

## Implementing a Randomized Controlled Trial through a Community-Academia Partnered Participatory Research: *Arte con Salud* Research-Informed Intervention

Patricia Noboa-Ortega, PhD\*; Wanda I. Figueroa-Cosme, MD†; Alana Feldman-Soler, MA‡; Christine Miranda-Díaz, PhD†

**Objective:** “Arte con Salud” is an HIV/AIDS prevention intervention tailored for Puerto Rican women who have sex with men. The intervention curriculum was refined through a community-academic collaboration between Taller Salud, the UPR-Cayey Campus, and the UCC-School of Medicine, subsidized in 2012-13 by PRCTRC. The collaboration has been crucial to validate the impact of using art as a tool to facilitate sexual negotiation skills and safer sexual practices among adult women have sex with men participating in HIV prevention education.

**Methods:** This article describes the vision, valley, victory phases endured to establish a community-academia partnership based on the CPPR framework as an effective mean to implement a randomized controlled trial intervention (RCT). We also discuss the barriers, outcomes, and lessons learned from this partnership.

**Results:** Some of the identified solutions include: setting goals to secure funding, regular meetings, and the inclusion of undergraduate level students to assist in the implementation of the intervention. These solutions helped to build trust among the community and academic partners. As a result of this collaboration, a total of 86 participants were enrolled and 5 competitive research grants have been submitted.

**Conclusion:** The community-academic collaboration was essential in order to build a solid research infrastructure that addresses the complexities of HIV prevention education among groups of Puerto Rican women. [*PR Health Sci J* 2017;36:86-91]

*Key words:* HIV/AIDS intervention, Hispanic women, Community-partnered participatory research

Hispanic population is disproportionately affected by HIV/AIDS. New infections in this growing population group are 3 times higher than in Whites, accounting for 21% of the cases (1). In United States (US) mainland, Hispanic women accounted for 14% of estimated new infections in 2010 (1). Puerto Rico is one of the 12 metropolitan areas with the highest AIDS prevalence in the US and its territories (2). A cumulative of 45,787 HIV/AIDS cases in the adult population were reported in Puerto Rico, 26% of these cases were in women; more than half-through heterosexual intercourse up to January 2014 (3).

The National Institutes of Health has fomented the adoption of best practices at the community level generated through translation research to improve population health (4). Community participation is essential to promote the design, implementation of sustainable health promotion programs, the adoption of best clinical practice, and the improvement of population health (5). Community engagement is the process of working collectively with others that shared geographic proximity and the same interest to resolve issues affecting

their well-being (5). The goals of community engagement approach are to develop trust, to share resources, to improve communication channels, to improve health status, to develop effective health education programs, and to establish durable partnerships among community members and the academia (5-7). Moreover, previous researchers suggested that community participation contributes to the development of culturally supported interventions that are efficient and sustainable and with equitable distribution of services (8-9).

The Community-Academia Partnered Participatory Research (CPPR) framework focused on a shared goal, collaborative work, and a product obtained through three phases: vision, valley, and victory (10-11). The CPPR is a variant from the

\*University of Puerto Rico-Cayey Campus; †Universidad Central del Caribe-School of Medicine, Bayamón, Puerto Rico; ‡Taller Salud, Inc.;

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Address correspondence to: Patricia Noboa Ortega, PhD, University of Puerto Rico Cayey Campus, Social Sciences Department, P.O. Box 372230 Cayey, PR 00736.

community-based participatory research (CBPR) framework in which community-based organizations (CBOs) function as intermediaries to reach the community members which promotes active community participation. CPPR stages include the vision, the valley, and the victory (12). CPPR requires that partners shared a sense of power in the establishment of an authentic partnership and in the development and implementation of an effective intervention product (13). CPPR research informs interventions that are effective including health issues identified by the community, the involvement of stakeholders, the engagement of the community, capacity building and working groups to develop the intervention's products (14). Following this approach, the community is considered an active member in the research activities and both academic researchers and the community form a council to support and guide action plans through the CPPR stages (14).

The outcomes of CBPR research is to improve health outcomes and to reduce health disparities by developing and testing community supported interventions and the added value of community participation (15). Previous researchers have summarized challenges faced during community-academia partnerships including the level of community participation and community consent, power and privilege concerns, and discrimination and social change issues (15). The level of community participation or the involvement of community members in all the research process is often diminished by previous problematic relationship with the academia partners and lack of shared program goals (15). This issues are often solved by forming research advisory committees and focusing on community capacity instead of disease-oriented research programs (15). Community consent or how the researchers are granted permission to enter the community which dependent on the history of collaboration might poses challenges for the involvement of community in community-academia partnerships (15). The second barrier arises from who are perceived as having greater power (i.e. knowledge and resources) in this partnership (15). Also, issues regarding race and ethnic discrimination might evolve during a community-academia partnership. To minimize this issue, the concept of cultural humility needed for develop and maintain a trustworthy partnership between the community and the academia (15). Finally, another challenge is the perceived belief that the research relationship outcomes will served to promote social change (15). This article describes the vision, valley, victory phases endured establishing a community-academia collaboration based on the CPPR framework as an effective mean to implement a randomized controlled trial intervention. We also discuss the barriers, outcomes, and lessons learned from this collaboration.

