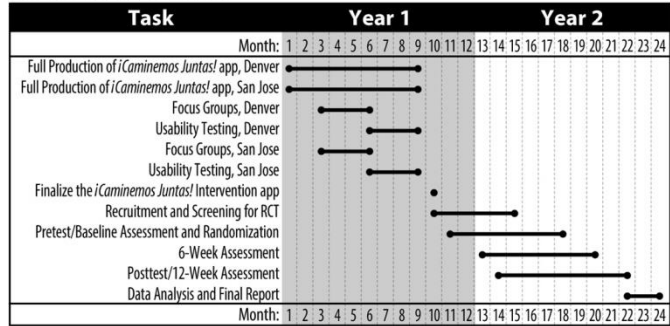
During Phase I, KB was selected for a technology NICHE Analysis as an awardee of the NIH's SBIR/STTR Niche Assessment Program. This program is designed to help small businesses with their commercialization efforts by providing market insight and data that can be used to help small businesses strategically position their technology in the marketplace during the early phases of development. The market analysis is an objective evaluation conducted by Foresight Science & Technology, Inc. on behalf of the NIH. This independent review included an Android Market, Apple AppStore, and patent search and revealed that there is no product that is a true geo-location technology dedicated to walking with a social emphasis, for any population. Thus, *¡Caminemos Juntas!* is a first-in-class geo-local social networking service for physical activity. The fact that it is focused on the Latina population makes it even more unique. The report confirmed the viability and need for an app that guides Latinas in walking promotion and for its commercialization potential.

Multiple sales and marketing models could be employed in Phase III such as: (1) selling *¡Caminemos Juntas!* through app stores; offering a free app supported by advertising, user-purchased subscriptions or in-app purchases; (2) selling ad-space and online games to businesses or having businesses purchase "preferred status" on the app; (3) exploring potential partnerships with companies that are increasing their brand outreach to Latinas (e.g., cosmetics, clothing); (4) generating revenue by selling marketing data to researchers, businesses, or health organizations; (5) partnering with local and state-level entities interested in public health improvement campaigns; and (6) partnering with Latino community organizations and non-profits that do not have the expertise to create their own app.

3C. Approach

3C.1. Phase II Project Overview. The Phase II project will be conducted over 24 months. The *iCaminemos Juntas!* app will be fully developed in Months 1-9 and evaluated for disseminability (i.e., can LBS database procedures and LBS functionality from Phase I be translated to a new geographical location) and behavior change (i.e., increased PA) in Months 10-24 among a sample of Latinas aged 18-55 years (upper age limit was increased per Phase I feedback from EAB, CAB, and study participants). *iCaminemos Juntas!* will be a stand-alone app that provides person-specific, location-based feedback to help users connect with Latinas in neighborhood-specific geographic areas to promote increased walking behavior. Using the user-centered design (UCD) approach from Phase I, focus groups and usability testing conducted in Colorado and California will guide final app development. A comparative-effectiveness trial[136] will enroll and randomize Latino women in a randomized pretest-posttest controlled design. Participants will be recruited from Denver, CO and San Jose, CA and randomized individually to either the *iCaminemos Juntas!* app (experimental condition) or the *World Walking* app (comparison condition). All participants will use the apps for 12 weeks. The primary outcome will be improvements in physical activity post-treatment. Participants (n=200; n=100 per site) will complete baseline, 6-week, and 12-week assessments.

FIGURE 3: Project Timeline

3C.2. Investigative Team. <u>Klein Buendel, Inc. (KB).</u> This project will be led by Valerie Myers, Ph.D. Dr. Myers is a Senior Scientist and licensed psychologist. She studies technological approaches (websites, apps, telehealth, and interactive media) to deliver weight and diabetes management, and promote PA to health disparate populations in real-world settings. She has served as a PI or Co-I on several NIH- and state-funded grants, and is currently PI on three NIH studies. KB has conducted successful health behavior research using technology-based approaches,[122,137-139] and has extensive experience with formative research production, prototype testing, and full development for web, smartphone, tablet, and smart television projects, employing an iterative, user-centered design process in which researchers and media developers produce interventions based on extensive user feedback. Mr. James Shane, KB's Programming Manager, will lead the programming of the app. Ms. Liu, KB's Biostatistical Manager, will lead the work by KB's data team with supervision from Dr. Cutter, the project biostatistician.

<u>Stanford University.</u> Dr. Abby King will serve as Co-I and site PI for the California location. She is Professor of Health Research and Policy (Epidemiology) and of Medicine (Stanford Prevention Research Center). Dr. King's studies using state-of-the-art communication technologies and community-based participatory research perspectives to address health disparities among disadvantaged populations. She has extensive experience in PA promotion among Latinos and PA engagement through technology. Drs. Myers and King collaborated on the Phase I project and have previously worked together on successful PA promotion multi-site trials.[140,141]

3C.3. Description of *iCaminemos Juntas! app*.

The goal of *iCaminemos Juntas!* is to connect Latinas with one another near their neighborhood to encourage increased PA partnerships (e.g., walking). Connections between registered app users will be accomplished through push/pull technology. Push/pull technology describes a style of internet and LBS-based communication where an information transmission request (e.g., "I am interested in going for a walk…is anyone else?") can be initiated by the app user (i.e., "pull") or by the app (i.e., "push"; e.g., a notification sent to an app user indicating that someone would like to walk). Women who are interested in going for a walk can send a request to all other registered app users through the *iCaminemos Juntas!* app. Women who receive a push notification can decline or accept the request. Using LBS, *iCaminemos Juntas!* identifies each assenting user's location and, using LBS algorithms, triangulates each user to one another. Next, using publicly-available geographic information systems (GIS) and LBS data sources,[142-144] the app determines the location of nearby PA resources (e.g., parks, recreation centers, etc.) that are the best proximal match for the identified users. Users are sent a push notification and map of the PA location. The app requests the user to confirm or decline meeting at this location and sends a meeting location and time confirmation. Using LBS, the app is able to determine whether the user arrived at the designated location. At the user's preferred contact time, the app sends a push notification asking the user to answer four questions: (1) Did you meet a *iCaminemos Juntas!* partner?; (2) Did you walk today?; (3) How long did you walk?; and (4) Did you find the location safe?

The app gathers user profile information, PA preferences, and walking goals. Time- and location-specific notifications are the app's foundation, connecting users and influencing theoretical constructs (e.g., conscious raising, social support) to increase PA. Benefits of using a mobile app include an instantly available source of

social support once a user creates an account, convenience and ease of use, and geographically-relevant information tailored to the user. To ensure users' privacy and safety, the app serves as the "gatekeeper:" Users cannot be located by another user without permission and cannot set up meetings to walk with an unauthorized user. All participants will be fully informed of these privacy policies.

3C.3.1. Description of *¡Caminemos Juntas!* App Development (Specific Aim 1). Table 1 displays the new features planned for Phase II that will be further developed and tested with formative research prior to launching the RCT: (1) Fitbit device integration; (2) Mapping of walks; and (3) Social media (Facebook and Instagram) integration were identified as top priorities. Development will be guided by the Phase I specifications document using KB's iterative design approach.

