

Study Protocol and Statistical Plan for
Virtual Advisors for Physical Activity Promotion in Underserved Communities

NCT02111213

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1. Introduction

Physical inactivity is responsible for nearly 10% of major non-communicable diseases (NCDs) worldwide.¹ In the U.S., population-level data suggest that increasing regular moderate physical activity could reduce annual medical costs by as much as \$76.6 billion.² While national guidelines for physical activity promotion emphasize the importance of appealing and convenient physical activities such as walking,³ a significant proportion of Americans (33%) remains inactive.⁴ This is particularly true for older (45% inactive), low-income (46% inactive), and Latino adults (44% inactive),⁴ who have high rates of obesity and other chronic conditions (e.g., Type 2 diabetes)⁵ in combination with often reduced access to programs to improve physical and mental health.⁶

Few physical activity programs have taken into account the cultural preferences and needs of Latino Americans—among the fastest growing segments of the U.S. population, including aging adults.⁷ The major objective of the COMPASS Trial is to systematically compare culturally adapted and individually tailored physical activity counseling for midlife and older Latino adults delivered through two different communication channels: trained peer advisors (called *promotores de salud*) vs. a virtual advisor (i.e., a computer-based embodied conversational agent named “Carmen”). Peer or lay health advisors, which have been in existence in Latino communities for decades,⁸ are typically members of the community in which they work, sharing the community’s culture, language, and environment.^{9,10-12} However, few such programs have specifically targeted physical activity counseling.¹³ Similarly, while evidence suggests that aging adults as well as Latinos and other racial/ethnic minorities

are increasingly using computer technology and e-Health platforms,¹⁴ most people targeted by e-Health programs have been well educated, younger (<55 years), and White.¹⁴⁻¹⁷ These circumstances increase concerns that e-Health may intensify the “digital divide” and exacerbate health disparities for under-represented communities.^{14,18,19} In particular, restricted computer access and lower computer, health, and language literacy levels are significant barriers for underserved populations.¹⁴ Few websites have been designed for persons with less than a high school education,¹⁴ and few e-Health programs incorporate cultural factors in health communications.²⁰ For web-based programs that do offer information in Spanish, content quality often has been substandard.²¹ This may help to explain why only 42% of Latino adults ages 55 and older use the Internet, compared with 57% of non-Latinos.¹⁹ In response to these often-cited barriers, the state-of-the-science “virtual advisor” computer technology being employed in COMPASS requires minimal computer skills or literacy, and provides personally and culturally tailored physical activity advice and support in multiple languages.²²

The COMPASS Trial allows for a direct determination of program comparative effectiveness for the Peer vs. Virtual Advisor programs. It also provides the opportunity to explore which Latino adult subgroups may do best with which type of communication channel. Given the dearth of community-based clinical trials in the health promotion area that have specifically targeted low-income aging Latinos, the COMPASS Trial also presents a unique opportunity to evaluate recruitment channels of particular relevance to Latino adults. The study design and procedures, including recruitment, intervention, and assessment procedures, constitute the major focus of this paper.

2. Methods and Procedures

The Stanford University School of Medicine Institutional Review Board approved the study protocol for the COMPASS (Computerized Physical Activity Support for Seniors) Trial. All study materials, including informed consent and recruitment, intervention, and assessment forms, were produced in English and underwent thorough translation into Spanish by certified translators. Participants provided written consent upon reviewing the consent form with a bilingual staff member. The trial was registered at Clinicaltrials.gov (#NCT02111213).

2.1. Study design

The primary aim of this randomized trial is to test whether the Virtual Advisor intervention is as efficacious as the Peer Advisor intervention in promoting significant 12-month increases in weekly minutes of walking—a form of moderate-intensity activity that is readily accessible and appealing to substantial numbers of midlife and older adults across the socioeconomic spectrum.^{3,23} The study employs a cluster-randomized design of community centers located in neighborhoods with at least 20% midlife and older Latino residents.²⁴ In addition to location, other factors that were considered in choosing community centers included interest and willingness of center staff to participate in the study, appropriate space to accommodate computer equipment for the Virtual Advisor or Peer Advisor sessions, and a steady flow of Latino midlife and older adults who utilize the center's regular programs and services. Community centers were matched by geographic location and randomized to either the Peer Advisor or Virtual Advisor intervention arm. The comparative effectiveness of these two interventions constitutes the major objective of the study and is the focus of this paper. To take

advantage of the study design to begin to explore new dietary intervention strategies in this underserved population, an additional pilot substudy is also underway. As part of this pilot substudy, two other similar community centers (one in each county in which the study is located) have been selected to receive culturally adapted dietary information via mail and face-to-face modalities across the one-year study period.