## Patients and Methods

The community-academia partnership (CAP) was composed of three members from the CBO, three academic researchers

from a public and a private higher education institutions, and 3 undergraduate level students. This community-academia partnership was established to measure the effectiveness of the Arte con Salud (AcS), as a tailored evidence-based group-level intervention for Puerto Rican heterosexual women.

This research study was conducted in five low-income communities in the northeast area of Puerto Rico with a purposive sample of four public housing developments. Participants were randomly assigned to the control or experimental conditions. In the control group, Salud Mujer (SM) a standard of care intervention that involves the delivery of information in the traditional format was implemented. In the experimental group, AcS an evidence-based intervention that incorporates the use of art (i.e. drawings) as the delivery strategy was implemented. The program implementation phase began on September 2013 and ended on December 2014. Participants completed previously validated instruments prior to the first intervention session (baseline), after the completion of the intervention, and three months after baseline measure. A total of 94 heterosexual women were recruited with a mean age of 31 years old. Most women were married or with a partner with a mean of 7 years into their relationship. Educational attainment was higher for those who completed high school education or a higher degree. About 72% were unemployed. The Universidad Central del Caribe Institutional Review Board (IRB No. 2012-23) approved this research.

## Results

We provide a summary of the research activities, barriers, and outcomes encountered in each phase. Beginning with the vision phase or the development of a shared goal; the valley, or the implementation and evaluation of research action plan, and the final stage or victory which focused on the research products.

### Vision phase

The Puerto Rico Clinical and Translational Research Consortium (PRCTRC) is a clinical and translational research service program that focus on health disparities research prevalent in our community. Within PRCTRC, the Office of Community Research Engagement (OCRE) served as a link between CBO and the academia to develop a T-3 translational research project which served to test the effectiveness of an intervention at the community level (16). The PRCTRC funds duration covered the fiscal year 2012-2013. During a previous collaboration, between the CBO and one of the academic partner, AcS intervention, was developed and implemented with Puerto Rican heterosexual women in a low-income setting. This first pilot project received support from the HHS Office of Women Health (2007-2009) and the AIDS United Foundation (2010-2012). The intervention curriculum incorporates art and intergenerational communication as program delivery strategies to promote sexual negotiation skills and safe sexual practices among women. The preliminary AcS pilot project outcome

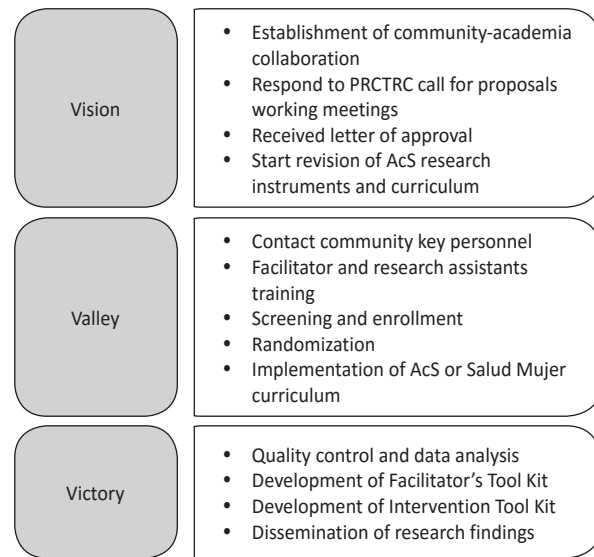
evaluation showed that the intervention helped to increase HIV knowledge (24% to 66%; 18.9 p < 0.001), STI testing (24% to 36%; 1.7 p > 0.05) and condom use during anal (13 % to 43%) and vaginal sex (20 % to 30%).

Prior to grant submission, the community-academia team met bi-weekly to work on the call for proposal. The T-3 research aims were to test the effectiveness of AcS, to measure the program effect, and the psychometric properties of the instruments. The T-3 community research project was submitted on April 2012 and was approved on December 2012. Due to challenges in the PRCTRC administration, funds were not disbursed until April 2013. Therefore, the CBO was required to pay the AcS facilitator and coordinator salaries until funds were allocated. The academic researchers did not receive a monetary compensation. This fund was used to buy program materials and to reimburse CBO expenditures during this year.

