MY BODY, MY RHYTHM, MY VOICE PROMOTION OF PHYSICAL ACTIVITY IN BREAST CANCER SURVIVORS IN COLOMBIA

STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

OCTOBER 2018

A. Specific Aims (Overall Plan)

The goal of this project is to build a state-of-the-science regional center of research excellence in Colombia known as the <u>Stanford-Colombia Collaboratory on Chronic Disease</u> (S-C³). The Collaboratory will focus on primary and secondary prevention of the major non-communicable diseases (NCDs) facing Colombia and the Latin American region, including cancer, cardiovascular disease, diabetes, and depression.¹⁻⁴ Using a socio-ecological framework,⁵⁻⁹ the S-C³ will emphasize a multi-sectoral and transdisciplinary approach to develop, test, and disseminate impactful NCD prevention programs in Colombia, as well as from Colombia to the Latin American region. In Latin America, 69% of deaths are due to NCDs and these rates are increasing.^{1,2} In Colombia, the third largest country in the region after Mexico and Brazil, 71% of deaths are due to NCDs.^{1,2} Low- to middle-income countries (LMICs) like Colombia face significant challenges in effectively controlling this epidemic due, at least in part, to limited research to support innovative and effective interventions.

Physical inactivity is one of the most important contributors to the global burden of NCDs, responsible for ~6-10% of major NCDs worldwide.¹⁰ The prevalence of physical inactivity and sedentary behavior is increasing in LMICs and approaching levels of higher income countries such as the US.¹¹ In Colombia, 47% of adults and 74% of adolescents do not meet physical activity recommendations, comparable to levels in the US and higher than other Latin American countries such as Mexico, Ecuador, and Uruguay.¹¹ Multi-level approaches that promote physical activity (PA) at the individual, family, community, and societal levels hold substantial promise for effectively preventing and controlling the major NCDs.^{8,9,12,13} We and others have demonstrated effective strategies for increasing PA among residents across the socioeconomic gradient, including leveraging widely available information technologies such as smartphone applications (apps), SMS text messaging, interactive voice response systems, and culturally tailored virtual advisors.¹⁴⁻²¹ However, substantial gaps remain in developing and testing such potentially far-reaching PA interventions in LMICs such as Colombia.²²

In Latin America, existing research efforts in the field have centered primarily on surveillance and other observational methods that lack potential to directly impact the increasing prevalence of NCDs locally and regionally. With support from US-based colleagues, Colombian researchers and stakeholders from multiple sectors can develop the necessary infrastructure and capacity to serve as a model and resource for cutting-edge research aimed at developing effective PA interventions, rigorously testing these approaches in diverse communities, and effectively disseminating promising strategies. Developing the research capacity to support effective behavioral interventions to increase PA in Colombia will have far-reaching effects for the Latin American region given Colombia's position as a regional leader in PA research and other relevant domains.

This grant application builds upon an existing productive collaboration between scientists from the Stanford University School of Medicine, CA and the Universidad de los Andes (UniAndes) in Bogotá, Colombia. Building the S-C³ will allow scientists in the region to expand their expertise to include development and rigorous evaluation of behavioral interventions to promote PA that hold particular promise for impacting current NCD trajectories in the region. The S-C³ will emphasize, in particular, innovative applications of technology tools to increase intervention effectiveness and scalability. Additionally, the S-C³ partnership will include organizations from multiple sectors such as sports and recreation, education, and urban planning.

The Specific Aims of the overall project are to:

- Establish the necessary infrastructure to support a regional center of research excellence for NCD prevention in Colombia. The S-C³ will represent a partnership between Stanford School of Medicine, Universidad de los Andes, and their academic, governmental and non-governmental partners from the sectors of Health, Sports and Recreation, Transport, and Urban Planning.
- 2. Build sustainable mechanisms for increasing research capacity aimed at developing and rigorously testing theory-based interventions that leverage widely available technologies aimed at primary and secondary prevention of NCDs in Colombia. Capacity-building activities in Colombia will serve as a resource and a model for other Latin American countries.
- 3. Demonstrate the partnership's capability for engaging in cutting-edge behavioral intervention research to promote physical activity and prevent NCDs. We will conduct 2 pilot studies that target individual and community levels of impact to increase physical activity in underserved populations.
- 4. Develop short-, mid-, and long-term transdisciplinary research plans that focus on optimizing regional capacity for impactful change in the prevalence of NCD's in Colombia. The research plans will leverage the partnership's expertise in utilizing technology for physical activity promotion in diverse Latino populations from the US and in the Latin American region.

Successful completion of these aims will result in the needed infrastructure and mechanisms for building research capacity, experience conducting research, and comprehensive research planning to initiate a regional center of excellence focused on promotion of physical activity and reduction of NCDs in Colombia. The plans for the S-C³ will support a regional model and resource that will serve the Latin American region.

B. Research Strategy – Overall Plan

B.1. Overview of Proposed Plan

The proposed regional center of research excellence is labeled a *collaboratory*, which refers to a borderless research environment in which scientists in the US, Colombia, and the Latin American region can work and interact with each other to develop, evaluate, and disseminate the most effective and scalable strategies for NCD prevention.²³ **Table 1** summarizes proposed aims and objectives. Successful completion of these aims will result in a multi-sectoral and transdisciplinary partnership, robust research enhancement activities, two pilot research projects that will demonstrate the team's ability to collaborate and publish research together, and a well-conceived research plan for advancing the aims of the Collaboratory both currently and into the future. These aims and objectives will serve as a road map for other Latin American partners to support rigorous research aimed at NCD prevention and control in the region.

Table 1. Stanfor	d- <u>C</u> olombia <u>C</u> ollaboratory on <u>C</u> hronic Disease (S-C ³) Aims and Objectives
Aims	Objectives
1. Establish Collaboratory infrastructure	1.1 Enhance multi-sectoral research partnerships and communication pathways for capacity building and intervention development;1.2 Finalize shared cores that will provide support for training and research activities.
2. Build/expand mechanisms for capacity building in Colombia	 2.1 Scholar exchange between UniAndes and Stanford University; 2.2 Professional certificate program focused on planning and evaluation of theory-based interventions for health promotion/disease prevention; 2.3 Masters Program in Epidemiology with a track focused on behavioral interventions; 2.4 1-day seminar courses for community members and key stakeholders.
3. Conduct joint pilot projects	3.1 Community-based intervention to promote physical activity among breast cancer survivors; 3.2 Longitudinal evaluation of community-wide Ciclovía/Recreovía programs.
4. Finalize center research plans	 4.1 Needs assessment with community members and key stakeholders using interviews and a network analysis of organizational and communication pathways and connections in Colombia; 4.2 Finalize short-, mid-, and long-term goals and expected outcomes.

B.2. Structure, Leadership, and Experience

The Collaboratory expands an existing partnership between scientists from the Stanford University School of Medicine and Universidad de los Andes (UniAndes). The partnership will include organizations from multiple

Partner	Sector	Description	Role
Stanford University	Education	One of the world's leading research and teaching universities.	Oversight of research and training, advising in implementation and evaluation of projects and courses
Universidad de los Andes (UniAndes)	Education	One of Latin America's top universities and the highest ranked university in Colombia.	Lead research and training efforts with support from Stanford; Coordinate partnership with multi- sectoral partners
Universidad del Rosario	Education	Leading academic institution in Colombia for physical activity research, including measurement and interventions.	Steering committee member and collaborator for pilot studies
Fundación Simmon	Health	Non-governmental organization that advocates for cancer prevention and treatment.	Steering committee member and collaborator for pilot studies
National Institute of Cancer in Colombia	Health	National institute that advocates for primary and secondary cancer prevention.	Steering committee member and collaborator for pilot studies
Institutes of Sports and Recreation of Bogotá (IDRD)	Sports and Recreation	Government institution in charge of the implementation and coordination of the Ciclovía and Recreovia programs in Bogotá.	Steering committee member and collaborator for pilot studies
Ministry of Sports (COLDEPORTES)	Sports and Recreation	Government institution in charge of the Network of Ciclovías and Recreovias of Colombia.	Steering committee member and collaborator for pilot studies
Administrative Department for the Defense of the Public Space (DADEP)	Transport & Urban Planning	Government institution in charge of protecting Bogotá's public space.	Steering committee member and collaborator for pilot studies

sectors representing sports and recreation, education, and urban planning (**Table 2**). The main center for S-C³ and the majority of activities will occur at UniAndes, with Stanford playing a supporting role.

Olga Sarmiento, MD PhD (UniAndes) and Abby King, PhD (Stanford) will serve as Multi-Pls. Carolyn Finck, PhD (UniAndes), Robert Haile, DrPH MPH (Stanford), and Lisa Goldman Rosas, PhD MPH (Stanford) will serve as co-investigators (Table 3). The investigative team brings complementary expertise representing multiple scientific disciplines, and has prior experience engaging in successful collaborations. **UniAndes experience:** Drs. Sarmiento and Finck bring extensive experience in evaluation and cultural adaptation of multi-sectoral programs to promote physical activity (PA) in Colombia such as the Ciclovía and Recreovía programs. They have experience in testing, developing, and validating instruments for the assessment of PA, physical and mental health, and quality of life. UniAndes also has experience in reaching and working effectively with policy makers through the Schools of Medicine, Government, and Law. Stanford experience: Drs. King, Haile, and Goldman Rosas bring broad experience in collaborating with LMIC institutions in Latin America on research related to chronic disease and cancer prevention and control. Dr. King was one of two US behavioral scientists participating in the 2011 CDC-sponsored International Think Tank aimed at Changing Physical Activity and Diet Behaviors in the Context of Latin America, held at UniAndes; she led, with Dr. Haile, a 2016 follow-up PA intervention Think Tank at Stanford; has led US-funded PA intervention research in Mexico in collaboration with the Mexican National Institute of Public Health (INSP); and sponsored an initial UniAndes graduate scholar traineeship at Stanford. Dr. Haile directs the Latin American Cancer Epidemiology (LACE) Consortium, established with NCI to facilitate and coordinate cancer epidemiology research in Latin America, with over 20 investigators in ten countries. Dr. Goldman Rosas has an ongoing collaboration with Mexico's INSP focused on obesity prevention and treatment among children and adults.²⁴⁻²⁶

Table 3. Research team				
Investigator	Expertise	Role		
Olga Lucia Sarmiento MD PhD	 Development of epidemiologic studies of behavioral lifestyle multi-sectoral community programs Experience teaching biostatistics, epidemiology and PA measurement methods Experience in multi-country studies 	PI: primary role Aims 1-4		
Carolyn Finck Barboza, PhD	 Psychometric validation of instruments to assess health related quality of life and mental health Assessment of mental health issues in breast cancer patients in Colombia and Germany Experience in teaching personality and health psychology courses 	Co-I; primary role Aim 2		
Abby King, PhD	 Applications of behavioral science theory and research in promoting NCD prevention interventions in US and globally Development and evaluation of culturally adapted mobile health interventions in diverse communities Tailoring of health promotion interventions, using a socio-ecological framework, for underserved populations 	PI; primary role Aims 1-4		
Robert Haile, DrPH	 Extensive experience establishing and directing international research consortia Experience in cancer epidemiology and prevention trials 	Co-I, primary role Aim 1, 4; supporting role Aims 2, 3		
Lisa Goldman Rosas, PhD MPH	 Development and testing of behavioral lifestyle interventions Effective community engagement Significant experience developing educational programs focused on community health and preventive medicine 	Co-I, primary role Aim 2, 3; supporting role Aims 1, 4		

Collaborative experience: The UniAndes and Stanford teams have successfully collaborated on several pilot projects using mobile technology,¹⁴ facilitated bi-directional training in both sites, and, as noted above, participated in regional think tanks focused on behavioral change and PA interventions, first held in Bogotá in 2011 and again in 2016 at Stanford. During the latter, organized and hosted by Drs. King and Haile, this Collaboratory was identified as a critical priority for Colombia and the region. The successfully implemented pilot projects included: 1) using the Nuestra Voz (Our Voice) citizen scientist model in evaluating Ciclovías in Bogotá;¹⁴ and 2) initiating adaptations of three smartphone apps based on distinct motivational frameworks to promote PA among UniAndes employees. Both pilot projects were the result of training exchanges between Stanford and UniAndes; Dr. King conducted training in behavioral science at UniAndes in 2011 and Susana Barradas, predoctoral student with Dr. Finck, subsequently came to Stanford for 6 months.