2.2. Study location and participants

The study is located in two San Francisco Bay Area counties—Santa Clara and San Mateo counties. Approximately 26% of the population across these two counties report being of Latino or Hispanic ethnicity [www.census.gov, 2015 American Community Survey]. Latinos in the western U.S. come largely from Mexico and Central America.²⁴ Of those born outside the US, approximately 50% have lived here for 15 or more years.

The following study eligibility criteria were used to enroll study participants: (a) ages 50 years and older; (b) insufficiently active,³ i.e., engaged in less than 100 minutes/week of moderate intensity activity over the past six months; based on initial study physical activity screening items (see below), followed by a final baseline physical activity determination using the full CHAMPS questionnaire;²⁵ (c) able to safely engage in moderate forms of physical activities such as walking based on the Physical Activity Readiness Questionnaire;²⁵ (d) living within close proximity to one of the study-designated community centers to allow regular (e.g., weekly) attendance to the community center-based intervention sessions; (e) able to read and understand English or Spanish sufficiently to provide informed consent and participate in all study procedures; and f) planning to live in the area for the next twelve months. The study screen, typically by phone, to determine physical activity status included the following

questions: 1) In the last three months have you regularly participated (at least two times per week) in any physical activity that has increased your breathing, such as aerobics, brisk walking, dancing, swimming, or playing sports. If the participants answered “yes”, they were asked to describe how many days per week they regularly exercised and how many minutes per day. These numbers were multiplied to calculate the total number of minutes per week. If the total number was 100 min or more, the individual was deemed ineligible. If the total number of minutes per week was reported as < 100, then individuals were asked to report, in a typical or normal week over the past four weeks, the total number of minutes per week they engaged in dance, walking or hiking uphill, walking fast or briskly for exercise, and water exercises other than swimming. Individuals were deemed eligible if participation in the above exercises totaled < 100 min per week. A final determination of study eligibility based on physical activity status occurred at baseline using the full CHAMPS questionnaire.

2.3. Study participant recruitment and screening methods

To enhance external validity, three complementary recruitment methods were employed: geographically defined targeted mass mailings, cultural media-based promotion, and community outreach.²⁶⁻²⁸ For the geographically defined targeted mass mailings, mailing addresses of residents in geographically defined Census block groups near the community centers were accessed via a private mail service company and selected based on age and Latino ethnicity. Introductory bilingual letters describing the study and business reply cards were sent to households, along with a toll-free number to call to obtain further study information and undergo initial screening for study eligibility. Those individuals judged to be initially eligible based on the telephone screen

were invited to attend a group study orientation session at their designated community center, during which time the study objectives and procedures were explained in further detail, all questions were answered, and interested individuals were scheduled for an individual baseline assessment visit also held at the community center. Those individuals found to be eligible and willing to enroll in the study were scheduled for an initial individual intervention session at the community center.

To broaden the types of individuals enrolled in the trial, the targeted mass mailings were augmented with bilingual media-based promotion and community outreach.²⁶⁻²⁸ The media promotional methods included study announcements placed in local Latino newspapers. As part of community outreach activities, study information was placed at participating community centers and was made available at local stakeholder events attended by bilingual study staff, such as health and resource fairs, back to school nights, Parent Teacher Association (PTA) meetings, local school council events, and parent group meetings, as well as neighborhood libraries, churches, local health clinics serving Latino adults, and local grocery stores.²⁹ Study participants and others who expressed interest in the study also were encouraged to refer others or share study information.

2.4. Study participant retention methods

To promote high levels of participant retention across the 12-month intervention and assessment period, group-based study orientation sessions were employed following the telephone screening process and prior to baseline assessment to ensure that all individuals considering study participation were fully informed about the study objectives, what would be expected of them throughout the study, and what they in turn

could expect from the study staff. The interactive group session included the weighing of the pros and cons of participating in the study, along with related motivational interviewing techniques and behavioral strategies, such as structuring of realistic expectations related to study outcomes. This type of pre-enrollment educational session has been associated with high levels of study retention in health behavior change trials across periods lasting up to 18 months.³⁰

2.5. Peer Advisor recruitment and screening methods

Recruitment of Peer Advisors was accomplished using a variety of strategies. Study interventionists worked with the community center staff to identify activities within the community center through which Peer Advisors might be recruited. In addition, study staff requested referrals of people who attended the community centers regularly and who center staff identified as potentially viable candidates for the Peer Advisor role. In addition to collaborating with the community centers directly, Peer Advisor recruitment was also conducted through collaborating with different agencies external to the community centers. These agencies included local social and civic service agencies along with educational institutions such as schools and libraries. In addition, some recruitment efforts occurred through partnering with local fitness centers and targeting their physically active population as potential study peer advisors.