3C.3.1a. App architecture. *¡Caminemos Juntas!* will be built on a full stack Webview using HTML5/Javascript/CSS technologies and Ionic, Cordova, and Angular.js frameworks. KB will utilize Ionic 3.0 and Angular 1.6.4 frameworks to provide prebuilt UI components and Javascript tools. Angular will manage user interaction and logic to collect user data. UI-Router will control the user's navigation/views. Angular-Translate will manage both English and Spanish translations of the UI. The Moment.js library will manipulate various types of dates and times. Ionic uses Cordova framework to port *¡Caminemos Juntas!* to the Android and iOS platforms. Backend data collection will use Microsoft SQL Server with ASP .NET as the business layer. KB will use Node.js and Express.js to build the backend management of communication with Ionic-Cloud services and send out notifications to users. Data will be retrieved and stored on a remote server provided at KB following standardized infrastructure profiles and security protocols.

3C.3.1b. Database for *¡Caminemos Juntas!*. In Phase I, the feasibility of developing a database, cross-referenced between person-specific location and LBS of exercise locations to determine the accuracy of current mapping tools for PA location choices within a 2-mile radius of the user was established. In Phase I possible exercise meeting locations were limited to parks, trails, schools, recreation centers, and malls. Using the development procedures from Phase I, we will replicate the LBS database in the San Jose area. In Phase I, data on exercise venue attributes were obtained using established mapping tools and other locally-based sources (e.g., Yellow Pages, Open Data Catalog on the City and County of Denver website, etc.) and were entered via an online form into a structured Relational Database Management System (RDMS). The RDMS allows the program to access facility information via the standard Structured Query Language (SQL). The app uses parameters (i.e., user location and preferences for exercise venues) to build an SQL query and return the top facilities matching these criteria and location. The query results are formatted using eXtensible Markup Language (XML). During Phase II (**Specific Aim 2**), KB will translate these database procedures to another location outside of the Denver area, i.e., San Jose, CA, which is crucial to the future marketability of the *¡Caminemos Juntas!* app. This will demonstrate it is feasible to adapt the *¡Caminemos Juntas!* database procedures in various locations across the U.S.

3C.3.1c. Development of new components. Phase I focus groups and usability testing participants expressed a consistent and decided interest in optimizing the existing app features first and then including new app features. Fitbit integration and mapping of walks emerged as the top priorities for new development, so the investigative team will focus on refining the Phase I app to fully develop the Create-a-Walk and Join-a-Walk components through comprehensive back-end and front-end (i.e., "look and feel" for user) programming. New

FIGURE 4: Mapping of Walks
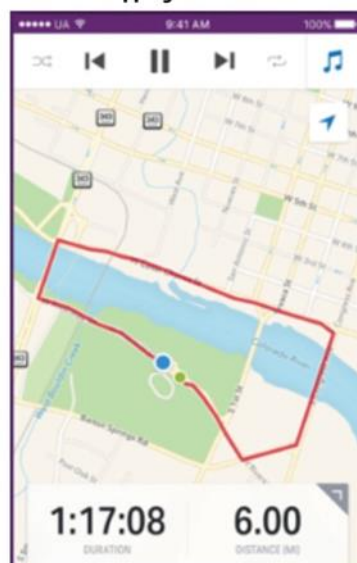
features to be prioritized are (1) Fitbit device integration (2) Mapping of walks; and (3) Social media (Facebook and Instagram) integration. (1) <u>Fitbit integration:</u> Phase I participants who owned a wearable PA tracker suggested that being able to connect their tracker to *¡Caminemos Juntas!* would be an important app feature. Approximately 1 in 10 adults own a wearable health tracker (e.g., Fitbit, Apple Watch) and 54% are women.[145] Fitbit® is one of the most common wireless PA trackers in the consumer market and can record the number of steps taken per day for self-monitoring purposes. Fitbit® can accurately measure step counts when compared to observed step counts and step counts from pedometers.[146,147] Using existing application programming interface (API) algorithms already in place between KB and Fitbit®, exercise data (steps/day) will be automatically and wirelessly sent from Fitbit® to the KB server which will then connect the Fitbit® data to the *¡Caminemos Juntas!* app for display. For the *¡Caminemos Juntas!* users who do not own a Fitbit®, step estimates will be calculated using the LBS distance tracking feature (map of distance walked). (2) <u>Mapping of walks:</u> Smartphones can track and map physical activity using LBS. The app will track the walking route, time, and distance using the phone's on-going GPS service while on the *¡Caminemos Juntas!* walk. The app will map that walk and display it in the app for the user to share with connected friends (via the app or social media outlet) or to keep private. (3) <u>Social media integration:</u> Over 80% of adults who are online use at least one of five social media

sites – Facebook, Instagram, Pinterest, LinkedIn and Twitter. Facebook is the most widely used regardless of race or ethnicity, with 79% of adult Internet users reporting they use the site.[148,149] Latinos, African Americans, and Whites use social media networks about equally, but have different preferences for specific social media sites.[148,150] Our Phase I participants reported that Facebook and Instagram were the social media sites used most frequently and ability to share input from their app to their social media profiles was an important feature. KB will used Facebook's "sharing" API to push content from the app to the *¡Caminemos Juntas!* users' Facebook and/or Instagram pages.[151] Sharing is triggered when the user clicks a social plugin (e.g., "Share" or "Send" button). There a number of sharing interfaces from Facebook/Instagram that have open-access API. The type of API used will depend of the end-user experiences chosen in formative research.

3C.3.1d. Formative research for app components. In the research team's experience, it is essential to obtain qualitative data to inform app content. In Phase I, we conducted focus groups to determine the key elements and features of the *¡Caminemos Juntas!* app and test a prototype. We will do the same in Phase II for the new app components/features. Focus group members will be asked about the new app features added in Phase II (see **Table 1**) and provide input on additional features of interest. They will be asked their perceptions, ease of use, and interest in using an app to improve their walking habits. Focus group testing will occur in two stages; the first stage in Denver and the second stage in San Jose. For both stages, recruitment will use existing research participant databases, newspapers, and online and social media ads. Active informed consent must be given, and all procedures will be approved by the KB and Stanford IRBs. In Stage 1, Latinas will be recruited from the Denver area (see **Table 3**) and KB staff will conduct the focus groups. Sixteen participants (n=16) will be recruited across two rounds (n=8 per round). The Denver-based groups will obtain qualitative feedback on the new app features prior to formative research with the California population (San Jose community). In Stage 2, Latinas will be recruited from the San Jose, CA area. See **Table 3** for inclusion criteria. Using established KB protocols to ensure fidelity, Dr. King's

TABLE 2: Social Media Sharing Option

Button Trigger	Sharing Interface Launched	Publishing Behavior
f Share Share Button	**Web:** Share dialog **Mobile:** Fast-app switch to native Share dialog	Appears in Timeline and Activity Log. May appear in News Feed.
Send Send Button	**Web:** Message Dialog **Mobile:** Fast-app switch to native Message dialog	Sent as Facebook message
Custom Button	**Can Launch:** • Share Dialog • Message Dialog • Custom sharing interface	A custom sharing interface which follows the publishing behavior of the share dialog.