B.3. Setting and Value added: Why Colombia?

Colombia is an ideal setting for the proposed regional center of research excellence due to existing national multi-sectoral programs to promote PA with the potential for scalability in the Latin American region, recent shifts in policy to support NCD prevention, and a strong scientific foundation.

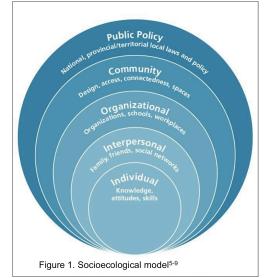
B.3.1. Colombian context. Colombia is an international leader in developing innovative PA programs, some of which have been in place for more than 20 years. For example, programs like Ciclovía and Recreovía were implemented in Colombia years ago and are now being implemented in other LMICs as well as higher income nations (see **B.6.2** and Montes et al., 2012²⁷). However, their effectiveness has never been evaluated in a rigorous manner. In terms of the policy context, Colombia's priorities related to NCD have shifted from acute treatment to primary and secondary prevention, providing critical support for the research of the S-C³. PA promotion is a priority topic in Colombia for NCDs prevention in the public health agenda. The National Development Plan 2014-2018 establishes healthy lifestyles promotion, including PA, as one of the strategies to reduce the morbidity and mortality associated with cancer, cardiovascular disease, diabetes and other NCDs.²⁸ The Ten-Year Plan of Public Health establishes goals and strategies to improve PA levels among the Colombian population.²⁹ Other policies that prioritize PA as one of the targets for NCD prevention are: the Obesity Law.³⁰ the National Plan of Food and Nutrition Security, and the Ten-Year Plan of Cancer Control, which includes PA promotion as one of the strategic lines for primary prevention, establishing goals and specific action items at the levels of policy, community, and health services.³¹ Building on a strong political agenda, Colombia is at an ideal juncture to leverage scientific expertise in observational research methods and apply this experience to the development and rigorous evaluation of behavioral interventions. Researchers, led by Drs. Sarmiento and Finck, have made strong contributions to the understanding of PA patterns and determinants in Colombia and Latin America,^{22,32-37} and are now poised to utilize this body of research to support cutting-edge intervention research. Finally, Colombia is the third largest country in Latin America, with numerous demographic and social factors that make it characteristic of other countries in the region. For example, the sub-cultures found in the Andean region share elements with other Latin American countries with similar characteristics, while the Caribbean region resembles other Caribbean countries. Thus, strategies and approaches that are developed by $S-C^3$ would likely be relevant to other countries in the region. Additionally, Drs. Sarmiento and Finck are members of academic networks with researchers in other Latin American countries (e.g., Network of Physical Activity of the Americas, Network of Ciclovías of the Americas, Active Healthy Kids Global Alliance) that will facilitate the translation of results to the region.

B.3.2. Value added. A primary value added by S-C³ will be to facilitate the transition of behavioral sciences in Colombia (and the region) from observational studies to intervention studies in a manner that we believe will be scalable and sustainable. We will avoid duplication in two ways: 1) we will involve representatives of the multiple sectors that have a shared interest in this field to collaborate with us throughout this process (note that Drs. Sarmiento and Finck are already well connected with the relevant sectors); and 2) our focus will be on intervention-based research, of which there is currently virtually none of relevance in Colombia.

B.4. Aim 1: Establish S-C³ Infrastructure

S-C³ leaders will cultivate strong multi-sectoral partnerships and develop cores that will provide the infrastructure needed to support the Collaboratory's training and research endeavors. The S-C³ is guided by the socio-ecological framework that describes how health behaviors, such as PA, are influenced by multiple factors at the individual, family, organizational, neighborhood, and policy levels (**Figure 1**).⁵⁻⁹ The partnerships and shared core resources will support program development, evaluation, and dissemination across these multiple levels of influence. Partnership development activities will be guided by Community-Based Participatory Research (CBPR) principles emphasizing the importance of equitable and genuine participation in all phases of research.³⁸⁻⁴⁰

B.4.1. Enhance multi-sectoral partnerships. The rationale for the partnerships that will form part of S-C³ is twofold. First, the institutions and organizations selected represent sectors that are well positioned in Latin America to address the multiple levels of



influence on PA for adults and children as described by the socio-ecological model. We recognize that NCD risk factors such as physical inactivity can rarely be modified through policies and interventions within the health sector alone. Rather, prevention measures that address physical inactivity embrace a range of different

sectors, including education, sports and recreation, and urban design and transport, along with civil society and the private sector. Second, the specific types of partnerships formed through S-C³ will have high potential for replication in other Latin American countries.

Enhancement activities: The partners that form an integral part of S-C³ (**Table 2**) have already been engaged in developing this proposal, with local meetings with stakeholders in Colombia conducted by Drs. Sarmiento and Finck, two international meetings (Bogotá and Stanford), and weekly teleconferences for the past two months. These relationships will be fortified further during the project period with support from the Community Engagement Core (see **B.4.2**). Using principles of CBPR,³⁸⁻⁴⁰ representatives from each partner will form a Steering Committee that will be a central governing body for the Collaboratory (see letters of support). The Steering Committee will meet monthly in the first six months, quarterly thereafter, with additional as-needed meetings for specific projects. These meetings will provide opportunities for research enhancement activities (see **B.5**), and will be used for strategic coordination of all Collaboratory activities. Drs. Sarmiento and Finck will facilitate these meetings with support from the Community Engagement Core (see below). The partners also will be engaged in the training and research activities of the Collaboratory. The Steering Committee will proactively identify and agree by consensus if additional partners are needed to complete its objectives. **B.4.2.** Cores. Drs. Sarmiento and Finck engaged scientific leaders and key stakeholders to identify the primary gaps in advancing behavioral intervention research in Colombia and the region, which included: 1) Data management and analysis of observational and experimental behavioral intervention studies; 2) Development of theory-based behavioral interventions and evaluation design; and 3) Community engagement and translation. Based on these gaps, the S-C³ will provide three Cores described below. Each Core will be led by members of the investigative team and will include a knowledge bank and training opportunities. A transdisciplinary advisory panel of researchers from Stanford, UniAndes, and partner organizations will be available to consult on Collaboratory activities (e.g., Drs. Michele Barry [global health], Mike Baiocchi [biostatistics in global contexts] Sanjay Basu [cross-country data modeling and comparisons]). The Cores will provide a foundation for research enhancement activities (B.5).

1. Data management and statistical analysis core. This core will focus on data management and analysis from observational and experimental research. It will be centered at UniAndes and led by Dr. Sarmiento with support from Andrés Medaglia, director of Industrial Engineering and the Analytics program at UniAndes, and Dr. Haile. We will develop a knowledge bank of resources for effective data management and other online data collection tools (e.g., REDCap, data visualization tools), as well as data analysis resources with help from Dr. Haile. The core will establish an online repository where scientists can share analysis code (e.g., R code for analyzing accelerometry data, procedures for analyzing PA diary data) and other analysis resources (e.g., instructions for scoring international PA questionnaires, and forms for systematic observation of spaces for PA, GIS data analysis, and network analysis).

2. Development and evaluation of theory-based behavioral interventions core. This core will support the development of innovative behavioral interventions for increasing PA and decreasing sedentary behavior as well as the design of rigorous evaluations of these programs. Dr. King will provide overall leadership for this core with support from Dr. Finck and Diana Agudelo PhD, director of the psychology department at UniAndes. We will develop a knowledge bank with the following content: 1) information on existing evidence-based PA interventions; 2) strategies for successful adaptation of evidence-based interventions to the Latin American context; 3) validated measures for intervention evaluation; and 4) strategies for validation of other measures.

3. Community engagement and translation core: This core will provide knowledge and resources for effectively engaging community members and key stakeholders to support the development, evaluation, and dissemination of PA interventions. Dr. Goldman Rosas will lead this core with support from Catalina Gonzalez MA, MSc, PhD, director of the Epidemiology program at UniAndes. The knowledge bank will include information on best practices for engaging community members and key stakeholders in intervention research, as well as key resources such as partnership agreement templates and data sharing plans, training materials for community members engaging in research, and information on training in the ethical conduct of research.

B.5. Aim 2: Building Sustainable Mechanisms for Capacity Building

We propose bi-directional training methods between Stanford and UniAndes that build on existing multidisciplinary programs. The UniAndes programs are relatively new and will greatly benefit from the experience at Stanford. We will also engage trainees through providing hands-on research experience as part of the two innovative pilot projects.

B.5.1. Scholar exchange. An aim of the S-C³ is to build a scholar exchange program, initially focused on postdoctoral and graduate-level scholars, that will emphasize mutual learning opportunities. For example, Stanford postdocs would spend an average of two weeks in Colombia helping to present information and participate in relevant research projects under the guidance of Drs. Sarmiento and Finck. Similarly, fellows from Colombia would spend an average of two weeks at Stanford, participating in selected lectures and

discussion groups along with relevant research and training activities under the guidance of Drs. King, Haile, and Goldman Rosas. During the first two years, we plan on one Stanford fellow spending time in Colombia and one from Colombia spending time at Stanford to gain relevant experience in how to optimize training experiences in both locales. Additional trainees can participate with support from outside sources. B.5.2. Professional certificate program. We will develop a Professional Certificate Course in behavioral science for health in Colombia that will be accessible to trainees, partnership organizations, key stakeholders and others. Professional certificate courses are commonly used in Latin America and are an effective strategy for enhancing research capacity; the course can also serve as an elective for masters students. Based on a successful professional certificate program at Stanford (Stanford Health 4 All, Dr. Goldman Rosas is a core faculty member) the professional certificate course will use case studies based on relevant behavioral science research.^{15,21,41} Participants will learn about health behavior theories and behavior change constructs, relevant measurement approaches, and program design and implementation. The certificate program will also serve as an elective course in currently offered master programs at UniAndes (MPH, psychology, engineering). B.5.3. Masters program. We will lay the groundwork to develop a Masters of Epidemiology program at UniAndes in 2017. The specific objectives of the Masters of Epidemiology are: 1) understanding of the contributions of epidemiology and biostatistics to health research in interdisciplinary contexts: 2) design. conduct, and analysis of clinical and social epidemiologic investigations; 3) critical appraisal of epidemiologic studies, including synthesis and integration of epidemiologic research and causal inference; and d) interpretation and communication of epidemiological research for interdisciplinary audiences. The S-C³ team will draw on the extensive experience that Stanford has in developing and maintaining an MS in Epidemiology and Clinical Research and an MS in Community Health and Prevention Research. **B.5.4. Sources of trainees in Colombia.** Sources of potential trainees include the following: Doctoral students from the Ceiba Foundation: "Ceiba" is the Spanish acronym for Center of Interdisciplinary Studies in Basic and Applied Complexity. Ceiba includes four top universities in Colombia (UniAndes, Universidad Nacional de Colombia, Universidad Javeriana, la Universidad del Rosario). Ceiba started 7 years ago in response to a call from the National Department of Science. Technology and Innovation to create Excellence Centers in Colombia, and has had more than 40 affiliated doctoral students. **MPH students:** The MPH program at UniAndes is a unique joint program between the Schools of Medicine and Government, begun in 2012. Specific objectives of the MPH program are to: (1) provide a basic foundation of knowledge in public health and health policy; and (2) teach concepts and scientific skills in epidemiology, biostatistics and health policy. We propose to add training in behavioral sciences as an elective course. MS and Doctoral students and postdocs in Psychology: The Masters of Science in Research in Psychology is a two-year program with mandatory courses in advanced gualitative and guantitative methods as well as in program evaluation and design. There is also a 4-year doctorate program in Psychology and postdoctoral programs there through which additional synergies can be explored. **B.5.5.** Sources of trainees in US. Trainees at Stanford will primarily come from 3 programs: Stanford Prevention Research Center (SPRC) Postdoctoral Fellowship (Dr. King is Co-Director): There

is funding for 6-8 postdoctoral fellowships each year to focus on chronic disease prevention research. **Masters of Science programs:** Masters-level students in Community Health and Prevention Research (Dr. Goldman Rosas is a core faculty member) and Epidemiology (Dr. King is Chair of the program admissions committee and a core faculty member) may participate in bi-directional training opportunities as part of S-C³.