Peer Advisor eligibility criteria consisted of the following: (a) ages 30 years and older; (b) physically active on a regular basis (i.e., engaged in approximately 150 minutes/week or more of moderate intensity physical activity over the past 12 months); (c) free of any medical problems that might make it difficult to participate in regular physical activity or serve as a Peer Advisor in the study (e.g., any unstable chronic

conditions); (d) willing to participate in the peer advisor 12-hour training program and volunteer an average of 2-3 hours per week to advise their participants on physical activity; (e) willing to participate in monthly Peer Advisor supervision meetings; (f) able to read and understand English or Spanish sufficiently to provide informed consent and participate in all study procedures; and (g) planning to live in the area for the next 12 months. Peer Advisor selection and training consisted of screening interested individuals by phone to determine initial eligibility. Eligible individuals then attended an orientation session during which time the study objectives and procedures were explained in further detail, all questions were answered, and interested individuals provided informed consent related to study confidentiality protocols and information sharing. Individuals then completed a 12-hour Peer Advisor training program based on the successful peer-led physical activity training programs conducted previously by the Stanford team.³¹⁻³³

2.6. Peer Advisor oversight and quality assurance methods

Ongoing Peer Advisor oversight and quality assurance have been accomplished through monthly Peer Advisor supervision meetings, periodic review of Peer Advisor logs and notes completed after each Peer Advisor-participant advising session, and random check-ins by study staff with study participants. Each monthly study staff-led, group-based Peer Advisor supervision meeting lasts approximately 120 minutes and focuses on the following activities: (a) sharing among Peer Advisors of their experiences and challenges with their participants, along with receipt of problem-solving advice and ideas from study staff and other Peer Advisors; (b) ongoing physical activity-relevant

information and updates; and (c) provision of relevant resources such as tip pages and newsletters that Peer Advisors can use in their meetings with their participants.

2.7. Peer Advisor retention methods

In addition to the monthly supervision meetings, other Peer Advisor retention methods include annual informational and motivational workshops provided by Stanford investigators and staff, modest monetary payment for the general time commitment accompanying Peer Advisor activities (i.e., a \$10 local store gift card received upon completion of each participant introductory intervention session; a monthly store gift card commensurate with the number of participant advising sessions completed that month, equaling \$5.00 per advising session), intermittent receipt of low-cost project incentives (e.g., project apparel, project mugs and tote bags), and a certificate of completion honoring each Peer Advisor's contributions to the project at the end of his or her study advising period.

2.8. Development and delivery of study interventions

The two physical activity interventions are based on the theoretically derived cognitive-behavioral advice and support strategies used in the evidence-based Active Choices physical activity counseling program and similar behaviorally based interventions in the field.³⁴⁻³⁷ The primary behavioral theory utilized in the program is Social Cognitive Theory³⁸ combined with the contextual framework of the Transtheoretical Model.³⁹ Social Cognitive Theory (SCT) recognizes the dynamic interplay of cognitive, behavioral, and social factors in influencing behavior change.³⁸ Among the variables derived from SCT are self-efficacy, the use of self-regulatory skills (e.g., self-monitoring, goal-setting), factors related to the physical activity behavior itself

(e.g., format, intensity), and social environmental factors (e.g., modeling, social support, feedback from others), as predictors of physical activity participation.⁴⁰ Applications of the Transtheoretical Model to the health promotion area include the use of a range of behavioral and cognitive strategies aimed at an individual's motivational readiness to change a particular behavior (e.g., consciousness raising and other cognitive approaches in the preparation and action phases early in the program; reinforcement management and related behavioral approaches in the later phase of the program).³⁹

The Virtual Advisor program consists of an embodied conversational agent (ECA)-- an interactive, animated computer character that simulates face-to-face counseling and support using simple speech as well as nonverbal behaviors (e.g., facial cues, hand gestures).^{41,42} (**See Figure 1.**) Individuals interact with it through touching one of several simple conversation boxes shown on the screen throughout the interaction, which eliminates the need to utilize a computer mouse, track pad, or keyboard. The conversation boxes are aimed at less than an eighth grade education level.^{41,43}

The ECA communication interface has been shown to be effective in changing behavior in individuals with little to no computer experience and low levels of health literacy.⁴³ The initial adaptation of the Virtual Advisor program to the Latino population being targeted was accomplished through a smaller intervention study that preceded the current trial²² that was based on earlier work with embodied conversational agents (i.e., virtual advisors) conducted by Dr. Bickmore.⁴² This work was augmented with information from Dr. King et al.'s Active Choices physical activity intervention program.³⁵ The formative testing and pilot work that was conducted also suggested that "Carmen", the virtual advisor, could be acceptable to other midlife and older ethnic minority groups

as well, including Asian, Filipino, and African-American adults. The intervention protocol derived from this prior work was applied, in conjunction with similar intervention work with peer advisors,⁴⁴ in establishing a parallel physical activity counseling program delivered in the trained Peer Advisor arm.⁴⁴

Both individually adapted programs are delivered at each participant's designated community center and focus in particular on walking and similar forms of moderate-intensity physical activity. Both interventions begin with an introductory session that covers the following information:³⁵ (a) review of the participant's physical activity history, long-term goals, and anticipated barriers to and facilitators of regular physical activity; (b) provision of information on the physical activity national guidelines, safety tips, and community center resources; (c) co-creation of a weekly physical activity plan; (d) training in the regular use of a pedometer and a project calendar to log steps and walking minutes; and (e) scheduling of the next intervention appointment.