TABLE 3: Inclusion Criteria

Denver FG & Field Usability Testing & RCT	San Jose FG, Field Usability Testing & RCT
Self-identify as Hispanic/Latina	Self-identify as Hispanic/Latina
Female	Female
Between 18 and 55 years old	Between 18 and 55 years old
Ability to read/speak English or Spanish	Ability to read/speak English or Spanish
Not Pregnant	Not Pregnant
Own a smartphone	Own a smartphone
Consent to participate	Consent to participate

research team will conduct the San Jose focus groups (n=16 FG participants; 8 per round x 2 rounds).

All focus group discussions will be recorded, transcribed, and stored securely on KB's server. They will be analyzed using Atlas.ti© qualitative data coding software. An iterative process of summarizing data will be used to achieve saturation, and a thematic content analysis approach will be used to analyze the data. All focus group participants will be compensated $25 for 1 hour of their time. These focus groups will occur between months 3 and 5 of the project.

3C.3.2. Production Procedures and Laboratory and Field Usability Testing. App development will be performed by KB following its standard iterative production steps. Investigators will develop goals, instructional and behavioral objectives, and content based on focus group results, empirically-validated intervention materials for PA, and existing app 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 app elements. The user interface design will be created by KB designers and reviewed by investigators. KB programmers will produce the app for Android and iOS platforms, beta test it in-house for stability and code errors, test it for usability, and revise it. Where required, the app will conform to federal Section 508 standards for accessible information technology.

The app will be subjected to usability testing to validate the design approach and identify and correct usability problems, and validating those corrections to confirm that solutions are sound and improve the app. Similar to the focus groups, this will be a two-staged approach with usability testers in Denver (Stage 1) and San Jose (Stage 2). At least 10 users are needed to capture 95% of errors[152-154]; therefore, we will capture and remedy a large number of errors that would impact successfully implementing the RCT (n=200).

Stage 1: The Denver usability testing will consist of 2 rounds with 8 participants per round (n=16). For each round, test scenarios will mimic real-world use of the app. In the first round, basic functionality will be tested, using findings to recommend immediate improvements to app design. In Round 2, enhanced functionality will be tested to identify and correct usability problems before the app is complete. After Round 2, a field usability test (i.e., beta test) of the fully-programmed app will be conducted in the Denver area with Latinas (n=20) who will use the app for 2 weeks to test the LBS, using the Phase I protocol. Participants will receive a one-on-one orientation, downloading the app onto their device and completing an app tutorial. Participants will return for an individual exit interview. They will rate their satisfaction with the app's design, appeal, and functionality,

and complete the System Usability Scale (SUS),[133] a validated tool for assessing the usability of technology-based products.[134,135] After field usability is complete, KB will validate the fixes and identify any remaining problems that will be corrected before the app is made available to users at the San Jose site.
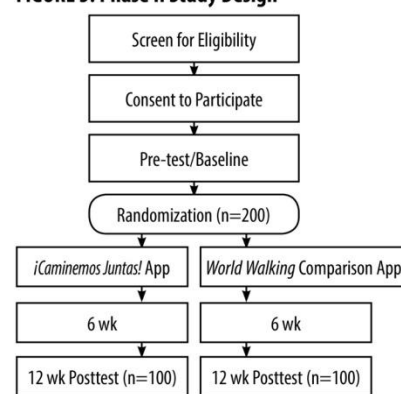
Stage 2: The San Jose lab usability testing will have two rounds with 8 participants per round (n=16), and utilize the same methods as in Denver. After Round 2, a 2-week field usability test will be conducted in the San Jose area with 20 Latinas. Usability outcomes will guide finalizing the app prior to the RCT.

Recruitment and Compensation: Inclusion criteria for usability testing (lab and field) participants will be the same as the Denver and San Jose focus groups (see **Table 3**). Lab usability testers (n=16 in Denver; n=16 in San Jose) will be compensated $25 for 1 hour of their time. Field usability testers in Denver (n=20) and San Jose (n=20) will be compensated $50 for the 2-week testing. Recruitment will occur via mass mailings, existing research participant databases, newspapers, and online and social media ads. Informed consent will be obtained and all procedures will be approved by the KB and Stanford IRBs.

Usability outcomes: Field usability testing interviews will be recorded, transcribed, and analyzed using Atlas.ti© software. Emerging codes will be assigned to phrases and text passages that categorize views, themes, and opinions. The qualitative analysis will rely on constant comparative analysis (based on grounded theory methodology),[155] and a phenomenological approach.[156,157] To identify problems that impact $\geq$ 10% of app users[158,159] with a 95% chance of detection ($\log(1-.95)/\log(1-.10)$), 28 usability testers are needed. The SUS measure will serve as the primary usability outcome. Additional usability testing outcomes will include app usage data (e.g., log-ins, walks created, etc.). Frequency of responses and proportions and means will be calculated and compared on demographics, using chi-square, t-tests, and correlations, with 2-tailed p=0.05.

3C.4. Experimental Design (Specific Aim 3). The *¡Caminemos Juntas!* app will be evaluated in a randomized two-arm, comparative-effectiveness pre-post design. *¡Caminemos Juntas!* will be compared to a free and readily available comparison app (*World Walking,* selected because of its primary focus on walking) over 12 weeks. Individuals will be randomized to one of two experimental conditions, using a customized computer program written by KB's biostatistician, Dr. Gary Cutter. We will recruit a total of 200 community-dwelling Latinas; 100 from the Denver area and 100 from the San Jose area. The primary outcome is change in PA (as measured by the Community Healthy Activities Model Program for Seniors [CHAMPS][160]) relative to baseline. PA was chosen as the primary outcome because Phase I participants strongly expressed that improving their PA level was the main reason why they would use the app.

FIGURE 5: Phase II Study Design

Screen for Eligibility → Consent to Participate → Pre-test/Baseline → Randomization (n=200) → *¡Caminemos Juntas!* App | *World Walking* Comparison App → 6 wk | 6 wk → 12 wk Posttest (n=100) | 12 wk Posttest (n=100)

3C.5. Target Population. There are two target populations: community-dwelling Latinas in (1) the Denver area and (2) San Jose, CA area. Two locations were chosen because: (1) the Phase I functional prototype was developed and field tested in Denver so testing the fully-developed app in the same location saves costs and allows iterative changes to the app to be made quickly, and (2) testing the fully-developed app in a second, remote location (a) allows the research team to test the fidelity of the LBS-database development protocol in a new location, which provides valuable insight on database development for Phase III, and (b) tests the app with a different demographic makeup of U.S. Latinas.

