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Description:

The informed consent form included below corresponds to the English translation of the document used in Spanish, as the study takes place in Mexico, to enroll participants to the “Comunidades y Espacios Activos” (CEA) Project. The project has been approved by the IRB of the Instituto Nacional de Salud Publica, and the full protocol has IRB approval by the University of Texas at Austin.

Appendix 12. Written Informed Consent Form for Hybrid Type III Cluster-Randomized Controlled Trial Active Communities and Spaces (Comunidades y Espacios Activos) Project (CEA)

The community _____ has been selected to participate in a study conducted by the National Institute of Public Health and the University of Texas at Austin (United States). This study evaluates how to adapt certain community programs from other countries to the Mexican context that have been effective in increasing the use of urban spaces for physical activity (for example, parks, bike lanes, plazas) that have been recently improved or constructed. This community is eligible to participate in the study because it has at least one renovated or new space.

Purpose of the study:

The aim of this study is to evaluate dissemination and active participation strategies to increase the reach, adoption, and implementation of these types of community programs in Mexican contexts. You are being asked to participate in Phase II of this study due to your unique experience as a community leader (for example, through your participation in a neighborhood association or other community groups or events), or your current role in an organization relevant to the purpose of this project (for example, governmental or non-governmental organizations focused on urban health, infrastructure, public space, public transportation, urban mobility, safety, the environment, civic participation, equity, and social justice, among other relevant topics).

Study procedures:

We are inviting community leaders and representatives of organizations from different eligible communities to participate in this study. Your community may be selected if enough community leaders/organization representatives from your community agree to participate. In that case, your community will be randomly assigned to one of the following two groups:

Group 1

Participants in communities assigned to Group 1 will be invited to participate in the following activities over a period of 2 years:

1. At the beginning of the study, and at 6 months, 12 months, and 24 months, our research team will ask you to complete a survey. These surveys will collect information about your knowledge of activities available in your community (or lack thereof) that may promote physical activity, as well as general information about you. Each survey will take between 1 and 1.5 hours to complete.

Group 2

Participants in communities assigned to Group 2 will be invited to participate in the following activities over a period of 2.5 years:

1. At the beginning of the study, and at 6 months, 12 months, 24 months, and 30 months, our research team will ask you to complete a survey. These surveys will collect information about your knowledge of activities available in your community (or lack thereof) that may promote physical activity, as well as general information about you. Each survey will take between 1 and 1.5 hours to complete.
2. You will be invited to join a community coalition of approximately 15 members, including other participants from your community, such as neighborhood leaders and governmental or non-governmental representatives with roles or responsibilities in your community. As part of this coalition, you will be asked to:
 - a. Attend a 3-day workshop where you will:
 - Meet other members of your community coalition
 - Learn about community strategies used in other countries to increase the use of public spaces for physical activity in Mexico
 - Work together to identify priorities for your community
 - Decide, with support from the research team, on a one-year implementation plan to maximize the use of public spaces for physical activity in your community that have been recently built or improved

- b. Join a social media group with coalition members and the research team. Through this group and other channels (decided collectively, such as WhatsApp or Facebook groups), the research team will support you in implementing the plan, solving problems, adjusting strategies, etc.
- c. At 12 months, attend a one-day workshop with coalition members and the research team to share progress, challenges, and lessons learned.
- d. At 28 months, complete a survey about your capacity to continue implementing your plan over time and the challenges faced.
- e. At 30 months, participate in a 3-hour co-creation meeting with coalition members and other community members to gather broader perspectives and identify opportunities to sustain strategies over time.
- f. At 31 months, participate in a final project meeting where community achievements and lessons learned will be shared.

Because this study is conducted in collaboration with the University of Texas at Austin, United States, and is funded by the National Institutes of Health of the United States, a description of this project will be available on <https://www.clinicaltrials.gov> in accordance with U.S. law. This website will not include information that can identify you. At most, it will include a summary of the results, which you may access at any time. The Principal Investigator responsible for this study at The University of Texas at Austin is Dr. Deborah Salvo (dsalvo@austin.utexas.edu).

Study risks:

There are no known physical risks associated with this study, and participation is unlikely to cause negative psychological or social consequences.

Study benefits:

There are no direct individual benefits from participating. However, the information you provide will help generate an overall understanding of how urban communities in Mexico can use and benefit from interventions that have been effective elsewhere in promoting physical activity. This may motivate decision-makers and policymakers to support and implement such interventions in ways that fit the local context and culture, and improve infrastructure and activities available in your community to promote physical activity, health, and well-being.

Compensation:

1. Group 1 will receive 400 Mexican pesos for each completed survey (baseline, 6, 12, and 24 months), for a total of up to 1,600 pesos.
2. Group 2 will receive:
 - 400 Mexican pesos per survey (baseline, 6, 12, 24, and 30 months), for up to 2,000 pesos total.
 - Additional incentives: 800 pesos for attending the initial 3-day workshop; 800 pesos for the 12-month workshop; 800 pesos for completing the pre-meeting survey and attending the 30-month meeting; and 1,000 pesos for attending the final meeting at 31 months, for up to 3,400 pesos total.
 - Total possible compensation: up to 5,400 pesos over 2.5 years.

Simplified Privacy Notice:

The principal investigator in Mexico, Dr. Alejandra Jáuregui de la Mota, is responsible for handling and safeguarding your personal data, in accordance with the Mexican General Law on Personal Data Protection.

Confidentiality:

All collected information will be used for research purposes. Your personal information will remain strictly confidential. Your name will not be used in any publications. You will be identified by a number in all study files, and only the principal investigators in the U.S. and Mexico will know your identity. No personal health information will be requested. If you are in Group 2, your participation in group activities will not be anonymous to other participants, but your identity will remain confidential in all reports and publications. You may request corrections or deletion of your data, or withdraw consent at any time by contacting the local investigator at alejandra.jauregui@insp.mx

Voluntary participation:

Participation is completely voluntary, and you may withdraw at any time without affecting your relationship with the researchers or any organization you represent.

Contact information:

This is an international study. The international principal investigator is Dr. Deborah Salvo at the University of Texas at Austin (dsalvo@austin.utexas.edu). For questions, contact Dr. Alejandra Jáuregui de la Mota in Mexico at (777) 329-30-00 ext. 7409 (10:00 a.m. to 5:00 p.m., Central Mexico time) or alejandra.jauregui@insp.mx. For questions about your rights as a participant, contact the Chair of the Ethics Committee, Dr. Angélica Ángeles Llerenas, at (777) 329-30-00 ext. 7424 (Monday–Friday, 8:30 a.m.–4:30 p.m.) or etica@correo.insp.mx.

Based on the above, please confirm:

(1) You are at least 18 years old: YES / NO (not eligible)

(2) Your primary residence is within the study area: YES / NO (not eligible)

If you agree to participate, circle “YES” and complete the information below. If not, circle “NO”.

YES / NO

Participant name: _____

Email: _____ Landline: _____

Mobile: _____ May we contact you via WhatsApp? YES / NO

Participant signature: _____ Date: _____

Thank you for agreeing to participate! Our research team will contact you to schedule your interview.