Following the introductory session, each session follows a standard counseling protocol that is similar across the two interventions and which generally consists of the following elements: greetings and introductory social dialogue, checking for important health changes, review of pedometer-measured steps and minutes walked since the last advising session, acknowledgement of successes, problem-solving around barriers to physical activity, provision of relevant information to continue with physical activity or to overcome barriers, goal-setting for the period between the current and the next advising session, scheduling of the next advising session, and summary and wrap up. The typical advising session for each intervention was developed to average approximately 10-15 minutes, and the general schedule of advising sessions for both

arms over the one-year intervention period, based on previous research,^{31,35} is as follows: weekly sessions for the first two months; and twice-per-month sessions for the remaining 10 months.

In the *Peer Advisor* arm, peer advisors meet with their individual participants in a location within the community center that affords privacy. The *Virtual Advisor*, meanwhile, is housed on a dedicated computer (supplied by the study) located in a private, secure area at each designated community center receiving that intervention. Participants are trained in a brief introductory session with project staff and are provided with a private log-in to initiate sessions with the advisor. Similar to the Peer Advising arm, participants are taught to use an Omron pedometer (Omron Healthcare, Inc., model HJ-720ITC, Lake Forest, Ill, 60045, USA), which provides a valid, reliable daily step count under prescribed and self-paced walking conditions in normal-weight and overweight adults.⁴⁵ Participants are instructed to wear the pedometer on a daily basis, and download it on the Virtual Advisor computer via USB port at each session. The Omron can reliably store data for up to 41 days. Participants also complete a brief survey of personalized information at enrollment (e.g., favorite entertainment, names of supportive relatives/friends) that is programmed into the computer to personalize Virtual Advisor dialogue. Participants are encouraged to wear headphones during Virtual Advisor sessions to ensure privacy. As described earlier, Virtual Advisor and Peer Advisor sessions include individualized social interaction, progress review based on downloaded pedometer information, personalized feedback and problem solving, and goal setting based on current progress.⁴⁶ Educational information can be received if desired in both arms.

2.9. Intervention fidelity and quality assurance

To maintain intervention fidelity and quality assurance in the Peer Advisor arm, trained staff members conduct regular quality control checks and activities as described above.^{31,47} Virtual Advisor quality assurance includes regular monitoring of system performance and backup along with participant log-in activity, and ongoing availability of a study helpline for participants and center staff to call for assistance in correcting any problems. A designated Stanford staff member is in regular contact (twice a month or more frequently as needed) with the Virtual Advisor programming and oversight team at Northeastern University to ensure that any problems that occur can be resolved in a timely manner.

2.10. Assessment: Primary outcome measures

The primary outcome is change in walking activity across the 12-month intervention period. Walking is assessed at three time points (baseline, six months, 12 months) using the four walking items from the validated CHAMPS questionnaire (interview format) for older adults, which is available in English and Spanish.⁴⁸⁻⁵⁰ The CHAMPS questionnaire assesses usual weekly minutes of walking over the previous 4 weeks. Such validated self-report instruments represent the most direct and reliable means for assessing walking patterns, given that device-based assessment tools (pedometers, accelerometers) typically capture more general movement levels beyond walking behavior. The CHAMPS walking items have been significantly associated with pedometer steps in previous studies, and were sensitive to change in the earlier conducted Virtual Advisor physical activity intervention study in a similar group of midlife and older Latino adults.²² The CHAMPS total activity as well as moderate and more

vigorous physical activity (MVPA) variables have been consistently associated with objective physical activity measures in prior studies and therefore will be evaluated as secondary measures of physical activity in the COMPASS Trial.^{51,52} We will also describe the proportion of each arm meeting the national physical activity recommendations of at least 150 minutes/week of MVPA.³

Physical activity measurement using the CHAMPS is accompanied by the validated Actigraph® accelerometer (model wGT3X) at each of the three assessment time points.⁵³ The accelerometer provides objective information related to overall physical activity amounts and intensity (though not the types of activities engaged in). The accelerometry protocol from a large study of 860 older adults is being applied.⁵⁴ The activity monitor is worn on the hip during waking hours for seven consecutive days at each time point, ensuring a sufficient number of days of physical activity data (at least five days is considered as complete data) commensurate with current physical activity studies in older adults.⁵⁵ Participants are instructed to wear the accelerometer for at least eight hours per day during their waking hours. Wear-time validity will be determined through applying the wear and non-wear time analysis and classification algorithms reported by Choi et al.,⁵⁶ and analysis and interpretation of the accelerometry data will be based on our prior investigations and those of other older adult populations.⁵⁷