3C.6. Trial Conduct.
3C.6.1. Recruitment and Visit Procedures.
Recruitment and Screening: Potential study participants will be recruited primarily through mass mailings, newspaper and social media ads, and existing research participant databases. Interested participants will be sent an email describing the study and a link to a screening survey administered on KB's secure server that assesses inclusion and exclusion criteria (see **Table 3**), demographic characteristics, and physical activity readiness measured by the Physical Activity Readiness Questionnaire (PAR-Q).[161] Prior to enrollment in exercise RCTs, participants' level of risk regarding their ability to safely participate in and increase their level of PA should be assessed.[162,163] The PAR-Q is commonly used for this purpose and can identify individuals who can safely participate in PA without obtaining medical clearance.[163] The online screener will take about 5 minutes. Participants will receive an email to inform them of their eligibility status. Eligible participants will be scheduled for an orientation and baseline assessment visit; a reminder email and text message will be sent 3 days prior to the assessment date (similar reminders will be sent for 6- and 12-week visits).

Orientation and baseline/pre-test assessment: Participants will attend a one-on-one orientation and baseline assessment session. Participants will have the study explained and provide written consent. They will complete five online surveys using a tablet computer, which should take about 45 minutes to complete. After survey completion, participants will be randomized using the software and randomization allocation.

Participants will be assisted with downloading the appropriate app, provided instructions on how to use the app (*iCaminemos Juntas!* or *World Walking*), and encouraged to use the app daily.

6-week interim assessment: Participants will complete interim assessments of initial changes. An invitation email and text messages containing a link to the interim surveys along with their unique password (PIN number) will be sent. Participants will complete the web-based surveys using either their computer or smartphone; no in-person meeting will be required. Participants who do not complete the surveys within 3 days will receive an email and text reminder (and 3 more reminders at 3-day intervals if still not completing it).

12-week post-test assessment: Participants will complete an in-person post-test assessment. They will meet individually with a study staff to complete the online surveys on a study tablet and a brief post-test interview.

3C.6.2. Outcomes: Baseline, Interim, and Post-test Measures. The baseline, 6-week interim, and 12-week post-test surveys will use validated scales to measure the primary outcome – physical activity - and secondary outcomes of social and environmental support and quality of life (QOL). Surveys should take 30-45 minutes to complete. See **Table 4** for schedule of measurements.

TABLE 4: Schedule of Measurements

Assessment	Screening	Pre-test/Baseline	Week 6	Week 12/Post-test
Inclusion Screener	X			
Physical Activity		X	X	X
Social & Environmental Support		X	X	X
Quality of Life (QOL)		X	X	X
Usage Data (*iCaminemos Juntas!* app only)			X	X
System Usability Scale (*iCaminemos Juntas!* app only)				X

Physical Activity:

The Community Healthy Activities Model Program for Seniors (CHAMPS[160]) is a 41-item PA questionnaire that measures self-reported minutes-per-week of PA calculated as total weekly caloric expenditure in all PA. It was developed for underactive populations and validated among older adults.[160] However, CHAMPS has been used with younger and racially/ethnically diverse populations; it is sensitive to change specifically in Latino and other populations including ones younger than senior age.[164-167] The CHAMPS asks about activities undertaken for exercise, daily activities that are physical in nature, and physically active recreational activities during "a typical week in the past 4 weeks." CHAMPS has strong psychometric properties,[160,168] including validation in Spanish and sensitivity to change.[169-171]

Social and Environment Support:

Neighborhood Environment Walkability Scale-Abbreviated (NEWS-A)[172]: The 54-item NEWS-A assesses residents' perception of neighborhood design features related to PA, including residential density, land use mix, street connectivity, infrastructure for walking/cycling, neighborhood aesthetics, traffic and crime safety, and neighborhood satisfaction. It is a validated measure of neighborhood walkability with adequate levels of factorial and criterion validity,[172,173] and has been used with Latino populations.[174]

Social Support for Exercise Survey[175]: This 13-item self-report measure assesses perceived receipt of social support for exercise, i.e., how often their friends or family members (separately rated) encouraged their exercise behaviors during the previous 3 month. It yields two separate scores for friends- and family-encouragement (score range=13 to 65 for family and friends with higher scores reflecting higher encouragement). This measure has good psychometric properties and has been used with Latino populations.[176-178]

Quality of Life (QOL):[179] The 12-Item Short Form Health Survey (SF-12) measures functional health and well-being (i.e., health-related quality of life; HRQOL). The SF-12, an abbreviated version of the SF-36, covers the same 8 health domains, and produces a physical and mental component summary score (PCS; MCS). The SF-12 is often used in population studies including those focused on Latinos[180-182] and has been found to be a reliable and valid measure of HRQOL.[179,183] Higher scores indicate better physical and emotional well-being.[183]

Environmental Supports for Physical Activity Questionnaire – Social and Physical Environment Survey[184]: This questionnaire assesses neighborhood physical and social environments, i.e., neighborhood safety, access to recreation and shopping destinations, and conditions of neighborhood and facilities. It was tested for reliability and validity among 1200 adults, and has shown good psychometrics properties in other studies.[173,185-187]

¡Caminemos Juntas! only measures:

Accelerometry and App Usage: Better understanding of the feasibility, accuracy, and added value of accelerometry will inform commercialization efforts. Fitbit® devices will monitor PA for participants who own that device. The Fitbit® will automatically record daily step data in the *iCaminemos Juntas!* app and progress towards the steps/day goal will be graphically presented on the app, using a color-coded graph automatically sent to the participant's phone. For participants who do not own a Fitbit®, the phone's built-in GPS will record the route walked. Data on the time spent during the walk plus the distance derived from the GPS and the walking pace provided by the user in her profile will be combined to estimate steps. *iCaminemos Juntas!* participants will also enter other exercise activities (non-*Caminemos* walks) (minutes/day) using the app. User-entered data will be compared to PA data gathered using the Fitbit® or LBS distance tracking feature.

App usage will be measured by having participants register on the server when downloading the *¡Caminemos Juntas!* app. The server will record the number of times (date and time) the app connects to the server and users use various app features (number of uses, initiating walks, accepting walks, app tools used, etc.). Ecological momentary assessment (EMA) will be utilized to evaluate the app's ease of use. EMA's repeated sampling of experiences and behaviors in real time at random intervals should minimize recall bias and increase ecological validity,[188-190] highlight individual differences in behavior and distribution over time, and detect factors affecting behavior.[191-195] EMA will be used to assess level of interest and likability of the *¡Caminemos Juntas!* app. Participants randomized to that condition will be sent "push notifications" via the app once a week at various times of day that ask them to rate their opinions on the app. Users will also evaluate the app on the System Usability Scale at the 12-week post-test.[134]

3C.6.3. *¡Caminemos Juntas!* Intervention (n=100). A description of the *¡Caminemos Juntas!* app was provided in **Section 3C.4.** Participants will download the app following the procedures outlined in **Section 3C.7.1**. Project staff will provide *¡Caminemos Juntas!* users a one-one-orientation to the app and how to use its unique features. Daily alerts and notifications will engage users in daily use of the app and provide up-to-date information on users' progress. Participant responses will also be used to evaluate additional or on-going support of users' needs (e.g., increase/ decrease prompts based on user preferences, tailored messages around a set goal, etc.). To protect privacy and to ensure that the participant is the person completing the app activities, KB will uniquely identify the user's smartphone based off the device's "hardware footprint". The app will upload all app activity data to the KB secured web server database.