B.6. Aim 3: Conduct Joint Pilot Projects

We will complete two joint pilot projects that will demonstrate the Center's ability to collaborate effectively, engage partners from multiple sectors, and develop and conduct preliminary evaluations of interventions at multiple levels of impact (e.g., individual, social, environmental, community).

B.6.1. Pilot Study # 1: Promoting physical activity (PA) among breast cancer survivors in Colombia *Rationale:* Breast cancer is the most common cancer in women worldwide.^{42,43} In Colombia, nearly 5,000 new cases are diagnosed annually.⁴⁴ PA is associated with decreased cancer risk.¹⁰ A growing body of evidence supports the idea that increasing PA provides important benefits to psychological and physical wellbeing in breast cancer patients.⁴⁵ We will design a theory-based intervention to integrate PA promotion into clinical care for breast cancer survivors, with the ultimate goal of secondary prevention and enhanced survival. *Methods:* We will conduct a small, randomized controlled study of a PA intervention or a control group that will receive an education program not related to PA. The intervention will include supervised exercise through dancing and a culturally relevant and piloted smartphone app aimed at promoting PA and decreasing sedentary behavior. The primary outcomes for this pilot will be weekly minutes of PA, quality of life, and mental health – specifically, anxiety and depression. This project will involve partnerships between researchers at Stanford School of Medicine, the Institute of Sports and Recreation in Bogotá, the Universidad del Rosario, the Foundation Simmon, the National Cancer Institute of Colombia, and UniAndes.

Analysis: We will use a mixed methods approach to access acceptability, feasibility, and preliminary effectiveness of the intervention. Acceptability/feasibility: Qualitative methods will include focus group discussions with participants at the conclusion of the study to explore acceptability and feasibility. Nonparticipants will be included in focus groups to examine factors influencing participation. Quantitative methods will include ratings of intervention components to capture acceptability, practicality, and motivational capabilities on a Likert-type 7-point scale (with a goal of obtaining acceptability mean ratings >6 out of 7). Preliminary effectiveness: To assess preliminary effectiveness, we will use repeated measures ANOVA, Kruskal–Wallis and McNemar tests to establish the change in outcomes before and after treatment. Outcomes will include physical activity/sedentary behavior,⁴⁶ health-related quality of life,⁴⁷ and anxiety and depression.^{37,48} (All measures have been tested in and shown to be appropriate for Latino populations.) B.6.2. Evaluation of community Ciclovía/Recreovía programs to promote PA in public spaces Rationale: The Ciclovía is a multi-sector program in which streets are closed to motorized vehicles and open exclusively for individuals to enjoy safe, free spaces for leisure activities.^{32,35,49} Ciclovías at least twice/year are implemented in at least 496 cities in 27 countries, and 93% of programs are in Latin America. The model for many of them worldwide is the Bogotá Ciclovía. The Recreovía is a community-based PA program that comprises free PA classes in public spaces (parks, plazas, streets, malls, community centers) led by trained instructors.⁵⁰ In 2015, Recreovía offered PA classes in 41 hubs in 95% of Bogotá's districts, with 75% of those hubs in low- to middle-income neighborhoods. We will design the prospective evaluation of the Ciclovía/ Recreovía programs to promote PA and cancer prevention among women (ultimate goal=primary prevention). *Methods:* We will: 1) design and develop the logic model/ theory-based instruments for these existing programs that promote PA in public spaces; 2) assemble, based on previous cross-sectional studies, an appropriate cohort study including 100 adults \geq 30 years old who are regular users of the programs (i.e., participate every week) and irregular users of the program (i.e., once a month or less) with a follow-up after 6 months; 3) measure initial uptake of the program and demonstrate the feasibility of follow-up over time. This project will involve partnerships between Stanford researchers, the Institute of Sports and Recreation in Bogotá, the Health Department of the city of Bogotá, DADEP, and UniAndes.

Analysis: We will use mixed methods to assess the longitudinal impact of the Ciclovía/Recreovía on physical activity levels among adults and children. For qualitative methods, we will use the citizen scientist *Nuestra Voz* (Our Voice) model that employs a tablet-based application to empower residents to document features of their neighborhoods that promote and hinder physical activity.^{14,41} Drs. King, Goldman Rosas, and Sarmiento have successfully used this approach in diverse communities including with Latinos in the US and in Latin America. For quantitative methods, we will assess the median differences in moderate to vigorous PA (pre-post) and interquartile range (IQR) of the self-reported⁴⁶ and objectively measured (via accelerometers) PA outcomes, which will be compared using the Wilcoxon Signed Rank Test.

B.7. Aim 4: Develop Center Research Plans

B.7.1. Needs assessment. We will conduct a needs assessment in the first 3 months of the project period with the goal of identifying the needs and assets related to NCD prevention and PA promotion among the Collaboratory partnership and the communities that they serve. The methods for the needs assessment are described in the Coordinating Unit description in section B.5. These results will help to assess research plans, priorities and opportunities for the Center and its expansion in the Latin American region.
B.7.2. Finalize plans. To finalize short-, mid-, and long-term goals, the S-C³ will utilize principles of CBPR (see Planning Unit description-Table 1 for proposed goals).³⁸⁻⁴⁰ We will engage two stakeholder groups to gather input on research and education priorities for the partnership. Stakeholder groups will include participants in pilot studies, multi-sectoral colleagues from the Steering Committee, and other groups as needed. The investigative team will meet with stakeholders to strategize and finalize short-, mid-, and long-term goals.

B.8. Sustainability and Future Directions

The ultimate goal of the activities planned during this 2-year period are to create, enhance, and support the infrastructure and capacities that are needed to maintain a sustained effort focused on NCD prevention in Colombia and the Latin American region. This project is built on an existing partnership that has already successfully maintained collaborations and will expand to engage additional partners from diverse sectors, thus promoting sustainability. The partnership development activities will promote sustained engagement in research activities. Research enhancement activities, including scholar exchanges and various training programs, are designed not only to sustain research activities, but also to expand and grow these activities over time and throughout the Latin American region. Finally, the pilot projects are aimed at producing the necessary preliminary experience and evidence to support future larger scale projects. As described in **Table 1** of the **Planning Unit** description, short- and mid-term goals include submitting proposals for larger-scale studies that build on findings from the pilot studies.

A. Specific Aims (Coordinating Unit)

The <u>S</u>tanford-<u>C</u>olombia <u>Collaboratory</u> on <u>C</u>hronic Disease (S-C³) will focus on prevention of major noncommunicable diseases (NCDs) facing Colombia and the Latin American region, including cancer, cardiovascular disease, diabetes, and depression. NCDs are responsible the largest proportion of deaths in Latin America (69%) and in Colombia specifically (71%).^{1,2} Prevention will focus on promotion of physical activity given that inactivity is one of the most important contributors to the global burden of NCDs, responsible for ~6-10% of major NCDs worldwide.¹⁰ In Colombia, 47% of adults and 74% of adolescents do not meet physical activity recommendations.¹¹ Essential to effectively controlling the NCD epidemic in low- and middleincome countries (LMICs) in Latin America, such as Colombia, is to increase research capacity in the areas of theory-based behavioral intervention research, statistical methods to assess impact and potential for dissemination, and strategies for effectively engaging community members and key stakeholders. The S-C³ includes a systematic and coordinated plan to support such research capacity building activities.

S-C³ is built upon an existing strong partnership between Stanford University School of Medicine and the Universidad de los Andes (UniAndes) in Bogotá, Colombia and is the result of regional think tanks focused on behavioral change and PA interventions, first held in Bogotá in 2011 and again in 2016 at Stanford. The research plans are informed be a socio-ecological model for health promotion and guided by principles of Community-Based Participatory Research (CBPR). These frameworks will also guide the Coordinating Unit.

The **S-C³** Coordinating Unit's function will be to provide seamless administrative support to facilitate dayto-day operations of the S-C3, including the two proposed pilot studies, all three cores, all communications internal to the study and external to the study (e.g., with granting agencies, outside collaborators, and outside investigators who express interest in using the cores), oversight of the database and data management system, financial and grants management, and regulatory requirements, such as IRB approvals and annual progress reports.

The Specific Aims of the Coordinating Unit are to:

- 1. Provide administrative support to facilitate the conduct of the two proposed pilot studies, including the clinic-based intervention to integrate physical activity prescription and practice into the clinical care of breast cancer survivors and the community-based intervention focused on initial evaluations of Ciclovias and Recreovias in Bogotá.
- 2. Provide administrative support for the proposed training and research enhancement activities, including a scholar exchange program between Stanford and the Universidad de los Andes (UniAndes), a professional certification program in behavioral sciences for health, development of the Master's Program in Epidemiology, and the specialized seminars.
- 3. **Provide administrative support for the three proposed cores:** 1) Data Management and Statistical Analysis, 2) Development and Evaluation of Theory-Based Behavioral Interventions, and 3) Community Engagement and Translation.

The partnership between Stanford University and UniAndes is uniquely positioned to provide seamless and unified coordination given their existing successful collaborations that include scholar exchanges, regional think tank workshops, and joint research projects. The investigative teams at both Stanford and UniAndes have extensive experience conducting large-scale and complex research projects, including international collaborations. Detailed plans and milestones, developed and executed as part of the proposed S-C³, will provide a foundation to monitor and track progress, identify barriers and solutions, and strategically plan for the future.

B. Research Strategy – Coordinating Unit

The Coordinating Unit will be located at UniAndes. This Unit will provide all administrative services and support to facilitate the completion of the research and capacity building goals. This unit will be directed by Dr. Olga Lucía Sarmiento, a renowned researcher in the field of physical activity (PA) in Colombia, with local participation of Dr. Carolyn Finck, a well-respected behavioral scientist/psychologist with expertise in the behavioral theories and interventions related to behavior change in promoting physical activity and experience in the assessment of mental health issues. UniAndes has the capability of serving as the home institution for the planned collaboration. Established in 1948, UniAndes is a private non-profit organization with approximately 18,000 students and more than 640 full-time faculty in 12 Schools. UniAndes offers 39 undergraduate programs, 15 doctoral, and 55 master level programs. UniAndes has been ranked consistently among Latin America's Top 10 Universities according to QS World University Rankings. In 2016, it was ranked eighth in the region. Furthermore, UniAndes has extensive experience in international collaborations and the administration of grants with international funding. For example, it has received funding by the World Bank, USAID, and the European Commission. At Stanford, Drs. Abby King, Lisa Goldman Rosas, and Robert Haile will play collaborating/consulting roles in this Unit. Their relevant expertise is summarized in the Overall Plan and Bio Sketches sections of the current application.