As part of this phase, a memorandum of understanding (MOU) was signed by each partner to address research priorities and to share responsibilities and resources needed for the implementation of AcS. The CBO contributed with office space, community experience, and human resources. The program facilitator of AcS had the following responsibilities: (1) identify research communities, (2) arrange meetings with communities coordinators, (3) randomization of research communities, (4) conduct participant recruitment, (5) implement AcS or standard education intervention, (6) coordinate the follow-up measures (3 months after the intervention), and (7) participate in research group meetings. The program coordinator supported the program facilitator to accomplish each implementation activities. The public higher education institution contributed the Principal Investigator’s time effort and the creation of undergraduate level course to assist in the implementation of the intervention. In this course, 4 undergraduate level students were trained in qualitative and quantitative research activities. The students were assigned to various intervention sessions to do multiple research tasks: (1) documenting curriculum fidelity; (2) documenting silhouette creation process; (3) supporting intervention facilitator during sessions and in the administrative work (attendance sheet, evaluation sheet); and (4) coding questionnaires and satisfaction evaluation sheet, (5) doing screening interview. The private higher education institution provided the time and effort of two investigators. The investigators developed the AcS conceptual framework and contributed to improving the previously validated survey and the intervention curriculum. These academic researchers were in charge of monitoring intervention fidelity, solving research ethics issues, and of performing quantitative data management and analysis. Figure 1 shows the CPPR activities done by each phase.

After 2013 fiscal year ended, we continued to receive technical assistance from the OCRE to support our community-academia partnership. A no-cost extension grant for the fiscal year 2013-2014 was granted by PRCTRC. The funds were used to pay the program facilitator. The academic and community partners

**Figure 1.** Research activities by each CPPR phase.



worked together to obtained a research grant from the public higher education institution granted on January 2014. This fund was used to pay participants incentives and to buy program materials and equipment and to continue the implementation of the intervention.

#### Valley phase

In the valley phase, the implementation and evaluation of research action plans were delineated. The research action plan was constantly modified due to challenges confronted in the vision and valley phases. The research team met bi-weekly; this helped to develop trust among members. Capacity-building activities were held to increase research team knowledge on CPPR approach, AcS intervention, and the community culture and history. Also, weekly meetings between the public higher education institution partner and undergraduate students were held to improve fidelity and intervention effectiveness. Each meeting had an agenda and minutes were documented. During meetings each partner had a voice. During this phase, several meetings were held to refine the intervention questionnaire, fidelity checklist, satisfaction questionnaire, and the curriculum. Training for undergraduate level students and the new facilitator were also performed at this phase.

The intervention was implemented in five low-income settings located in San Juan and in Loiza, Puerto Rico. Each community had different challenges. Conflicts and disputes that emerged during the intervention implementation were addressed and feedback was given to strengthen this collaborative effort. The project implementation phase began on September 2013 and ended in December 2014.

#### Victory phase

The commitment of the academic and community partners continues beyond the scope of the AcS intervention to

help improve services at the community level, particularly regarding HIV/STI-related services. In the victory phase, we refined the research products: a culturally sensitive HIV prevention program intervention kit and a facilitator toolkit. The established community-academic collaboration promoted the development of research activities to document the AcS intervention as a promising evidence-based program for Hispanic women. For this purpose and to address and overcome barriers, we worked together to request additional funding and in-kind resources. We submitted five competitive grants; three were funded and served to increase sample size and to pay research expenditures. The AcS intervention was an award winner of the United Nations Joint Program on HIV/AIDS in its 2013-14 contest Best practices and innovative approaches to gender, young women, and HIV in Latin America and an award winner of the Merck Health Innovation Award in 2014. Preliminary research findings have been presented at local conferences and symposia through different format presentations by members of the research team.

### Barriers

Developing trust among partners and a common language to execute the implementation of the pilot project was very challenging at the beginning. The CBO community PI took a leave of absence for one year, therefore, administrative process was undertaken by another member of the institution. The agreements that we had established at the beginning and the trust that had been built was weakened.

We also faced administrative barriers that had subsequent setbacks during each phase. Due to the nature of the grant opportunity, contract delays between the CBO institution and the PRCTRC poses several challenges, a reduction in time to carried out the intervention and expenditure of PRCTRC funds in less than three months due to the end fiscal year. On January 2013, one of PI resigned mainly due to work-related responsibilities and lack of academic discharge to perform research activities. However, new collaboration agreements were proposed between partners to reduce workload and continue to work together to carry out the pilot project. The CBO trained facilitator resigned on June 2013, therefore, we faced a challenge to recruit and train a new facilitator with the necessary knowledge and skills to implement AcS intervention. The new facilitator with knowledge about gender issues and women sexuality and with skills in arts and crafts was hired in less than a month. In the vision phase, we encountered a period of tension and instability due to these challenges. The diversity of the community and the academia expertise provided different points of view to solve the barriers encountered and trust was built with the new member of the team.