3C.6.4. *World Walking App* Comparison Group (n=100). *World Walking* (www.worldwalking.org) is an app available for free on both iOS and Android platforms.[196] It allows users to track walking steps using the phone's LBS features, display walks on a virtual route, create virtual walking groups (you and other users can have shared goals for walking a certain distance such as walking the Great Wall of China), chat with virtual group members, earn badges for meeting goals, connect to Fitbit, and receive push notifications. There are a number of similarities between to the two apps; participants will be able to track their walking, have a reward-based system for meeting goals, map their walks, use Fitbit, and have a social network component. The app encourages social interaction by letting walkers form virtual clubs, working together to meet distance targets.
However, while there are similarities between the two apps, *World Walking* will not allow for real-time, in-person social connection (meeting other women in-person and walking locally), or connection to social media.

Selecting the best comparison condition is a critical question when designing a RCT.[197] We considered a number of possible control conditions (e.g., no treatment control, waitlist control, etc.). Initially, we considered a 3-arm design (*Caminemos* vs. *World Walking* vs. No treatment) but rejected it due to resource demands, need for more programming, and large sample size to obtain sufficient power. The purpose of a Phase II grant is to continue the research and development efforts initiated in Phase I and prepare for commercialization objectives resulting from the Phase I and II activities. Our primary goal is to determine if the *¡Caminemos Juntas!* app is more effective at improving PA behavior compared to other products available in the market. Therefore, we decided to choose an active control app that was: (a) readily available; (b) had features similar to the *¡Caminemos Juntas!* app; and (c) had scientific merit. Our study design choice was a comparative effectiveness trial so choosing an existing app with similar features (i.e., a potential market competitor) was paramount. It was this high level of similarities that made *World Walking* a reasonable comparator.

3C.6.5. Adherence, Dropouts, and Participant Compensation.
Retention, Tracking, and Attrition: Although participants can withdraw at any time, steps will be used to minimize dropouts to ensure high internal validity. Participant progression will be tracked. Staff will use behavioral reinforcement strategies known to be effective in the behavior change literature[198-200] and be trained to develop rapport with participants by communicating expectations for participants and staff. Personalizing this relationship will enable participants to be more direct about problems, providing a strong foundation for problem-solving. While drop-out rates vary in community walking program for Latinos, we conservatively planned for 20% attrition.[201] Our Phase I attrition was 10%. We assume equal adherence across the two treatment groups, because we have no data to predict otherwise. Our method of tracking and multiple contacts will help us retain some of these participants for intent-to-treat purposes, despite their discontinued app use. Participants will provide contact information for two individuals who can always contact them and update contact information at each assessment. If they do not respond to email/text reminders, we will follow-up by phone. Finally, we will create a dummy coded variable for each respondent where 1=completers and 2= drop outs and test for associations with key variables in our analytic models. If bias is identified, we will control for it by adding it as a covariate.
Compensation: All participants (n=200) will be compensated to incentivize and improve study retention. A $100 gift card will be given for completing all study assessments (baseline, 6-week, and 12-week).

App Use: Implementation of technology-based interventions can be challenging due to participants forgetting, fatiguing, or believing they have learned all they need to know. In order to bolster compliance with using either of the assigned app, weekly reminders to use the app will be sent to participants by text message.

3C.6.6. Safety Considerations. Participant safety is a priority. This study will include a Data and Safety Monitoring Plan (DSMP) plus IRB approvals. The team will monitor progress, discuss concerns, problem-solve, and take corrective actions. Dr. Myers (PI) is a licensed psychologist in Colorado (#3630) and Louisiana (#1197) and will assemble a group of experts including at least one licensed mental health professional and one biostatistician. Participants who express distress will be referred to local community centers which provide health and mental wellness outreach. Based on our experience and demonstrated ability to conduct this type of research, we are confident we can achieve safe intervention delivery.

3C.7. Data Collection, Management, and Security. KB has used online data collection successfully in a number of studies. Study consents and pretests and posttests will be collected online via a tablet computer. Six-week assessments will be collected online over participants' personal smartphones or computer devices. Surveys will be programmed using QuestionPro software on KB's secure web server to ensure a structured approach and reduce errors/missing values. All procedures will be approved by KB and Stanford IRBs.

KB has considerable experience maintaining large databases and ensuring high-quality data. Ms. Lucia Liu, KB's Biostatistical Manager, will supervise data management. All data will be uploaded in real-time using KB's secured network; data will be de-identified and stored in KB's secured database. Established KB protocols for quality assurance (valid ranges; internal consistency checks, etc.) will ensure high quality data. The KB data team will compile master data files. Survey and app usage data will be linked. Missing data should be limited since data is recorded electronically. Staff will identify missing responses and check that entries were not intentionally skipped. Analyses will be done on data collected. While unlikely, data may not be missing at random (NMAR). KB 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.

Data security: KB's server farm has 5 Dell PowerEdge servers with two 3.2 Ghz Xeon processors, four with 32 gigabytes of RAM and one with 64 gigabytes, and three 1 Terabyte hard drives that operate off a hardware RAID5 system, connected to a local area network (LAN) running the Windows 2008 or 2012 operating system and to the Internet through a 20-megabyte Fiber connection. KB programmers monitor and maintain all programs and databases. Sensitive information is protected by a hardware firewall (Cisco ASA 5505) and each server has its own native Windows security software. All KB servers are connected via 1 Gigabit high-speed switched network, ensuring high-speed transfer between machines. All networked computers are protected from viruses by Sunbelt Vipre Enterprise. Nightly backup of each computer protects against the loss of data.

3C.8. Statistical Power Calculations and Analysis.
Sample size: We expect results similar to those previously revealed in a study by Co-I, Dr. King.[202] In that study, participants in a peer mentor arm reported an average increase of moderate-to-vigorous physical activity of 216.2 minutes/week (*SD* = 355.7) from baseline to 12 months compared to a 178.0 minutes/week (*SD* = 234.9) increase among those in the comparison arm. The comparison arm increased an average of 71.5 minutes/week (*SD* = 179.1) from baseline to 12 months. Comparing the two arms, with a change of 71.5 minutes/week, shows sample sizes of 81 and 81 achieve 90% power to reject the null hypothesis of equal means when the population mean difference is 144.7 with standard deviations of 355.7 for peer mentor arm and 179.1 for the comparison arm, and with a significance level (alpha) of 0.05 using a two-sided two-sample unequal-variance t-test. Adjusting for a conservative level of dropout at 20% allows for 100 per group for a total sample size of 200. If our active arm is similar to the comparison arm, because of the smaller standard deviation, the sample size necessary to achieve 90% power only increases to 82 per group, despite the lowered difference.
Analyses:
There 3 specific aims that will be evaluated. The analyses for Aims 1 and 2 are heavily descriptive in nature. Means (standard deviations), medians (Interquartile range), distributions, frequencies and percentiles, etc. will be used to characterize the outcome measures.

Aim 1 will be assessed by examining the number of connections/matches for walking (creating and/or joining a walk). We believe that at least 70% of the *iCaminemos Juntas!* intervention group will establish at least one connection and participate in at least one walk (e.g., 78% of users in Phase I created at least one walk). The distribution of number of connections and walks completed will be examined. We will test whether there is a difference between the groups in connections that occurred using a chi square test and will further test a single proportion that the *iCaminemos Juntas!* group will have significantly more than 70% active participation as evidenced by making at least 1 connection.