B.1. Organizational Chart

The Coordinating Unit for this Collaboratory will be situated physically and organizationally at the School of Medicine in UniAndes. The leader of this School is the Dean, Andrés Sarmiento, who is very supportive of this application. Dr. Sarmiento is the Research Director of the School. The Coordinating Unit will lead operations in Colombia and will be assisted by a full time research assistant and the consulting experts from Stanford. The Steering Committee will guide the Coordinating Unit in decision-making and problem solving. The Steering Committee will be co-chaired by Drs. Sarmiento and King (as Dual PIs), and will include the other co-investigators (Drs. Finck, Goldman Rosas, and Haile) and a representative each from Universidad del Rosario, Fundacion Simmon, Institutes of Sports and Recreation of Bogotá, Ministry of Sports, National Institute of Cancer in Colombia, and the Colombian Obesity Foundation. The **Organization Chart** below (**Figure 1**) summarizes the infrastructure and key partnerships for the proposed S-C³ projects and activities.

B.2. Modes of Operation

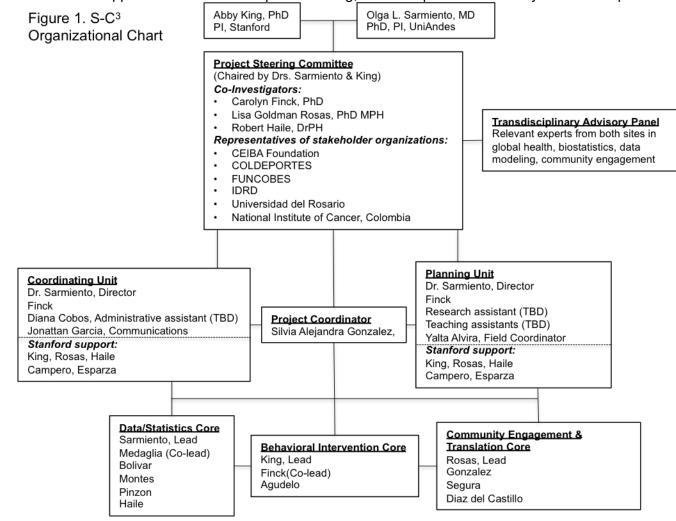
The Coordinating Unit will maximize efficiency of the research through its recruiting and other activities, which include providing assistance with identification of potential research subjects, coordinating meetings among research staff, facilitating subject retention throughout the studies, providing oversight of human subjects and data safety and monitoring, overseeing budgets and expenditures, and coordinating the management of staff, writing of papers, submission of ancillary studies, presentations at scientific meetings, and addressing problems in all of these areas as they occur. The Coordinating Unit also will avoid duplication of effort while assuring efficiency and coordination of all scientific activities through some of the following processes described below:

- *In-person meetings in Colombia*: the Coordinating Unit will plan and oversee the in-person meetings in Colombia.
- **Teleconferences**: The Coordinating Unit will plan and arrange at least two teleconferences per month with the research team at Stanford to update the team and solicit feedback and ideas related to research progress and findings, any problems, and results as well as on the establishment and maintenance of the multi-sectoral research network.
- Annual meetings of Stanford and Colombia team in Bogotá: the Coordinating Unit will also plan and arrange the logistics related to travel, lodging, and other issues related to the team of Stanford researchers coming annually to Bogotá.
- **Communication strategy:** finally, the Coordinating Unit will develop and assess the needs and efficiency of different communication strategies (social media, webpage, etc.) to make the research projects and their results available to study participants and lay public as well as experts and researchers in the field.

B.3. Measures to Ensure Transparent, Efficient Administration to Serve All Institutions

The Coordinating Unit will take the lead on all activities to ensure a transparent and interdisciplinary collaboration between Stanford, UniAndes and the other involved institutions (IDRD, Coldeportes, etc.). As stated above, a multi-sectoral Steering Committee will be established, which will meet monthly to discuss progress, new developments, any emerging issues with standard operating procedures, and any setbacks/issues that need to be resolved. This committee will also oversee issues regarding data sharing, and

IRB related issues. Our plan is to invite all major stakeholders to designate a representative to serve on the Steering Committee, which will help facilitate efficient, transparent administration. We also believe that the inperson meetings, teleconferences, and annual meeting will enable the Coordinating Unit to ensure transparent, efficient administration. For each meeting, whether in person or by teleconference, minutes will be taken and reviewed/revised/approved at each subsequent meeting, and then posted on a study web site or portal.



B.4. General Areas to be Coordinated

The Coordinating Unit will coordinate activities in the following areas. Progress in each area will be discussed at the monthly Steering Committee meetings.

- **Coordination of two pilot studies:** The Coordinating Unit will coordinate administrative activities regarding all research activities of the two pilot studies, including IRB approvals, budget administration, hiring and salary payment for personnel, monitoring progress, providing the SC with updates, and preparing progress reports. Through experience providing coordination for the pilot studies, the partnership will develop skills to support future larger-scale clinical trials and longitudinal studies.
- **Coordination of training activities:** The Coordinating Unit will administer all training activities both for the development of the proposed masters program in Epidemiology and for the professional certificate training in behavior change theories and interventions. This will include students as well as professionals in several health related professions (medical doctors, psychologists, etc.). Specifically, the Coordinating Unit will be in charge of student recruitment strategies, course evaluation, and certificates. It will maintain relations and communicate with other areas of UniAndes that are involved in the training processes (School of Medicine, School of Social Sciences, Continuing Education).
- Coordination of the cores: The Coordinating Unit will oversee and assist in reaching the specific aims
 of the cores, including budget management of core budgets, scheduling of meetings, monitoring and
 ordering of supplies for the cores, monitoring of core usage, management of communications within
 and between cores and between cores and the Planning Unit, handling communications with

investigators outside of this program who express interest in using the cores, and scheduling presentations for core leaders to present at Steering Committee meetings.

- **Oversight of database and data management:** The Coordinating Unit will develop and review relevant data sharing and data management protocols, ensuring confidentiality and care of all participant and study information. It will also assume primary responsibility for the sharing of data internally and externally in accordance with an agreed upon data sharing policy. This Unit will also oversee the informed consent process and the legal permissions needed in Colombia for storage of medical and personal information (i.e., ley habeas data).
- Financial and grants management practices: To facilitate the research mission, the Coordinating
 Unit will monitor progress and oversee expenditures on the grant, including all consultant costs,
 salaries, supplies, travel, etc. Project staff will assist the PIs (Sarmiento and King) in preparing progress
 reports for the proposed project and will meet with PIs on a regular (monthly or more frequently if
 appropriate) basis. The project budget analyst will provide budget projections on a quarterly basis.
- **Regulatory requirements, such as IRB approvals:** The Coordinating Unit will develop the human subjects protocol and consent forms for each of the intervention projects and work with Stanford Human Subjects Administrative Panel as well as the Committee for Ethics in Research from UniAndes to maintain approval of all activities and monitor training and certification of staff. Forms will be developed, based on our extensive number of prior studies, to ensure full informed consent. IRB progress and issues will be included at each meeting of the Steering Committee.

B.5. Needs Assessment and Community Engagement

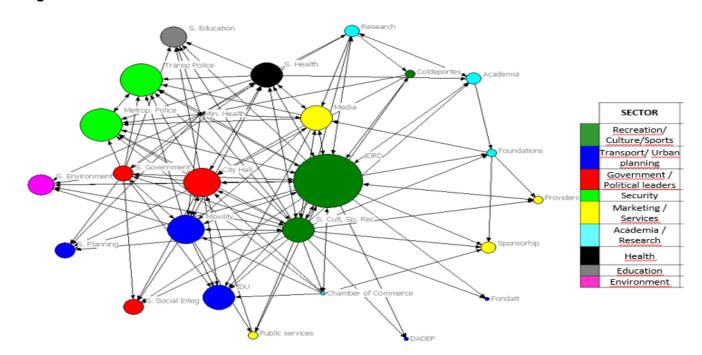
The needs assessment will employ mixed methods and genuine community engagement to identify needs and assets as they related to PA promotion for NCD prevention. Mixed methods will include focus groups, indepth interviews, and a social network analysis. This process will guide decision-making and strategic planning of the different actions and help identify primary gaps in advancing behavioral intervention research in Colombia and the region through a multidisciplinary approach. According to CBPR principles, community members and key stakeholders will be engaged in all phases of the research project.⁴⁰ Using a CBPR orientation to research, the needs assessment activities in the first 3 months of the project will include significant community and stakeholder engagement that will set the stage for ongoing engagement throughout the project period and for the long-term.

B.5.1. Qualitative methods. We will use focus groups and in-depth interviews with community members and key stakeholders. We anticipate conducting 4 focus groups with participants and their family members from the target populations involved in the pilot studies (i.e., breast cancer patients and Ciclovías/ Recreovías participants). Additionally, we will conduct up to 3 focus groups with stakeholders from the partner organizations. Key informant interviews will be used to examine needs and assets among community members and key stakeholders that were not able to participate in the focus groups. For gualitative data, all interviews with stakeholders will be recorded and transcribed.^{51,52} Led by Co-Investigator Dr. Goldman Rosas (see letter of support), we will use ATLAS.ti, a multifunctional software system, to code the focus group and interview transcripts. We will initially use the interview guide to organize and provide a starting list of codes related to needs and assets, which we will supplement with emergent codes to capture new factors that stem from the interview process. Two project team members will independently code the transcripts. Discrepancies in initial coding will be solved by discussion between project team members. Based on these discussions, the raters will conduct a final code of the transcripts. Intercoder agreement will be quantified for each coding domain using Cohen's Kappa: (Observed agreement – Chance) / (1 – Chance). If substantial intercoder disagreements exist, a third project team member will review the text in question to determine appropriate coding before finalizing the coding scheme.⁵³

B.5.2. Quantitative methods. Through network analysis, we will assess our multi-sectoral partnerships using methodology that Dr. Sarmiento (Dual PI) has employed previously.⁵⁴ This analysis is essential for a deeper understanding of the interconnections between groups and for revealing opportunities for partnership development. An example of such a network is provided in **Figure 2** below.

B.5.3. Community engagement. Investigators at both UniAndes and Stanford have extensive experience in partnering with diverse groups of community stakeholders to enhance the contextual relevance and impact of our community-based research activities. We will engage stakeholder groups to gather input on research and education priorities for the partnership. Stakeholder groups will include participants in pilot studies, multi-sectoral colleagues from the Steering Committee, and other groups as needed. The investigative team will meet with stakeholders to strategize and finalize short-, mid-, and long-term goals described in the Planning Unit description. Through applications of the Citizen Science model that Drs. King, Goldman Rosas, and

Sarmiento together have been employing in Colombia as well as with Latino populations in Mexico, Chile, and the U.S., we will collect and analyze information from residents as well as stakeholders pertaining to the programs being developed and evaluated.¹⁴ The *Nuestra Voz* (Our Voice) citizen science engagement model provides an evidence-based step-by-step approach for directly engaging residents from underserved communities in direct forms of neighborhood and community data collection around health issues of relevance to their community. Using a simple mobile health application, they are readily able to capture elements of their local environments that either promote or hinder PA as well as other types of health behaviors. Residents then learn how to prioritize relevant issues and communicate their findings to stakeholders in ways that promote relevant, low-cost solutions. In this model the information is evaluated by community members and subsequently presented in accessible and compelling ways to policy makers. Finally, in the last year of the project, we will hold a seminar with presentations of our Collaboratory and research projects. This seminar will have a panel including representatives of the multiple sectors (government and nongovernment) and community members representing our Collaboratory. **Figure 2.**



B.6. Evaluation, with an Emphasis on Metrics

We have identified short- and long-term outcomes for the overall aims of the S-C³ (**Tables 1A-D**). The aims and outcomes support long-term sustainability and promote policies that support PA in Colombia.