2.11. Secondary outcome measures

Secondary outcome variables of particular importance to aging Latino populations include the following: sedentary behavior, measured using a validated one-week recall survey responsive to change in older adults;⁵⁸ body mass index (BMI), derived using

standard clinical assessment protocols for height and weight;⁵⁰ resting blood pressure and heart rate, using standard protocols;⁵⁰ and quality of life and well-being, measured with the 10-item Vitality Plus Scale assessing well-being constructs associated with regular physical activity in aging adults, including sleep quality, energy, mood, and pain.⁵⁹

In addition to the above outcomes, program safety and adverse events are being tracked in both intervention arms using standardized forms and protocols used in prior physical activity intervention trials.^{31,36} Also, overall participant acceptability ratings of the novel Virtual Advisor intervention are being assessed at the end of the 12-month intervention period via a 19-item computer program acceptability scale,⁶⁰ a 4-item cultural congruity scale,⁶¹ and the Working Alliance Inventory's 12-item bonding subscale.^{22,62} Similar program acceptability questionnaires are being collected in the Peer Advisor arm at 12 months.³¹

2.14. Randomization of community centers to study arms

Block randomization by county locale was used to assign ten community centers to the two major study arms. Centers were randomized in pairs by locale via coin toss by staff not involved in study assessment or intervention procedures. Allocation concealment was in place for each block of centers during the randomization process to minimize selection bias with respect to subsequent blocks. Assessment staff members are blinded to randomization assignment and masked to prior assessment data for each participant.

2.15. Sample size calculation and data analysis plan

Sample size estimates have been developed to test the study's primary question related to whether the Virtual Advisor intervention is no worse than the intervention delivered by trained human advisors, i.e., a test of non-inferiority.⁶³ Using a two-tailed 95% confidence interval on the effect size (Cohen's d), the threshold of clinical significance between the two treatments, Δ , has been developed to demonstrate clinical noninferiority of the new intervention (Virtual Advisor) if the confidence interval lay completely above $-\Delta$, while clinical noninferiority of the Peer Advisor intervention will be demonstrated if the confidence interval lay completely below $+\Delta$. In this trial, the effect size (Cohen's d) is the standardized difference between the change in walking minutes/week over the 12-month intervention period. The critical value of Δ is based on a clinically meaningful difference between arms of 30 minutes of walking per week,³ and a within-arm standard deviation of 90, accounting for clustering within centers.⁶⁴ The noninferiority margin was based on a clinically meaningful difference, in one direction, between arms of 30 minutes walking/week,³ and a within-arm standard deviation of 90, accounting for clustering within centers ($\Delta=.30$).⁶⁴

We calculated that a sample of 112 per arm (224 total) would provide 80% power to demonstrate noninferiority between the two interventions using a simple pre-post analysis. We plan to use a mixed-effects linear regression model. Mixed-effects linear regression effectively addresses both missing data and early dropout in "intent-to-treat" analysis.^{65,66} In addition, the multiple assessment time points in the trial (at baseline, 6 months, and 12 months) will serve to provide more detailed information on changes over time relative to studies using pre-post assessment only.⁶⁷ Twenty-one additional participants were recruited to protect against loss to follow-up. Similar mixed-effects

linear regression techniques will be used to address the secondary outcomes of interest, e.g., intervention impacts on well-being variables across the study period.

3. Results

3.1. Selection and description of study community centers

Ten community centers located in Santa Clara and San Mateo Counties, California with at least 20% Latino households (range = 21-55% Latino households) living within a one- to five-mile radius from the center were identified and expressed interest in serving as a study intervention site. These sites were block-randomized by locale to either the Peer or Virtual Advisor arms. Soon after recruitment, one center experienced unforeseen changes in its administration that disrupted center operations and precluded center participation in the study. To ensure comparable participant enrollment in each study arm, additional participants were enrolled at the remaining four community centers assigned to that intervention arm.

In each center, there were center staff who were willing to support the research team in reserving meeting space for clinical assessments, recruitment meetings, and, when relevant, Peer Advisor meetings. For the sites that received the Virtual Advisor, designated staff members were instructed on how to maintain the computer kiosk (i.e., refilling printer paper, providing minor technical support related to the computer such as making sure that it was switched on and that the touch screen remained clean, and contacting a member of the research team if needed.)

All participating community centers offered, as part of their usual activities, a nutrition program for older adults as well as nonphysical activity-oriented classes and activities, such as bingo, karaoke, and arts and crafts. Additionally, 89% offered weekly

physical activity classes and had at least one general computer available for older adults visiting their center.