Aim 2 will be evaluated descriptively and via feasibility testing showing that location-based services can be replicated regardless of region.

Aim 3 is critical to product development and will evaluate whether *iCaminemos Juntas!* increases physical activity, social support, and quality of life (QOL) in Latinas. Three hypotheses for the comparative-effectiveness trial will be examined:

H_1: Latinas randomized to the *iCaminemos Juntas!* app will report greater improvements in their physical activity compared to Latinas randomized to the comparison app (*World Walking* app) at 12-weeks post-test.

H_2: Latinas randomized to the *iCaminemos Juntas!* app will report greater increases in their social support for exercise compared to Latinas randomized to the comparison app at 12-weeks post-test.

H_3: Latinas randomized to the *iCaminemos Juntas!* app will report greater improvements in their quality of life (QOL) compared to Latinas randomized to the comparison app at 12-weeks post-test.

Additional secondary analyses will (1) evaluate immediate changes in the PA, social and environmental support, and QOL measures at 6 weeks; (2) assess mediators at 6-weeks for a mediational analysis on 12-week outcomes; and (3) evaluate app usage data (e.g., number of log-ins, number of "check-ins", EMA responses for likability and satisfaction with the app).

Tests will be performed as per the design using simple t-tests followed by analysis of covariance to assess the outcome results adjusted for baseline (rather than change from baseline). Multivariate analyses will be conducted to assess the simultaneous direction of changes in the components between the treatment arms. We will test the outcomes simultaneously and examine the correlation amongst them within treatment arms. Hotelling's T^2 will be used to test the overall mean vector of responses. This analysis will utilize the pre- and post-measures, but additional analyses will be conducted using generalized least squares regression (PROC MIXED in SAS ver 9.3 or higher) to account for missing data (drop outs between 6 weeks and 12 weeks).

Characteristics of dropouts and/or noncompliant individuals (those who do not walk and/or form any connections) will be intensively examined to shed light on potential weaknesses of the app (differential dropout overall or within certain subgroups). The evaluation of the app will include its impact using the pre-post data. As noted, examination of the correlation matrices along with the mean changes will inform whether the variables appear to move similarly in both groups. Thus, one might argue that it is not necessarily the best control choice since we would then be measuring the intensity of intervention. Alternatively, very different correlation structures will inform us about how the interventions are working and may provide information on appropriate controls and or strengths and weaknesses.

Utilization data will be examined to understand the acceptability and intensity of interactions with the apps. The penetration of the apps into this minority at-risk population is very important in potentially understanding, not only market share, but also potential impact. Complier average causal effect models[203] will be used to examine the intensity of the intervention app's utilization. Mediation models using the latest bootstrapping methods[204,205] will be examined to enhance evidence that the changes induced by the treatment effects are consistent with the changes being mediated via the app and the intervention.

3C.9. Design Strengths, Potential Limitations, and Overall Impact. The study has numerous strengths and few limitations. We will use the latest technology for iPhone and Android systems. The app will be thoroughly tested, and user-friendly and effectiveness will be evaluated in a randomized design. The study team and environment are strong. KB is a leader in the development of health behavior research technology, and Stanford has a strong history with the conduct of clinical trials. Drs. Myers and King have extensive clinical trials experience and expertise in the behavioral PA content to be delivered and have competent research teams and resources to assist them. Potential study limitations are: (1) difficulty recruiting; (2) sample homogeneity; and (3) sources of bias (measurement; demand effects). We have tried to reduce these. We will work closely with the CAB to maximize our potential to recruit Latinas. While the study will only be conducted with Latinas residing in Denver and San Jose; studies suggest that poor PA habits are common among Latinas implying that the sample will represent the target population rather than just the Denver and San Jose populations. Outcomes are self-reported and open to bias; however, the use of validated measures is a strength.

5. PROTECTION OF HUMAN SUBJECTS
5A. Risks to Subjects
5A1. Human Subjects Involvement and Characteristics.
For this research, the subject population will include:

Focus Groups Participants (n=32). This subject population will include Latino female adults, ages 18 to 55, from Denver, CO (n=16) and San Jose, CA (n=16). The Denver-based focus groups will allow for the initial development and qualitative feedback on the new app features prior to formative research with the California population (San Jose community). An iterative process of summarizing data will be used to achieve saturation and a thematic content analysis approach will be used to analyze the data. Eligibility criteria will be a) the ability to read and speak English or Spanish, b) female, c) consenting to inclusion in the study, and d) self-identify as Hispanic/Latina. Exclusion criteria include a) being less than 18 years of age, b) being over 55 years of age; and c) unable to speak or read English or Spanish.

Lab Usability Testing Participants (n=32). This subject population will include Latino female adults, ages 18 to 55, from Denver (n=16) and San Jose (n=16) who will validate the design approach and identify usability problems. This will be a two-staged approach with usability testers in Denver (Stage 1) and San Jose (Stage 2). The lab usability testing will consist of two rounds with eight participants per round (n=16). For each round of lab usability testing, the test scenarios will be written to mimic real-world use of the app. In the first round, we will test basic functionality, using findings to recommend immediate improvements to design. In Round 2, we will test enhanced functionality to identify and correct usability problems before the app is complete. Eligibility criteria will be a) the ability to read and speak English or Spanish, b) female, c) consenting to inclusion in the study, and d) self-identify as Hispanic/Latina. Exclusion criteria include a) being less than 18 years of age, b) being over 55 years of age; and c) unable to speak or read English or Spanish.

Field Usability Testing (Beta Testing) Participants (n=40). This subject population will include Latino female adults, ages 18 to 55, from Denver (n=20) and San Jose (n=20). This subject population will test the final prototype. The field usability test (i.e., beta test) of the fully programmed app will be conducted with Latinas who will use the app for two weeks to test the location-based services (LBS). Field usability participants will receive a one-on-one orientation which will include downloading the app onto their device and an app tutorial. After completing the field usability testing, participants will return for an individual exit interview. They will rate their satisfaction with the app with regards to design, appeal, and functionality, and complete the System Usability Scale (SUS),[133] a validated tool for assessing the usability of technology-based products.[134,135] After field usability is complete, KB will validate the fixes and identify any remaining problems that must be corrected before the app is made available to users at the San Jose site. Usability outcomes will guide finalizing the app prior to launching the randomized control trial. Eligibility criteria will be a) the ability to read and speak English or Spanish, b) female, c) consenting to inclusion in the study, and d) self-identify as Hispanic/Latina. Exclusion criteria include a) being less than 18 years of age, b) being over 55 years of age; c) unable to speak or read English or Spanish; d) self-reported pregnancy; and e) responding "yes" to any item of the PAR-Q (Physical Activity Readiness Questionnaire).