Aims	Expected Outcomes/ Milestones	Steps to support sustainability	How activities will inform local public policy		
1.1 Enhance multi-sectoral research partnerships and communication pathways for capacity building and intervention development	 Short-term: Multi-sector partnerships are established Partnerships meet at least 4 times per year At least 2 partners are engaged in each of the pilot projects Mid- & long-term: Partners initiate their own research projects 	approach to promote long-term engagement	 Engaging diverse partners will inform policies for NCD prevention in various sectors Training provided to partners will increase potential to infuse NCD prevention policy in all policies. 		
1.2 Finalize shared cores that will provide support for training and research activities	 Short-term: Supportive cores are established and used by researchers in Colombia Mid- & long-term: All cores reside at UniAndes 	The cores will employ capacity building strategies (e.g., co-learning) in their support to increase research capacity in all encounters	Cores will strengthen research capacity among Colombian colleagues for conducting research to inform policies to address NCD prevention strategies		

Table 1 B. Performance metrie	cs for overall aims of S-C ³ for Aim 2:	Build/expand mechanisms for cap	acity building in Colombia
Performance metrics for overall aims	Expected Outcomes/ Milestones	Steps to support sustainability	How activities will inform local public policy
 2.1 Scholar exchange between UniAndes and Stanford University 2.2 Professional certificate program focused on planning and evaluation of theory-based interventions for health promotion/disease prevention 2.3 Masters Program in Epidemiology with a track focused on behavioral interventions 2.4 1-day seminar courses for community members and key stakeholders 	 At least 2 scholar exchanges have been successfully completed between Stanford and UniAndes Professional certificate program is 	Professional training activities are aimed at increasing research capacity in Colombia and the Latin American region to support long-term engagement in NCD prevention research	Training will focus on research aimed at sustainable policy change

Table 1 C. Performance metrics for overall aims of S-C ³ for Aim 3: Conduct joint pilot projects						
Performance metrics for overall aims	Expected Outcomes/ Milestones	Steps to support sustainability	How activities will inform local public policy			
 3.1 Community-based intervention to promote PA among breast cancer survivors; 3.2 Longitudinal evaluation of community- wide Ciclovía/Recreovía programs. 	 Short-term: Pilot studies successfully completed Manuscript describing findings submitted Grant for larger scale study submitted. Mid- & long-term: Larger scale studies implemented Behavior change (e.g., objective PA, self-report PA) documented among target populations 	Pilot studies will be conducted by Colombian researchers with support from Stanford peers to increase research capacity	Dissemination of findings through multi-sectoral stakeholder partnerships will promote changes in policies to support NCD prevention practices and policies			

Performance metrics for overall aims	Expected Outcomes/ Milestones	Steps to support sustainability	How activities will inform local public policy
4.1 Needs assessment with community members and key stakeholders using focus groups, interviews and a network analysis of organizational and communication pathways and connections in Colombia	 Short-term: 3-5 focus groups and 5-8 interviews completed and analyzed Network analysis completed Findings summarized in scientific manuscript and in policy briefs for key stakeholders <i>Mid- & long-term:</i> Research activities aligned with needs and leverage assets 	 Methods documented to enable periodic assessment of needs and assets to account for changes in epidemiology and policy environments 	Dissemination of findings through multi-sectoral stakeholder partnerships will promote changes in policies to support NCD prevention practices and policies
4.2 Finalize short-, mid-, and long-term goals and expected outcomes.	 Short-term: Multi-sectoral partners engaged to finalize goals and outcomes Goals and outcomes disseminated through policy briefs for key stakeholders <i>Mid- & long-term:</i> Goals and outcomes continuously communicated back to partners 	 CBPR approach will ensure that multiple stakeholders from various sectors are invested in the goals and outcomes to promote sustainability 	 Goals and outcomes will be focused on policy changes to sustain NCD prevention policies and outcomes

B.6.1. Steps to enhance longevity of activities. By employing a socio-ecological model and utilizing a CBPR orientation to research, all S-C³ priorities are designed to promote long-term sustainability of research plans, enhancement activities, and shared core facilities. The strategies for promoting long-term sustainability are provided in **Tables 1A-D**. To summarize, key strategies to promote long-term sustainability of S-C³ plans

include: 1) The training program we propose will help ensure longevity by training a cadre of scientists in behavioral intervention research and leaving in place courses and a Masters Program in Epidemiology; 2) We will engage the major stakeholders in this project as voting members of the Steering Committee since they represent sectors that will facilitate longevity of the program; and 3) We intend to use the pilot studies to generate preliminary results to seek major NIH grants in addition to other sources of funding to enable us to continue and enhance continuing research activities.

B.6.2. How activities will inform local public health policy. The strategies for informing local public health policy are provided in **Tables 1A-D**. Our primary means of informing public health policy is by engaging relevant policy making sectors to become part of our team by membership on our Steering Committee. We also plan a seminar at the end of the two years to present summary results to those groups that have the power to influence policy. Additionally, the steps to inform local public health policy in Latin America that are employed for this project will provide a road map for how this can be accomplished in other Latin American context.

B.7. Resource Sharing Plan

In keeping with current requirements, once the data collected through the Collaboratory have undergone final data cleaning and analysis, we will make the final data collected as part of the proposed research available in electronic form to researchers who request them. We will request that researchers submit a data request in writing to the project principal investigators so that the requested data can be made available while protecting the confidentiality of study participants. By setting up a centralized data request process, we will be able to provide requestors with information that will help to inform external research groups about duplicate data analysis activities on the part of other research groups related to the data set in question.

B.8. Study Timeline

The project period will span two years (Table 2).

Table 2. Study timeline	-											
			Ye	ar 1					Yea	ar 2		
Study (Bimonthly)	2	4	6	8	10	12	2	4	6	8	10	12
Project set up (e.g., IRB approval, Subcontracting, hiring)												
Specific Aim 1												
Multi-sectoral partnership meetings												
Establish cores												
Specific Aim 2												
Scholar exchange												
Behavioral science track in Epidem. MS												
Professional certificate course												
1-day mini courses												
Specific Aim 3												
Pilot study 1: PA among breast cancer pts.												
Pilot study 2: Ciclovía/Recreovía												
Specific Aim 4												
Needs assessment												
Finalize Collaboratory goals												
Publications and grant submissions												

B.9. Potential pitfalls and solutions

One challenge is that the proposed planning process supports a robust set of activities, and without careful coordination the project could miss key milestones. Careful monitoring of study milestones and timelines will be critical for ensuring successful completion of project aims. This will be accomplished by frequent communication, both in-person and via web conferencing, as we have done for planning the Think Tank workshops and preparing this proposal. A second challenge will relate to sustainability and potential to inform public policy, which are challenges in research aimed at promoting PA for NCD prevention. Employing a CBPR orientation to research will be critical for promoting sustainability and success in informing policy, as key stakeholders will be genuinely engaged in the process and capacity building is a focus. As other challenges arise, the Steering Committee will develop plans for rapidly identifying and implementing solutions.

A. Specific Aims (Planning Unit)

The goal of the Planning Unit for the <u>Stanford-Colombia Collaboratory</u> on <u>Chronic Disease</u> (S-C³) is to provide a structured roadmap for a set of coordinated activities aimed at increasing research capacity in the Latin American region for reducing the prevalence of non-communicable diseases (NCDs) through promotion of physical activity. Colombia is uniquely positioned to serve as a regional leader given the country's academic resources (e.g., Universidad de los Andes), emerging governmental support of NCD prevention, and numerous partnerships throughout the region. Stanford researchers, who have an existing strong collaboration with researchers at Universidad de los Andes (UniAndes), will act as a catalyst by providing strategic scientific and academic support to increase research capacity in the areas of behavioral science, technology, measurement and data analysis, and community engagement and translation methods.

The high burden of (NCDs) in low- to middle-income countries (LMIC) in Latin America, such as Colombia, calls for a highly coordinated, effective, and innovative research strategy to develop, test, and disseminate prevention and management strategies with high potential to improve population health. Close to 7 in 10 deaths in Latin America are due to NCDs, including cancer, cardiovascular disease (CVD), and type 2 diabetes.^{1,2} Fortunately, NCDs are largely preventable through low-cost, non-invasive, and culturally centered strategies such as promotion of guideline-concordant physical activity.^{8,9,12,13} Moderate- to vigorous-intensity physical activity (PA) of 150 minutes per week among adults and 60 minutes per day among children is associated with substantially lower lifetime risk of NCD. There is enormous opportunity to prevent NCDs in the Latin American region through promotion of physical activity given increasingly low levels of PA and high levels of sedentary behavior.¹¹ In Colombia, 47% of adults and 74% of adolescents do not meet physical activity recommendations, comparable to levels in the US and higher than other Latin American countries such as Mexico, Ecuador, and Uruguay.¹¹ If left unaddressed, physical activity levels in Latin America will continue to decline, with corresponding increases in NCD prevalence.

Evidence-based strategies to promote physical activity encompass approaches that target individuals, their families, the neighborhoods in which they live, work, and play, and the policies that shape their opportunities for leading active lives. Additionally, physical activity interventions are easily culturally targeted and tailored, especially when community-based participatory research approaches are employed, making them an ideal approach for reducing NCD risk in regions such as Latin America with rich and heterogeneous cultural backgrounds. To support such potentially effective approaches, significant investment in the research capacity in the region is needed. Currently, in Colombia and the Latin American region, research has focused largely on observational methods for physical activity surveillance and examination of multi-level determinants of physical activity levels (e.g., individual, family, and neighborhood).²² With this critically important information on activity levels and determinants, the region now has an opportunity to build upon this foundation to create a body of research focused on behavior change through multiple levels of influence. The plans for research studies, research enhancement, and shared core facilities will be informed by the mixed methods needs assessment as described in the Coordinating Unit.

The Specific Aims of the Planning Unit are the following:

1. Complete two pilot studies of physical activity interventions that focus on distinct levels of influence in diverse populations. One pilot study will use a randomized controlled trial design to examine the preliminary effectiveness of a physical activity intervention for breast cancer patients. A second pilot study will use a longitudinal cohort design of Ciclovías and Recreovías in Colombia.

2. Take advantage of Stanford's expertise in core research areas to train world leaders in behavioral science research at Universidad de los Andes to support regional expertise in physical activity intervention research. A multi-pronged educational approach is planned for increasing research capacity among research partners, students, and community members. Activities will include developing a masters of science degree, a professional certificate program, and mini-courses for key stakeholders.

3. Establish and sustain core research resources that will support development and implementation of cutting-edge behavioral science research focused on physical activity promotion. The supportive cores, described in section B.3, which were developed through a participatory process, will focus on behavioral science, measurement and data analysis, and community outreach and translation. This coordinated set of planning activities will provide a strong foundation to support an impactful research strategy with high potential to create and disseminate evidence-based physical activity interventions to prevent NCDs in Colombia and the Latin American region.