3.2. Study participants enrolled and recruitment sources

A total of 245 participants are enrolled in the primary trial (Peer Advisor arm: n = 122; Virtual Advisor arm: n = 123). Participant baseline demographic and health characteristics are summarized in **Table 1**. The study participants range in age from 50 to 87 years, and 79% are women, with about half of participants reporting being married or living with a partner. The predominance of women is common in such health promotion intervention studies, as is the reluctance of participants, especially from such lower-income communities, to report their household incomes. Forty-four percent of participants have high school or lower levels of education.

The highest recruitment yield (88.7% of enrolled subjects) was obtained from the geographically defined and demographically targeted bilingual mass mailings aimed at the Census blocks surrounding the community centers. The total number of targeted letters mailed describing the study and inviting individuals to contact the study team for more information was 107,930. The total cost of the targeted mailing recruitment strategy equaled approximately \$69,900.00.

3.3. Results related to recruitment and enrollment of Peer Advisors

During the recruitment process for Peer Advisors, 230 individuals expressed initial interest, and 119 individuals were found to be eligible based on the study's Peer Advisor eligibility criteria. Of these individuals, 56 completed the Peer Advisor training requirement, and 36 initiated Peer Advisor activities with at least one participant. Over

the course of the intervention period, six Peer Advisors had to relinquish their peer advisor activities due to a move out of the area, medical illness, or the initiation of a new job which put constraints on their time. Their study participants were transferred successfully to other Peer Advisors with minimal difficulties.

4. Discussion

The COMPASS Trial is among the first studies to systematically compare the effectiveness of physical activity advice delivered by humans versus automated advisors in aging Latino adults. Insufficiently active Latino adults are at elevated risk for a variety of chronic diseases and conditions, yet have rarely been targeted for tailored physical activity advice and support using communication sources (i.e., trained peer advisors, virtual advisors) that have great potential for population transferability and reach. The use of community centers for intervention delivery provides a readily available intervention access point in many communities across the U.S., and the one-year intervention period will provide insights related to initial physical activity adoption and more sustained behavioral maintenance. The multi-faceted recruitment plan allows for a more diverse and potentially generalizable sample, and the particularly high yield of the targeted mass mailings is notable, given its less frequent use in a number of community-based research studies. At least one study has shown that personalized direct mailings can increase response rates for Latino adults relative to non-targeted approaches.⁶⁸ While community-based *promotores de salud* (i.e., lay or peer advisors) are a known and effective mechanism for health promotion in Latino populations, the method has been limited by the ability to scale. If the technology-enabled Virtual Advisor proves comparable and cost-sensitive relative to the Peer Advisor arm, it represents a

scalable and replicable solution that could be readily integrated into current community and senior center infrastructures.

While the primary aim of this trial is to compare the 12-month effectiveness of the Virtual Advisor relative to Peer Advisors, a similarly compelling goal is to explore, through the planned moderator analyses, which participant subgroups may do best with which type of intervention. Referred to as “the whiches conundrum”,⁶⁹⁻⁷¹ ascertaining how best to target different interventions to different subgroups of people represents among the most important challenges currently facing the behavioral health and precision medicine fields.⁶⁹ Similarly, the planned mediator analyses will provide initial information on which types of variables may be of particular importance for achieving intervention-related impacts on physical activity levels.

5. Conclusion

If the promising preliminary Virtual Advisor evidence obtained from the original pilot study²² is confirmed in this comparative effectiveness trial, this intervention will represent a potentially low-cost, readily accessible option that could be broadly disseminated across a range of community settings (e.g., clinics, pharmacies, libraries, residential settings). As such, it has substantial potential to reduce the health disparities gap by influencing a key health behavior in underserved populations.⁷²

HUMAN SUBJECTS

Note: All investigators participating in the proposed research have completed the Human Participant Protections Education for Research Teams certification process in compliance with NIH and Stanford University or Northeastern University guidelines.

I. Consent Procedures

Prior to undergoing the initial telephone or face-to-face screening, the screening procedures will be explained and individuals will give verbal consent to answer initial eligibility questions (age, ethnicity, proximity to community center). Those who are initially eligible will then proceed to an information session where the study activities and procedures will be explained in greater detail. If interested in continuing at that point, individuals will read and sign an informed consent form approved by the Human Use Committee at Stanford Medical School. This consent form will describe the study assessment and intervention components of the project, and their rights as research participants. The consent form will inform individuals that all information is strictly confidential and will not be released to anyone without their written consent. They will be reminded that as volunteers they can terminate their participation at any time without negative consequences. They will be provided information to contact the Medical Committee for the Use of Human Subjects in Research at Stanford Medical School.

II. Potential Risks

The potential risks involved in this project include psychological complications resulting from the assessment procedures or medical risks associated with moderate intensity physical activity programs in persons in this older age group.