Randomized Controlled Trial Participants (n=200). This subject population will include Latino female adults, ages 18 to 55, from Denver (n=100) and San Jose (n=100). The app will be evaluated in a randomized two-arm, comparative-effectiveness pre-post design. *¡Caminemos Juntas!* will be compared to a free and readily available comparison app (*World Walking*) over 12 weeks. All participants will complete a pretest, a 6-week interim survey, and a 12-week post-test survey. The surveys will use validated scales to measure the primary outcomes. Eligibility criteria will be a) the ability to read and speak English or Spanish, b) female, c) consenting to inclusion in the study, and d) self-identify as Hispanic/Latina. Exclusion criteria include a) being less than 18 years of age, b) being over 55 years of age; c) unable to speak or read English or Spanish; d) self-reported pregnancy; e) responding "yes" to any item of the PAR-Q (Physical Activity Readiness Questionnaire).

5A2. Sources of Research Materials. Data from the focus groups, lab and field usability testing, and randomized trial will be collected in the form of handwritten notes, audio tapes, computer files, transcriptions, and questionnaires. Discussions will be recorded, transcribed, and analyzed using Atlas.ti© software. Data will be gathered from surveys used in the randomized trial. Data will be obtained specifically for research purposes and will be kept confidential with access limited to the Principal Investigator and specific project staff. All data will be kept in locked files.

5A3. Potential Risks. There are minimal risks associated with participation in this study. Participants may be hesitant or uncomfortable discussing their opinions regarding the *¡Caminemos Juntas!* app. In addition, participants may not feel comfortable responding to questions about their opinions on the appeal, ease of understanding, navigation, and functionality of the app. For participants in the field usability test and randomized trial, the potential risks involved in this project include psychological and/or medical complications resulting from increasing exercise (e.g., sore muscles, etc.). There is the possibility of adverse events ranging from minor musculoskeletal problems to, in very rare cases, cardiovascular events. Occasionally study participants experience minor orthopedic problems, but most are self-correcting with rest and standard first aid. The risk should be low in this study. Fatal events during exercise are extremely rare. We have conducted numerous exercise training studies and have never had a serious adverse event. There are no anticipated risks from completing the self-report questionnaires. If signs of minor stress or fatigue are apparent, participants will be given time to take a break from completing the questionnaires. It is estimated that the questionnaires will take 30-45 minutes to complete. All participants will be allowed to withdraw if they are uncomfortable with providing any of this information. Their responses will in no way be shared with anyone except project staff. Responses to the questions will be coded to protect confidentiality, and participants may choose to not answer questions.

5B. Adequacy of Protection Against Risks
5B1. Recruitment and Informed Consent. Human Subjects oversight will be conducted by Western Institutional Review Board (WIRB; DHHS IRB Reg. No. IRB00000533) and Stanford's Institutional Review Board (IORG0000208). All consenting procedures will be IRB-approved. The IRBs will review and approve subject materials (including recruitment advertisements, letters, consent forms, survey instruments) and data management procedures prior to study implementation.

We will recruit participants primarily through mass mailings, newspaper and social media ads, and existing research participant databases. For the randomized trial, we will recruit a total of 200 currently community-dwelling Latinas; 100 from the Denver area and 100 from the San Jose area. Participants will be presented with IRB-approved consent forms that will describe the purpose of the project, risks and benefits, and selection criteria. Participation will be voluntary, with the right to stop participating at any time. No clinical data will be captured. Responses to survey questions and the discussions would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation. All data coding, data entry, analysis and reporting activities will be conducted by KB and Stanford. Focus group and lab and field usability testing participants will read and sign IRB-approved consent forms. Randomized trial participants will consent online. Participants will be informed that they have a right to withdraw from the study at any time. No additional data will be collected from participants who decide to withdraw; however, the information collected prior to withdrawal will remain in the study. IRB-approved surveys and discussions will be carried out under the supervision of senior project staff.

5B2. Protection Against Risk. To minimize potential psychological risk, all focus group and usability testing facilitators will establish ground rules for discussion that includes an open, non-evaluative exchange of comments and ideas. All surveys and data collection forms will be approved by an IRB and employed under the supervision of senior project staff. Participants will be told that they do not have to answer any questions which make them uncomfortable and can terminate their participation at any time they wish.

Notes, surveys, audiotapes, and data will be accessible only by research personnel. Responses to survey questions would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. No clinical data will be captured. The data collected on this project will be obtained with the "use of educational tests, survey questions, [and] interview procedures."

In Phase I, we provided participants with safety tips and a resource guide based on information from National Cyber Security Alliance (www.staysafeonline.org) and National Crime Prevention Council (http://www.ncpc.org/topics/internet-safety/social-networking-safety). In addition to these safeguards, we worked closely with our Community Advisory Board (CAB) and Expert Advisory Board (EAB) to determine best approaches for maintaining the personal and Internet safety of our participants. For Phase II, we will utilize these same practices, but will also include multiple ID verification approaches and a security expert. Additionally, we will work with our CAB and security consultant to maintain rigorous standards for safety that are also agreeable to our users. Specifically, KB's Programming Manager will lead the app programming, will complete his certification in ethical hacking (CEH) which will allow him to assess for weaknesses and vulnerabilities in the app. His certification should be completed by late Summer 2018. Mr. Matt Smith (President, Litchfield County Computer, LLC) will serve as a consultant and provide independent expertise on app security. Mr. Smith has a BBA in Management Information Systems with a concentration in Computer Security and is an app security expert. In addition, KB's IT Manager will be responsible for data security. He is certified with Window Servers, is a Microsoft Certified Systems Engineer (MCSE), and has continuously received an A+ rating for Network security in independent audits.

To ensure safety, all participants will be required to complete multiple ID verification approaches that are currently standard practice in other consumer areas (e.g., Airbnb). All participants will be fully informed of these privacy policies. Participants will submit a copy of their photo ID (front and back) to the study team. The study team will complete two verifications with the submitted ID: (1) the photo ID will be encrypted (ensuring privacy), submitted to the IDscan app (www.idscan.com), and a report will be delivered to the study team; and (2) the name will be entered into a publicly available, free website (www.checkingrecords.com) which accesses public record information, a social networking summary, a general online lookup, court and driving records. The study team will vet the information obtained from the ID verification for any potential concerns. If concerns arise, the study team will discuss with the participant the options for study discontinuation or continuation. All information obtained during the ID verification process will be confidential and not shared on the app. Participants will be required to consent to the ID verification. *¡Caminemos Juntas!* app participants will be required to provide a profile picture to be displayed on the app (it can be different than their issued photo ID). The study team will confirm that the profile picture is similar to the ID provided during the verification process.

With regards to walking environment, the database for meeting locations will be derived in a similar manner as Phase I. Our CAB and Phase I participants rated all of the walking locations as safe. Similarly, for Phase II, exercise locations will be limited to parks, trails, schools, recreation centers, and malls (venues that are public and well-lit). To ensure users' privacy and safety, the app will serve as the "gatekeeper". Users cannot be located by another user without permission, cannot set up a meeting time that is outside the app's allowable walking hours, and cannot set up meetings to walk with an unauthorized user. Also, users cannot change a meeting location unless the new meeting location is in the database. Any changes or deviations that are made are tracked by the app. All users will be asked to rate their opinion of the walking location, its safety, and whether they agree to use the location again. If a user prefers to not use a location, that location option will be removed from their available list of locations. If a location consistently receives poor ratings, it will be removed from the database as an available location option. Throughout the project, we will work closely with our CAB and security consultant to maintain rigorous standards for safety that are also agreeable to our users.