B. Research Strategy – Planning Unit

The Stanford-Colombia Collaboratory on Chronic Disease (S-C³) will support transformative research aimed at significantly decreasing the prevalence of NCDs, including cancer, cardiovascular disease, diabetes, and depression through effective promotion of physical activity. Two fundamental frameworks guide the plans for this Collaboratory. First, the socio-ecological model, which posits that health outcomes are shaped by factors at the individual, family, community/neighborhood, and policy/societal levels (see Figure 1 in Overall **Plan**),⁵⁻⁹ guides the design and evaluation of physical activity interventions in this project. Second, Community-Based Participatory Research (CBPR) approaches are utilized in partner development, research enhancement, needs assessment, and pilot studies. Utilizing CBPR approaches is essential for ensuring that the Collaboratory is relevant for Colombia and the Latin American region and sustainable over the long-term.⁴⁰ Among the CBPR strategies, we leverage the Nuestra Voz (Our Voice) model, originally developed by PI Dr. King and colleagues and extensively tested across the globe, including in Latin America by dual PI Dr. Sarmiento and Co-I Dr. Goldman Rosas, among others.¹⁴ The Nuestra Voz model empowers neighborhood residents to be "citizen scientists" through systematically collecting information about aspects of their neighborhoods that promote or hinder healthy living. Residents then learn how to effectively communicate their results to policy makers to promote realistic changes that will support healthier lifestyles. Thus, the Stanford-Colombia Collaboratory not only engages stakeholders from multiple sectors but also community residents themselves in the planning process. Using these frameworks, the S-C³ includes specific and coordinated plans to support research, research enhancement, and shared core facilities to develop a highly productive Center of Research Excellence focused on prevention of NCDs in Latin America.

B1. Planning for research activities

The rationale for the focus of the S-C³ builds directly from the Latin America Cancer Epidemiology Think Tank hosted at the Stanford Cancer Center in April 15-16, 2016. Ten researchers from Latin American academic institutions, four researchers from the US, and three scientists from the National Cancer Institute participated in a 2-day workshop focused on identifying strategic opportunities to impact the growing burden of cancer and other NCDs in Latin America. Physical activity (PA) promotion clearly emerged as a high priority given the potential effectiveness for prevention of cancer and other chronic diseases, existing expertise in physical activity epidemiology in Colombia and other parts of the region,^{22,34,55,56} and the flexibility offered to culturally target and tailor interventions to the heterogeneous cultural backgrounds in Latin America. **B.1.1. Rationale for targeting physical inactivity in ameliorating NCD burden in Latin America.** As

described in the Overall Plan, Colombia and other LMICs in Latin America share a high degree of burden from a constellation of NCDs, including cancer, cardiovascular disease and type 2 diabetes, in addition to mental health conditions such as anxiety and depression.¹⁻⁴ A key behavioral pathway is physical inactivity—one of three behavioral risk factors leading to the four major NCDs responsible for 50% of global mortality.⁵⁷ The development of evidence-based PA interventions at multiple levels of impact thus provides a potentially cost-and resource-efficient way to address multiple NCDs. However, while the prevalence of physical inactivity is increasing in LMICs in Latin America and elsewhere,⁵⁸ the development of effective, culturally relevant PA interventions aimed at NCD prevention and control in the Latin American region generally has lagged behind scientific efforts in other behavioral risk factor areas (e.g., diet).

B.1.2. Rationale for Stanford-Universidad de los Andes partnership. Scientists at the Universidad de los Andes (UniAndes) and their partner institutions in Bogotá, Colombia have a proven track record of scientific excellence and prominence in the Latin American region in relevant health areas, including PA epidemiology, assessment, and theory-building. They also have begun developing successful collaborations with PA intervention researchers at Stanford University. A major goal of the proposed Planning Unit is to take advantage of the research and training expertise and synergies across both academic institutions (UniAndes, Stanford) to create a coherent and collaborative set of research and training mechanisms and structures in Colombia that will lay the groundwork for developing an impactful and sustainable regional Center of Excellence (i.e., "Collaboratory") that can have a potentially transformative effect on NCD burden in Colombia and the Latin American region.

B.1.3. Research environment at UniAndes. Universidad de los Andes was founded in 1948. It has nine schools: Medicine, Business Administration, Architecture and Design, Arts and Humanities, Science, Social Sciences, Law, Economics, and Engineering. In addition, the University includes the first private school for public affairs--the Alberto Lleras Camargo Government School. There are 644 full-time professors in UniAndes in 2016. This number has increased by 60% between 2002 and 2014. Seventy percent of the faculty holds doctoral degrees. This percentage is the biggest in the country and has increased significantly in the past few years (it was only 39% in 2002) and it is above the national average (14% in 2014). There are approximately

18,000 students: 26% are enrolled in graduate and professional degree programs, 30% of the students come from outside Bogotá, and 87% of the undergraduate students come from the top 5% of high school students in the country. UniAndes is the only Colombian university within the top 450 universities of the world, according to the QS 2015 (World University Ranking). According to the 2016 QS Ranking for Latin America, Universidad de los Andes is the eighth best university of this region. Located on a total area of 163,961 square meters, Uni-Andes has excellent laboratory facilities, 428,490 books in the library system, which has been classified as one of the best libraries in Latin America, 2,507 computers for student use on campus, and a modern sports center. **B.1.4. Implementation of pilot studies.** The pilot studies, described in Section **B.6** of the Overall Plan, were specifically chosen to provide opportunities to develop and understand distinct behavioral intervention strategies, utilize different research methods, and engage diverse research partners. Additionally, the pilot studies will serve multiple functions. First, the pilot research will inform future larger-scale proposals with high potential for success. Second, the pilot studies will provide training opportunities for the various constituent groups engaged in the research enhancement activities. Third, the shared core facilities will support the pilot projects will provide key opportunities to engage partners in research activities.

B.1.5. Short-, mid-, and long-term goals. The S-C³ is aimed at short-, mid-, and long-term goals as described below. In the short-term, the S-C³ aims to create infrastructure to support research, increase research capacity, demonstrate the acceptability and feasibility of NCD prevention research approaches, and disseminate plans for NCD prevention research to multiple stakeholder groups from multiple sectors. In the mid-term, the S-C³ goals will include supporting ongoing partnerships, further building research capacity, utilizing pilot research to build larger scale research projects, and disseminating successes related to research infrastructure and capacity building. The long-term goals of the S-C³ are focused on expansion of the above S-C³ activities in the Latin American region and meaningful change in health and policy outcomes. The aspirational goals for each period are described below.

Table 1. S-C ³	Goals		
	Short-term (2 years)	Mid-term (2-5 years)	Long-term (5-10 years)
Research infrastructure and community engagement	 Supportive cores are established and used by researchers in Colombia Multi-sector partnerships are established and engaged in research 	 Increase utilization of consulting from cores in Colombia with expanded services for the Latin American region Infrastructure to support clinical trials and other large- scale studies is in place and utilized Colombian NCD prev. partner- ship is annually evaluated, sustained, and expanded 	 Continued utilization of supportive cores in Colombia with additional satellite cores established in the Latin American region Lessons learned from the partnership development process in Colombia are replicated in at least 3 additional countries in the Latin American region
Research enhancement	 At least 2 scholar exchanges have been successfully completed between Stanford and UniAndes Professional certificate program is developed and delivered at least once at UniAndes A behavioral science track within the epidemiology masters program is developed at UniAndes At least 3 1-day courses are provided to partner organizations in Colombia 	 At least 2 scholar exchanges occur annually between Stanford and UniAndes Professional certificate program is provided annually with increasing participation at UniAndes At least 5 students are enrolled in the behavioral science track annually at UniAndes At least 5 1-day courses are provided each year in Colombia 	 The scholar exchange program is expanded to include additional universities in Colombia and the Latin American region Additional universities in Colombia and the Latin American region offer the professional certificate program A behavioral science track is offered at additional universities in Colombia and the Latin American region The 1-day courses continue to be offered in Colombia (5 annually) and at least 3 additional courses are offered annually in Latin Am. region

NCD prevention research	 Two pilot studies are successfully completed At least 2 grant proposals are submitted for larger scale studies in Colombia 	 At least 2 larger scale studies are underway in Colombia At least 3 grant proposals are submitted for additional larger scale studies in Colombia and the Latin American region 	 At least 3 to 5 larger scale studies are underway in Colombia and the Latin American region At least 3 to 5 grant proposals submitted for additional larger scale studies in Colombia and the Latin American region
Health and policy outcomes	 Health outcomes: Changes in health outcomes are not expected in the short- term Policy outcomes: Policy changes are not expected in the short term 	 Health outcomes: Preliminary evidence of increases in physical activity among certain subgroups targeted in research studies is documented in Colombia Policy outcomes: Initial changes in policies related to NCD prevention research are documented in Colombia and the Latin American region Changes in Colombian policies to support active living are documented 	 Health outcomes: Increasing evidence of increases in physical activity is documented in Colombia and the Latin American region <i>Policy outcomes:</i> Sustained political support for NCD prevention research is documented in Colombia and the Latin American region Changes in policies to support active living are documented in Colombia and the Latin American region
Dissemination	 Scientific: At least 3 publications on research enhancement & pilot studies submitted Seminar of the results of pilot studies with policy makers, researchers and community members. Non-scientific: Policy briefs on the importance of NCD prevention research are created and disseminated through partner organizations Web portal is created to facilitate communication among partners 	 Scientific: At least 3 publications are submitted annually focused on NCD prevention research in Colombia and the Latin American region Non-scientific: Evidence from pilot studies is effectively disseminated through partner organizations to promote policy changes in Colombia 	 Scientific: At least 5 publications are submitted annually focused on NCD prevention research in Colombia and the Latin American region Non-scientific: Evidence from research studies is effectively disseminated through partner organizations to promote policy changes in Colombia and the Latin American region

B.1.6. How S-C³ activities complement existing research endeavors at UniAndes. The planned activities complement existing research, training, and core facilities to support rigorous research to evaluate theory-based behavioral interventions to increase PA and decrease sedentary behavior—with the ultimate goal of decreasing NCD prevalence in Colombia. The proposed pilot studies build on existing research, which has been largely observational in nature. The goal of the research activities is to facilitate a transition from observational studies focused on describing PA levels and determinants to intervention research focused on developing innovative new models for PA promotion and rigorous research methodology to evaluate these strategies. The training activities will serve as a catalyst for the research activities by providing critical training to academic and non-academic stakeholders. The proposed training activities will utilize the training experience at Stanford to build upon existing training resources at UniAndes. Together the pilot research projects and the training programs will help build capacity for theory-based multilevel and multi-sectoral behavioral interventions to promote PA. Finally, the shared core facilities will provide critical infrastructure support for the proposed planning activities and for future larger-scale research activities that emerge from this project.

B2. Planning for Research Enhancement and Capacity-building Activities

In line with a CBPR approach, the S-C³ includes plans for training scholars, research partners, and community members to enhance research at all levels. Enhancing research capacity within and outside of academic settings will promote long-term sustainability and increase the potential for effectiveness. The described plans for Colombia provide a road map that can be used in other Latin American contexts as well. Stanford's experience in training will complement existing training activities at UniAndes, resulting in a high-caliber and comprehensive training program focused on NCD prevention.