Psychological risks of the evaluation. There is a remote risk that persons completing questionnaires focusing on behavioral or psychological content may become distressed. There is no evidence that any permanent psychological dysfunction has resulted from such assessments.

Medical risks of physical activity programs. The major risks of physical activity programs by initially inactive persons aged 55 years and over are orthopedic and cardio-respiratory. Orthopedic problems primarily are of the overuse variety and usually can be treated by rest and change in the mode of physical activity. Frequent minor problems can occur, including temporary soreness or irritation of muscles, tendons and joints. The likelihood of orthopedic and cardio-respiratory risks are greatly minimized through the use of a moderate-intensity physical activity program that involves mild to moderate-intensity walking, as proposed in the current study, and a supervised, individualized, progressive approach to physical activity as proposed in the current program.

III. Minimizing Potential Risk

Study assessments will be conducted at the community centers by extensively trained and supervised study staff.

Physical activity programs. To ensure participant safety in this study, we will apply the set of screening and oversight procedures that are recommended in the American College of Sports Medicine's (ACSM) guidelines and that we have used successfully in our research studies over the past 30 years. As recommended in the current ACSM guidelines, to screen potential participants for appropriateness for the physical activity program, we will have each individual complete the Physical Activity Readiness Questionnaire (PAR-Q), an extensively validated and used screening questionnaire that

has been used throughout Canada and the U.S. to screen individuals for community-based physical activity programs. If individuals answer 'yes' to any of the medically related screening items, they will be directed to get physician clearance prior to entry into the study. This protocol has been shown to ensure participant safety without creating unnecessary medical expenses and barriers to participation for persons not deemed at risk for physical activity-related complications---an important issue for the low-income population being targeted. The use of a mild form of physical activity (walking) also diminishes risk. In addition, participants will be regularly monitored for any level of physical discomfort or injury as part of the virtual advisor and lay advisor programs, and all subjects will be evaluated for adverse events as part of the study assessments conducted every 6 months using the standard forms approved for use by the Stanford Institutional Review Board.

The risks of injury resulting from participating in the prescribed physical activity programs will be minimized in several ways:

- Exclusion from the study of any person with overt cardiovascular or orthopedic disease.
- Individualized physical activity program aimed at slow, gradual progression of physical activity amount.
- The use of moderate-intensity physical activity programs, involving walking, for all study participants.
- Ongoing personalized instruction of participants as part of the evidence-based physical activity advisor programs.
- Ongoing attention to and advice related to the experience of physical discomfort during physical activity as part of both evidence-based physical activity advisor programs. (In addition, standard advice from the current U.S. Department of Health and Human Services' national physical activity recommendations

concerning physical activity safety is provided as part of the health education attention-control program.)

The content of the moderate-intensity physical activity program that is being targeted is commensurate with the current national guidelines for physical activity promotion in older adults.

Confidentiality of participant data. Confidentiality of participant data will be maintained by handling individual data by ID number, rather than by name; storing all individual data in locked file cabinets and secured, password protected electronic hard drives and data servers; and not disclosing individual data to anyone other than project staff, except as requested by the participant in writing.

Adverse event monitoring and reporting. Adverse events information will be collected at all assessment points and recorded on standard forms that have been used in our other studies. We will collect information on all potential types of adverse events, including musculo-skeletal soreness and injury, as well as major medical events including injuries or conditions that result in health care provider visits, hospitalization, etc. Consistent with NIH and Stanford IRB policy, adverse events will be promptly reported in writing to the NIH and Stanford IRB.

IV. Risks versus Benefits

We believe the risks involved with the proposed physical activity interventions and associated tests are very small. Our own experience in studies involving the assessments proposed and the encouragement of progressive, moderate intensity physical activity in screened participants in this age group has been very positive. We

are not aware of a single long-term adverse reaction to such physical activity programs among the over 3,000 study subjects we have monitored over the past 30 years.

We believe that all participants will benefit by learning (from the study questionnaires) about their health status and physical activity levels. Those who successfully improve their physical activity levels will have achieved desired goals. Over the study period, all participants will benefit from receiving health information.

We believe society will benefit from the results of this project in that it will inform further research aimed at developing effective and appropriate physical activity programs for under-served ethnic minorities. It will shed light on how best to deliver physical activity advice to enhance adoption and maintenance of PA among Latinos using state-of-the-art informational technology that could conceivably be utilized in a range of community and home settings, thus substantially broadening the reach of the physical activity counseling program to underserved populations at potentially lower-cost than traditional face-to-face or health care provider-delivered approaches. These are public health issues of immense proportions, particularly with the continued growth of the elderly segment of the U.S. population and the substantial prevalence of inactivity among that population segment. In summary, we believe the risks can be kept very low whereas the benefits to participants and society are quite substantial.