Data will be de-identified before being submitted for analysis. All notes and printed data collection forms and questionnaires will be stored in locked cabinets at KB offices; all electronic data files will be stored on KB's secure network servers behind computer firewalls, with routine backup. All identifiers will be stored in secure files and behind computer firewalls and results will be shared in aggregate form only. All human subjects participating in this project will be 18 years and older.

To minimize the risk to participant data privacy and protection through the internet, KB programmers will monitor and maintain all programs and databases and use an established protocol for participant cyber safety and security. KB is HIPAA complaint and maintains vigorous technical safeguards which are built into KB's IT system to protect information and to control access to it. All participant information will be protected using 128-bit SSL encryption. All Internet information must travel through KB's CISCO ASA 5505 firewall using ASA software version 9.0(2) encrypted 3DES-AES. Traffic then moves to KB's web server. This server is a Dell Power Edge T-310 with 32 GB of RAM, 1.5 TB available disk space on a RAID 5 redundant drive system using Windows HyperV Operating System. The virtual web server uses Windows 2008 IIS Web server software. User click stream data is collected using Webtrends, and is saved to our SQL server. Enrollment data is transferred to our SQL server (Windows Server 2008) which uses MS SQL server 2008 R2 database software. This machine is also a Dell Power Edge T-310 with 32 GB of RAM, 1.5 TB available disk space on a RAID 5 redundant drive system using Windows HyperV OS, and has no access to the Internet. When a participant is directed to take a survey, their computer is linked to a third server in our system which is also a Dell Power Edge T-310 with 32 GB of RAM, 1.5 TB available disk space on a RAID 5 redundant drive system using Windows HyperV OS. This server runs Question Pro Survey software. Data from each survey is collected and saved to the SQL server mentioned above. All network traffic is sent from the CISCO firewall to a Syslog server using Manage Engine Firewall Analyzer 7 software. Login and network activity is required and monitored by Windows servers to an event viewer. Servers are kept in a locked room on site. All files are secured locally using MS NTFS. All traffic between servers and PCs on the LAN are digitally signed communications. Each local machine has a built-in operating system firewall. Data from the Question Pro surveys are exported for data analysis by local machines which are also behind KB's firewall. Access to this exported data by outside sources is done using File Transfer Protocol (FTP) protected by Secure Socket Layer (SSL). SQL databases are protected by the built-in security of MS Active Directory. Data is backed up using a Quantum SuperLoader 3 tape library using LT04 tapes that contain 800 GB/1.6 TB of info (depending on compression used). The device holds 16 tapes. The backup software used by KB is Symantec Back-up Exec. 2012. Daily backups are incremental and tapes are recycled weekly. Weekly backups are done every Friday and are recycled every 6 weeks. Monthly backups are done on the last Friday of each month, and are full backups of all data. These monthly tapes are stored in a secure offsite facility and are never recycled.

With regards to app security on personal devices, Apple (e.g., iOS programmed apps) completes a full security review of any app installed on a phone including beta/testing apps through their App Transport Security (ATS).[206] KB App programming will include all key developer-related features to ensure ATS security.[207] Google Play (Android programming) does not conduct a similar security check; however, KB has extensive experience with developing and marketing both iOS and Android programmed apps using an established protocol (SSL/TLS: Secure Sockets Layer/Transport Security Layer) and has never experienced a data breach. All usability testers will be informed that information being sent to and from their device will remain encrypted and password protected, and at any time they are allowed to opt-out and uninstall the app.

5C. Potential Benefits of the Proposed Research to Participants and Others

Potential benefits will be the knowledge that one has helped to develop and test a smartphone app that uses location-based social networking to connect Latinas in neighborhood-specific geographic areas to promote increased walking behavior. Also, we believe that field usability testing participants and randomized trial

participants will benefit from an increase in physical activity. In addition, participants will be compensated as follows: $25 for participation in the focus group and lab usability testing; $50 for participation in the field usability testing, and $100 for completing all study assessments (baseline, 6-week, and 12-week) in the randomized trial.

A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify the participant. At most, the website will include a summary of the results. This website can be searched at any time.

5D. Importance of the Knowledge to be Gained

The *¡Caminemos Juntas!* app will be the first smartphone app that uses location-based social networking to promote physical activity (PA), and the only app of its kind targeted to Latinas. *¡Caminemos Juntas!* will also expand upon what is known to be successful in Latina PA engagement (e.g., community-oriented, social support) while simultaneously addressing key barriers to PA (e.g., safety concerns).

5E. Multi-site Collaboration

The proposed research involving human subjects will be conducted by Klein Buendel, Inc. (FWA No. 00003715) and Stanford University, School of Medicine, The Stanford Prevention Research Center (FWA No. 00000935).

5G. Training in the Ethical Conduct of Research with Human Subjects

The Principal Investigator, Co-Investigator, and study personnel have completed the required training in the Ethical Conduct of Research with Human Subjects. Necessary documentation will be provided to NIH prior to funds being awarded.

6. Data and Safety Monitoring Plan

A data safety and monitoring plan will be implemented for this project, following well-established procedures. We will not set up an independent Data Safety and Monitoring Board because this study is low risk, does not include use of therapeutics, and psychological risk is not anticipated.

Study progress will be monitored monthly by the Principal Investigator, Project Coordinator, and Project Biostatistician. All critical events will be reviewed by the PI and Co-Investigator to ensure that our methods have not been intrusive or disruptive. The data management staff will examine the quality of data input throughout the data collection period following standard quality control and assurance procedures (e.g., double entry of hard-copy coded data; detection and estimates of keystroke errors, identification of systematic mistakes in coding or responses; range checks). Also, analyses of the data will be performed by Dr. Cutter and Ms. Liu at the conclusion of the data collection period to assess distributional assumptions and the success of randomization. By having the Project Coordinator, Project Biostatistician and data management staff monitor the data, the PI's conflict of interest is reduced.

The Project Biostatistician and data management staff will attend regular project meetings with the PI, Co-Investigator, Project Coordinator, and other project staff and routinely report on the quality of the data and other outcomes of this monitoring process. Compliance with data collection protocols will be monitored throughout data collection by the PI and Project Coordinator.

The PI and Co-Investigator are responsible for reporting all adverse events to the IRBs. Only Grade 1 events are expected on this trial. Thus, adverse events will be reported annually, as required by DHHS. This report will be reviewed by KB's, and Stanford's IRB. Any action taken by the IRB or project investigators resulting in a temporary or permanent suspension of the trial will be communicated immediately by the PI to the grant program officer.

7. INCLUSION OF MINORITIES

Since the *¡Caminemos Juntas!* app being developed for Latino female adults, all (100%) of the participants will be Hispanic. See Targeted Enrollment Table.

8. INCLUSION OF CHILDREN

Children under 18 will be ineligible for participation. Age will be self-reported by the participants.

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