B.2.1. Stanford training experience. Stanford University and especially the Stanford Prevention Research Center (SPRC) in the Department of Medicine and the Department of Health Research and Policy (HRP) are global leaders in training top scientists in behavioral intervention research focused on NCD prevention. Dr. King (PI) is a Professor in both departments and maintains an active role in training activities in both, and Dr. Goldman Rosas plays a central role in teaching activities for SPRC. For the past 35 years, SPRC has offered a postdoctoral fellowship that has trained over 200 high-caliber scholars who have gone on to assume faculty positions and other leadership roles in governmental and non-governmental organizations. Both SPRC and HRP offer the Masters of Science (MS) in Community Health and Prevention Research (CHPR) and Epidemiology, respectively. The CHPR MS was recently developed and launched (Fall 2015), which provides critical experience that will be translatable to the research enhancement activities proposed for S-C³. Additionally, SPRC offers a professional certificate program (Stanford Health 4 All) and other mini-courses for community members that will also provide a model that can be adapted for Latin America. Dr. Goldman Rosas sits on the faculty governance board for SPRC teaching programs and teaches three courses. Additionally, Dr. Haile brings extensive experience developing and delivering teaching programs, having developed one of the first genetic epidemiology programs in the country while at UCLA and one of the first international courses in genetic epidemiology presented at numerous universities in China.

B.2.2. UniAndes training experience. The Stanford experience will complement existing activities at UniAndes. UniAndes has recently launched a Masters of Public Health and a Doctoral program in Psychology, which will serve as a foundation for the proposed research enhancement activities. Additionally, plans are currently underway for a Masters of Science in Epidemiology. Professor Sarmiento teaches classes and advises theses of Masters of Public Health students, and is among the faculty designing the Masters of Science in Epidemiology. Professor Finck teaches classes and advises theses of the students in the Doctoral program of Psychology. The training programs (**Table 2**), coupled with the research opportunities provided by the pilot studies and other future larger scale studies, will provide critical infrastructure to train scholars and other professionals in theory-based multilevel and multi-sectorial behavioral interventions to promote physical activity. The limited availability of training opportunities is a major barrier to advancing research in physical activity promotion for NCD prevention.⁵⁹

B.2.3. Research enhancement plans. Building on the experience at Stanford and UniAndes, the research enhancement activities will encompass four strategies aimed at reaching distinct constituent groups to promote long-term sustainability in Colombia (**Table 2**). Additionally, these strategies were selected because of their potential for replication in other Latin American countries.

Table 2. Capa	city building through research tra	aining	
Program	Sources of trainees	Brief Description	Potential for capacity building
Scholar	Stanford and UniAndes	Short research visits to partici-	Training in effective intervention
exchange	students and researchers at	pate in courses or gain research	design, evaluation, & knowledge
	various levels of training	experience in specific areas	about the Colombian context
Masters	Graduates of various disci-	Track of the masters program in	Comprehensive training in
program	plines, practitioners in health	Epidemiology at UniAndes	design and implementation as
	related context (medicine,		well as evaluation of
	psychology, PA) at UniAndes		interventions to promote PA
Professional	Graduates of various disci-	Short course as elective for	Knowledge and practical
certificate	plines, practitioners in health	graduate studies in the MPH in	implementation of behavior
program	related context (medicine,	Epidemiology or the Psychology	change theories on health
	psychology, physical activity).	training programs	promotion (specifically PA
	Graduate students at UniAndes		promotion)
1-day	Members of partner	Mini courses focused on the	Widespread dissemination of
courses	organizations and community	importance of behavioral	research skills will promote
	members	interventions for NCD promotion	sustained and long-term
		and skills for engaging in	investment in multiple
		research as community partners	stakeholder groups.

B.2.4. Assessment of comprehension. Ongoing evaluation of each research training activity is vital to its continued success and sustainability. A specific evaluation plan is planned for each training activity over both the short- and long-term (**Table 3**).

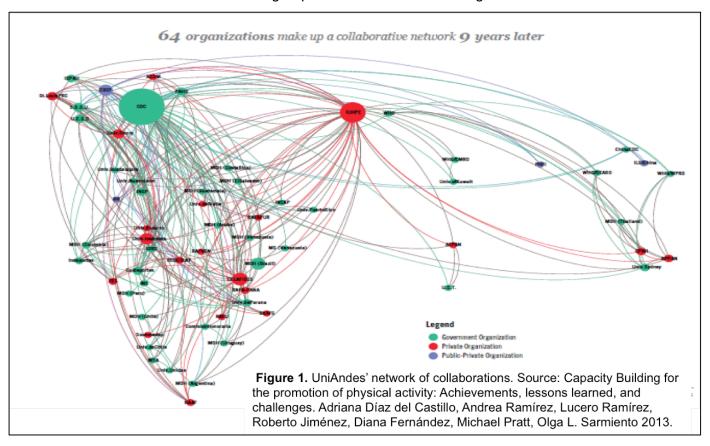
B.2.5. Plan for ensuring that research talent remains in Colombia and Latin America. One of the main concerns when building research capacity in low to middle income countries is "brain drain". To prevent this, we will conduct most of the training in Colombia with students of different regions of the country. Both Drs. Sarmiento and Finck are researchers highly trained outside of Colombia who came back to the country more than ten years ago to teach and build research capacity in the region. In fact, they belong to multiple networks

and groups that will prevent brain drain. **Figure** 1 illustrates graphically institutions that are part of academic networks like the Network of Physical Activity of the Americas, Network of Ciclovías of the Americas, Active Healthy Kids Global Alliance and the Network of Urban Health (the arrow shows UniAndes). In addition, we are members of the Ceiba group that started seven years ago in response to a call from the National Department of Science, Technology and Innovation to create Excellence Centers in Colombia, and have had more than 40 affiliated doctoral students. A goal of Ceiba is to train and retain top scholars in the region.

Table 3. Assessment of comprehension of training programs			
Program	Assessment of comprehension		
Scholar exchange	 Report submitted to research mentor with concrete plans for incorporating lessons learned into future collaborative research plans 		
Masters	 Qualifying exam 		
program	Masters thesis		
Professional	 Internship program where students apply concepts 		
certificate	in real-world setting; internship supervisors will		
program	provide assessment		
1-day	 Interactive response system during course (e.g., 		
courses	Turning Point)		

B.3. Planning for Shared Research Cores

The shared core facilities will be informed by the needs assessment conducted in Year 1. The proposed shared core facilities were identified during the Latin America Cancer Epidemiology (LACE) Think Tank (April, 2016) as representing major barriers to advancing the science of chronic disease prevention in Latin America. Thus, while the specific activities of the core facilities will be optimized through what is learned in the needs assessment, the primary functions will not change. The primary gaps in advancing behavioral intervention research in Colombia and the region include: 1) Data management and analysis of observational and experimental behavioral intervention studies; 2) Development of theory-based behavioral interventions and evaluation design; and 3) Community engagement and translation. The cores are embedded in existing academic programs, which make them financially sustainable and support economies of scale. Specifically, researchers at Stanford will work with Drs. Finck and Sarmiento from the schools of Medicine and Social Sciences. The latter, in turn, will work together with the Schools of Engineering and Government. In order to further support the cores, we will apply for additional grants within the Universidad de los Andes and Colciencias (Colombian National Science Foundation). Specific education grants from the Universidad de los Andes support the creation of blended courses (web based and in person classes). Blended courses, in turn, will serve as courses for other academic groups in the Latin American region.



1. Data management and statistical analysis core. This core will focus on data management and analysis of data from observational and experimental intervention research. This core will be centered at UniAndes and led by Dr. Sarmiento with support from Andrés Medaglia, the director of Industrial Engineering and the program of Analytics at UniAndes, and from Dr. Haile at Stanford. Dr. Sarmiento will develop a knowledge bank of resources for effective data management tools such as REDCap and other online data collection tools such as data visualization tools, as well as data analysis resources with help from Dr. Haile. The core will establish an online repository where scientists can share analysis code (e.g., R code for analyzing accelerometry data, procedures for analyzing PA diary data) and other analysis resources (e.g., instructions for scoring international questionnaires to measure PA, and forms for systematic observation of spaces for PA, GIS data analysis, and network analysis).

2. Development and evaluation of theory-based behavioral interventions. This core will support the development of innovative behavioral interventions for increasing PA and decreasing sedentary behavior as well as the design of rigorous evaluations of these programs. Dr. King will provide overall leadership for this core with support from Dr. Finck and Diana Agudelo PhD, Director of the Psychology Department at UniAndes. Dr. King will develop a knowledge bank with the following content: 1) Information on existing evidence-based PA interventions; 2) Strategies for successful adaptation of evidence-based interventions in the field; 3) Validated measures for evaluation of interventions; and 4) Strategies for validation of other measures.

3. Community Engagement and Translation: The community engagement and translation core will provide knowledge and resources for effectively engaging community members and key stakeholders to support the development, evaluation, and dissemination of PA interventions. Dr. Goldman Rosas will lead this core with support from Catalina Gonzalez MA, MSc, PhD, Director of the Epidemiology masters program at UniAndes. The knowledge bank will include information on best practices for engaging community members and key stakeholders in behavioral intervention research, as well as key resources such as partnership agreement templates and data sharing plans, training materials for community members engaging in research, and information on training in the ethical conduct of research.

B.4. Core Support Functions

The S-C³ will benefit from existing core support functions that will be further strengthened during the planning phases:

Research ethics committee: The Planning Unit will design and oversee all processes of IRB approvals and an ethics committee. It will designate the Coordinating Unit to develop the master human subjects protocols and consent forms for each of the intervention and related research projects, and will communicate with the Stanford team in order to assess if approval by the Stanford Human Subjects Administrative Panel is needed for specific activities. It will assure the approval of all activities by the Committee for Ethics in Research from UniAndes. This committee was first established in 2000, has strict processes and procedures, and is accepted by the Colombian Ministry for Research and technology (Colciencias) to oversee the ethical issues of research projects and activities in which UniAndes members participate. IRB issues will be included at each meeting of the Steering Committee.

Administrative and budget oversight: To facilitate the research mission, the Planning Unit will monitor progress and adjust activities to the expenditures on the grant, including all consultant costs, salaries, supplies, travel, etc. The Steering Committee will assist the PIs (Sarmiento and King) on financial issues arising from the project and will meet with PIs on a regular (monthly or more frequently as appropriate) basis. The project budget analyst will provide budget projections on a quarterly basis and the Planning Unit will also work with the Coordinating Unit and Steering Committee in examining funding opportunities that make the Collaboratory sustainable in the long-term.

B.5. Resource Sharing Plan

The Collaboratory will have a website to share information and datasets in Spanish and English. Through this center, we will also establish an online repository where scientists can share analysis code (e.g., R code for analyzing accelerometry data, procedures for analyzing PA diary data) and other analysis resources (e.g., instructions for scoring international PA questionnaires, and forms for systematic observation of spaces for PA, GIS data analysis, and network analysis).

In keeping with current requirements, once the data collected through the Collaboratory have undergone final data cleaning and analysis, we will make the final data collected as part of the proposed research available in electronic form to researchers who request them. We will request that researchers submit a data request in writing to the project principal investigators so that the requested data can be made available while protecting the confidentiality of study participants. By setting up a centralized data request process, we will be able to provide requestors with information that will help to inform external research groups about duplicate data analysis activities on the part of other research groups related to the data set in question.