Data and Safety Monitoring Plan

In addition to ongoing (weekly) project oversight by our senior investigators, the project's Data and Safety Oversight Committee, will meet at regular intervals (e.g., semi-annually or more frequently as indicated) throughout the project period to provide input and feedback related to study recruitment and retention rates, study eligibility

determination issues, data completion rates, and adverse events. During the study, participants will regularly monitor any discomfort that they are experiencing from the moderate-intensity physical activity program (consisting of walking) and will report them to their physical activity advisor on a weekly basis. We will use this information to revise the interventions as necessary to ensure that any risks of injury or discomfort are minimized.

Table and Figure Descriptions

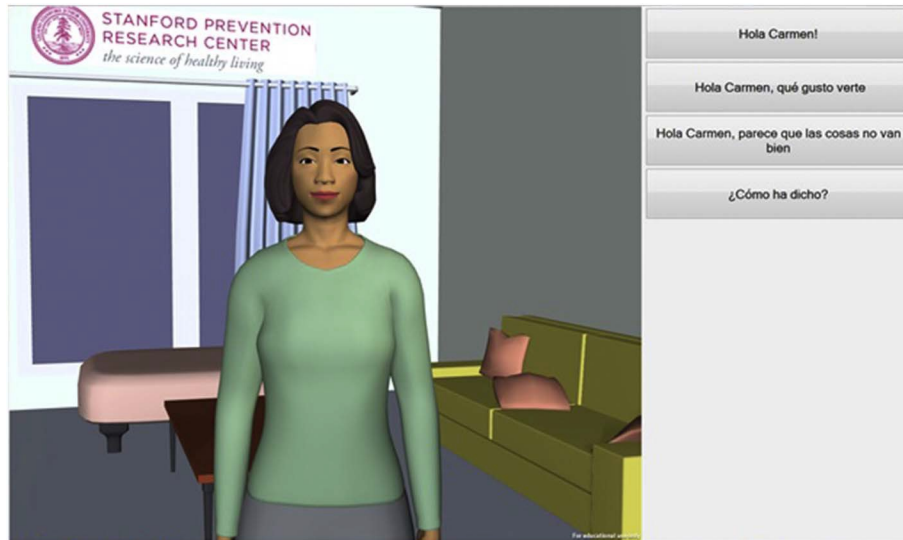
Table 1. Descriptive statistics for the trial sample and by randomization arm

Figure 1. Screenshot of the Virtual Advisor (“Carmen”)

Table 1
Descriptive statistics for the sample and by randomization arm.

	All		Virtual Advisor		Peer Mentor		Between group <i>p</i> value
Variable (categorical)	N	%	N	%	N	%	
Sex							
Women	193	78.8	98	79.7	95	77.9	0.73
Men	52	21.2	25	20.3	27	22.1	
Race/ethnicity							
Hispanic	241	98.4	120	97.6	121	99.2	0.71
Asian	3	1.2	3	2.4	0	0.0	
White	1	0.4	0	0.0	1	0.8	
Country of birth							
United States	100	40.8	53	43.1	47	38.5	0.01
Mexico, Central, South America	139	56.7	65	52.8	74	60.7	
Other	3	1.2	2	1.6	1	0.8	
Missing	3	1.2	3	2.4	0	0.0	
Marital status							
Married or living with partner	125	51.0	59	48.0	66	54.1	0.11
Not married or living with partner	118	48.2	63	51.2	55	45.1	
Refused	2	0.8	1	0.8	1	0.8	
Education							
Less than High School	62	25.3	27	21.9	35	28.7	0.42
High school	45	18.4	28	22.8	17	13.9	
Some college	80	32.7	39	31.7	41	33.6	
College	27	11.0	15	12.2	12	9.8	
Postgraduate	28	11.4	12	9.8	16	13.1	
Missing	3	1.2	2	1.6	1	0.8	
Household income							
< \$5000 to \$34,999	32	13.1	17	13.8	15	12.3	0.97
\$35,000 to \$49,999	23	9.4	11	8.9	12	9.8	
\$50,000 to \$74,999	30	12.2	16	13.0	14	11.5	
\$75,000 or greater	45	18.4	21	17.1	24	19.7	
Don't know, refused, missing	115	46.9	58	47.2	57	46.7	
Variable (continuous)	Mean	SD	Mean	SD	Mean	SD	
Age (yr.)	62.3	8.4	63.1	8.3	62.4	8.5	0.82
Years in US	47.4	17.0	47.7	17.2	47.1	16.8	0.80
Number in household	3.5	2.2	3.7	2.5	3.3	1.8	0.16
CHAMPS Q – baseline (min/wk.):							
Walking for exercise & leisure	45.9	91.6	48.0	98.1	43.6	81.4	0.71
Walking briskly	3.7	16.1	5.1	19.7	2.3	11.4	0.18

Fig. 1. Screenshot of the Virtual Advisor (“Carmen”).



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