References

- 1. Organization WH. *Noncommunicable Disease (NCD) Country Profiles: Colombia.* Geneva, Switzerland: World Health Organization;2014.
- 2. Organization PAH. Country Profiles on NonCommunicable Diseases. Washington DC2012.
- 3. Curado MP, de Souza DL. Cancer burden in Latin America and the Caribbean. *Annals of global health.* 2014;80(5):370-377.
- 4. Strasser-Weippl K, Chavarri-Guerra Y, Villarreal-Garza C, et al. Progress and remaining challenges for cancer control in Latin America and the Caribbean. *The lancet oncology*. 2015;16(14):1405-1438.
- 5. McLeroy KR, Bibeau D, Steckler A, Glanz K. An ecological perspective on health promotion programs. *Health education quarterly.* 1988;15(4):351-377.
- 6. Stokols D. Translating social ecological theory into guidelines for community health promotion. *American journal of health promotion : AJHP.* 1996;10(4):282-298.
- 7. Richard L, Potvin L, Kishchuk N, Prlic H, Green LW. Assessment of the integration of the ecological approach in health promotion programs. *American journal of health promotion : AJHP.* 1996;10(4):318-328.
- 8. Spence JC, Lee RE. Toward a comprehensive model of physical activity. *Psychology of sport and exercise*. 2003;4(1):7-24.
- 9. Sallis JF, Owen N, Fisher EB. Ecological models of health behavior. *Health behavior and health education: Theory, research, and practice.* 2008;4:465-486.
- 10. Lee IM, Shiroma EJ, Lobelo F, et al. Effect of physical inactivity on major non-communicable diseases worldwide: an analysis of burden of disease and life expectancy. *Lancet.* 2012;380(9838):219-229.
- 11. Hallal PC, Andersen LB, Bull FC, et al. Global physical activity levels: surveillance progress, pitfalls, and prospects. *Lancet.* 2012;380(9838):247-257.
- 12. Doak C. Large-scale interventions and programmes addressing nutrition-related chronic diseases and obesity: examples from 14 countries. *Public health nutrition*. 2002;5(1a):275-277.
- 13. Helen Ann Halpin PhD S, Morales-Suarez-Varela MM, Martin-Moreno JM. Chronic disease prevention and the new public health. *Public Health Reviews*. 2010;32(1):120.
- 14. King AC, Winter SJ, Sheats JL, et al. Leveraging Citizen Science and Information Technology for Population Physical Activity Promotion. *Translational Journal of the American College of Sports Medicine.* 2016;1(4):30-44.
- King AC, Hekler EB, Grieco LA, et al. Effects of Three Motivationally Targeted Mobile Device Applications on Initial Physical Activity and Sedentary Behavior Change in Midlife and Older Adults: A Randomized Trial. *PloS one.* 2016;11(6):e0156370.
- 16. King AC, Glanz K, Patrick K. Technologies to measure and modify physical activity and eating environments. *American journal of preventive medicine.* 2015;48(5):630-638.
- 17. King AC, Bickmore TW, Campero MI, Pruitt LA, Yin JL. Employing virtual advisors in preventive care for underserved communities: results from the COMPASS study. *Journal of health communication*. 2013;18(12):1449-1464.
- 18. King AC, Friedman R, Marcus B, et al. Harnessing motivational forces in the promotion of physical activity: the Community Health Advice by Telephone (CHAT) project. *Health education research*. 2002;17(5):627-636.
- 19. King AC, Friedman R, Marcus B, et al. Ongoing physical activity advice by humans versus computers: the Community Health Advice by Telephone (CHAT) trial. *Health psychology : official journal of the Division of Health Psychology, American Psychological Association.* 2007;26(6):718-727.
- 20. King AC, Hekler EB, Castro CM, et al. Exercise advice by humans versus computers: Maintenance effects at 18 months. *Health psychology : official journal of the Division of Health Psychology, American Psychological Association.* 2014;33(2):192-196.
- 21. King AC, Hekler EB, Grieco LA, et al. Harnessing different motivational frames via mobile phones to promote daily physical activity and reduce sedentary behavior in aging adults. *PloS one.* 2013;8(4):e62613.
- 22. Finck Barboza C, Monteiro SM, Barradas SC, et al. Physical activity, nutrition and behavior change in Latin America: a systematic review. *Global health promotion.* 2013;20(4 Suppl):65-81.
- 23. Wulf WA. {The Collaboratory Opportunity}. Science. 1993;261(5123):854-855.

- 24. Rosas LG, Guendelman S, Harley K, et al. Factors associated with overweight and obesity among children of Mexican descent: results of a binational study. *Journal of immigrant and minority health / Center for Minority Public Health.* 2011;13(1):169-180.
- 25. Rosas LG, Harley K, Fernald LC, et al. Dietary associations of household food insecurity among children of Mexican descent: results of a binational study. *Journal of the American Dietetic Association*. 2009;109(12):2001-2009.
- 26. Rosas LG, Harley KG, Guendelman S, Fernald LC, Mejia F, Eskenazi B. Maternal perception of child weight among Mexicans in California and Mexico. *Maternal and child health journal.* 2010;14(6):886-894.
- 27. Montes F, Sarmiento OL, Zarama R, et al. Do health benefits outweigh the costs of mass recreational programs? An economic analysis of four Ciclovía programs. *Journal of Urban Health.* 2012;89(1):153-170.
- 28. Planeación DNd. *Plan Nacional de Desarrollo 2014 2018: Todos por un nuevo país.* Bogotá, D.C: Departamento Nacional de Planeación;2015.
- 29. Social MdSyP. *La salud en Colombia la construyes tú* Bogotá:: Ministerio de Salud y Protección Social;2013.
- 30. Colombia. CdlRd. Por medio de la cual se define la obesidad y las enfermedades crónicas no transmisibles asociadas a esta como una prioridad de salud pública y se adoptan medidas para su control, atención y prevención. *Ley 1355 de 2009*. Bogotá2009.
- 31. Social MdSyP. *Plan Decenal para el Control de Cáncer en Colombia 2012-2021.* Bogotá, D.C: Instituto Nacional de Cancerología;2012.
- 32. Sarmiento OL, Del Castillo AD, Triana CA, Acevedo MJ, Gonzalez SA, Pratt M. Reclaiming the Streets for People: Insights from Ciclovias Recreativas in Latin America. *Preventive medicine.* 2016.
- 33. Sallis JF, Cerin E, Conway TL, et al. Physical activity in relation to urban environments in 14 cities worldwide: a cross-sectional study. *Lancet.* 2016;387(10034):2207-2217.
- 34. Salvo D, Reis RS, Sarmiento OL, Pratt M. Overcoming the challenges of conducting physical activity and built environment research in Latin America: IPEN Latin America. *Preventive medicine*. 2014;69 Suppl 1:S86-92.
- 35. Meisel JD, Sarmiento OL, Montes F, et al. Network analysis of Bogota's Ciclovia Recreativa, a selforganized multisectorial community program to promote physical activity in a middle-income country. *American journal of health promotion : AJHP.* 2014;28(5):e127-136.
- 36. Gonzalez S, Lozano O, Ramirez A, Grijalba C. [Physical activity levels among Colombian adults: inequalities by gender and socioeconomic status]. *Biomedica : revista del Instituto Nacional de Salud.* 2014;34(3):447-459.
- 37. Hinz A, Finck C, Gómez Y, Daig I, Glaesmer H, Singer S. Anxiety and depression in the general population in Colombia: reference values of the Hospital Anxiety and Depression Scale (HADS). *Social psychiatry and psychiatric epidemiology*. 2014;49(1):41-49.
- 38. Israel BA, Schulz AJ, Parker EA, Becker AB. Community-based participatory research: policy recommendations for promoting a partnership approach in health research. *Education for health*. 2001;14(2):182-197.
- 39. Minkler M, Wallerstein N. *Community-based participatory research for health: From process to outcomes.* John Wiley & Sons; 2011.
- 40. Wallerstein NB, Duran B. Using community-based participatory research to address health disparities. *Health promotion practice.* 2006;7(3):312-323.
- 41. Winter SJ, Goldman Rosas L, Padilla Romero P, et al. Using Citizen Scientists to Gather, Analyze, and Disseminate Information About Neighborhood Features That Affect Active Living. *Journal of immigrant and minority health / Center for Minority Public Health.* 2015.
- 42. Society AC. Cancer facts & figures. 2012.
- 43. Jemal A, Bray F, Center MM, Ferlay J, Ward E, Forman D. Global cancer statistics. *CA: a cancer journal for clinicians.* 2011;61(2):69-90.
- 44. Pineros M, Gamboa O, Hernandez-Suarez G, Pardo C, Bray F. Patterns and trends in cancer mortality in Colombia 1984-2008. *Cancer epidemiology*. 2013;37(3):233-239.
- 45. Carayol M, Bernard P, Boiche J, et al. Psychological effect of exercise in women with breast cancer receiving adjuvant therapy: what is the optimal dose needed? *Annals of oncology : official journal of the European Society for Medical Oncology / ESMO*. 2013;24(2):291-300.

- 46. Stewart AL, Mills KM, King AC, Haskell WL, Gillis D, Ritter PL. CHAMPS physical activity questionnaire for older adults: outcomes for interventions. *Medicine and science in sports and exercise*. 2001;33(7):1126-1141.
- 47. Finck C, Barradas S, Singer S, Zenger M, Hinz A. Health-related quality of life in Colombia: reference values of the EORTC QLQ-C30. *European journal of cancer care.* 2012;21(6):829-836.
- 48. Kocalevent R-D, Finck C, Jimenez-Leal W, Sautier L, Hinz A. Standardization of the Colombian version of the PHQ-4 in the general population. *BMC psychiatry*. 2014;14(1):1.
- 49. Torres A, Sarmiento OL, Stauber C, Zarama R. The Ciclovia and Cicloruta programs: promising interventions to promote physical activity and social capital in Bogota, Colombia. *American journal of public health.* 2013;103(2):e23-30.
- 50. Paez DC, Reis RS, Parra DC, et al. Bridging the gap between research and practice: an assessment of external validity of community-based physical activity programs in Bogota, Colombia, and Recife, Brazil. *Translational behavioral medicine*. 2015;5(1):1-11.
- 51. Miles M, Huberman M. *Qualitative Data Analysis: An Expanded Sourcebook.* 2nd ed. Thousand Oaks, Calif: Sage; 1994.
- 52. Graneheim UH, Lundman B. Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. *Nurse Educ Today*. 2004;24(2):105-112.
- 53. Cohen J. A coefficient of agreement for nominal scales. *Psychological Measurement.* 1960;20:27-46.
- 54. Meisel JD, Sarmiento OL, Montes F, et al. Network analysis of Bogotá's Ciclovia Recreativa, a selforganized multisectorial community program to promote physical activity in a middle-income country. *American journal of health promotion.* 2014;28(5):e127-e136.
- 55. Kerr J, Sallis JF, Owen N, et al. Advancing science and policy through a coordinated international study of physical activity and built environments: IPEN adult methods. *Journal of physical activity and health.* 2013;10(4):581-601.
- 56. Van Dyck D, Cerin E, De Bourdeaudhuij I, et al. Moderating effects of age, gender and education on the associations of perceived neighborhood environment attributes with accelerometer-based physical activity: The IPEN adult study. *Health & place*. 2015;36:65-73.
- 57. Oxford Health Alliance. Oxford Vision 2020: Community interventions for health. Oxford, UK: Oxford Health Alliance;2009.
- 58. Lee IM, Shiroma EJ, Lobelo F, et al. Effect of physical inactivity on major non-communicable diseases worldwide: an analysis of burden of disease and life expectancy. *Lancet.* 2012;380(9838):219-229.
- 59. Barboza CF, Monteiro SM, Barradas SC, et al. Physical activity, nutrition and behavior change in Latin America: a systematic review. *Global health promotion.* 2013;20(4 suppl):65-81.