The time to implement the intervention was shortened which represented another potential challenge. The research team worked to shorten the curriculum from eight to six session based on evaluation reported prepared by one of the PI. Reasons for this change were long enrollment process (at least 6 participants

per group) and low retention rate (71%). Conversely, this change posed a new challenge on how the intervention will be implemented. To compensate for the lack of time, sessions were offered once per week in both control and intervention conditions. Modifications to fidelity and evaluation sheets were also done. During this period, training for research assistants in quantitative and qualitative research methods and how to facilitate the intervention were offered by the PIs.

On September 2013, the implementation phase began. During the implementation phase, barriers regarding community access were encountered caused by the nature of some communities. IRB was amended to include other communities to increase sample size. We also faced challenges in the facilitation of the intervention due to conflicts of the research assistants' academic schedules but were solved by requesting support from OCRE. Lastly, challenges on how the newly trained facilitator implemented the curriculum including lack of adherence to curriculum content in some sessions and how to handle the closing session of the first intervention groups were encountered. Facilitator and researchers assistants received constant training on how to implement and facilitate the intervention and on how to handle other research activities such as complexity of the coding system. Despite the fact, we developed a common language and a work pace that helped us manage all the challenges that emerged. Table 1 illustrates barriers and solutions encountered during this partnership period.

### Discussion

The involvement of the community, as well as that of the academic partners, was essential to improve the intervention curriculum and to test effectiveness of this randomized intervention trial. The academic partner's commitment, knowledge, and shared value are factors needed for the successful application of a CPPR approach

The first lesson learned is that carry out a project of this magnitude without secure funds is a challenge. We faced the loss of a trained facilitator, the overburden of teamwork, and we start prematurely to compensate for shortened of time to implement the intervention. The latter bring out another lesson, an intervention to improve women knowledge and skills to protect themselves from HIV/AIDS takes more than one year to implement. The third lesson learned is that building trust and a common language between academic and community partners requires more time and sense of commitment of all partners. Each partner that took part in this collaboration gained a better understanding of the diverse realities of the low-income settings of the northeast coast of Puerto Rico, developed sensibility for disadvantaged communities, and increased their knowledge and research skills.

Further research should provide more evidence on how including community involvement is beneficial to improve population health and to develop interventions that represent the community voice in research activities.

**Table 1.** Barriers and solutions encountered by CPPR phases.

CPPR phases	Barriers encountered	Solution
Vision	<ol style="list-style-type: none"> <li>1. Develop trust between academia members and CBO members.</li> <li>2. One PI resigned.</li> <li>3. The Executive Director of the CBO took 1-year leave of absence.</li> <li>4. Contract delays and disbursement of funds</li> <li>5. Short period of time to review curriculum (experimental and control) and evaluation instruments</li> <li>6. ACS facilitator resigned.</li> </ol>	<ol style="list-style-type: none"> <li>1. Through our actions, we begin to trust each other (e.g., doing our agreements in each research meeting)</li> <li>2. Reduced PI research working load.</li> <li>3. CBO Program Coordinator replaced CBO Executive Director in research team duties.</li> <li>4. CBO took over the payment of facilitator and coordinator's salaries.</li> <li>5. Re-assigned research task.</li> <li>6. A new facilitator was hired and trained.</li> <li>7. Three research assistants (RAs) were hired and trained. A course was created Interdisciplinary course (INTD 4116) to formalize the research experience of the research assistant.</li> </ol>
Valley	<ol style="list-style-type: none"> <li>1. Facilitator fidelity</li> <li>2. Short period of time to review curriculum and evaluation instruments</li> <li>3. During the quality control phase, UCC identified errors implementing the coding system. Also, identified potential difficulties with statistical analysis based on our sample)</li> </ol>	<ol style="list-style-type: none"> <li>1. Frequent meetings were held to improve adherence to interventions. Facilitator's manual was developed.</li> <li>2. Re-assigned reviews to both PIs the curriculum (experimental and control) and evaluation instruments.</li> <li>3. RAs received a second training workshop on data management and coding.</li> <li>4. IRB was amended to increase sample size.</li> </ol>
Victory	<ul style="list-style-type: none"> <li>• Sustainability of the community-academia partnership</li> </ul>	<ul style="list-style-type: none"> <li>• Internal and external grants were submitted.</li> </ul>

## Resumen

**Objetivo:** “Arte con Salud” es una intervención de prevención del VIH / SIDA diseñada para las mujeres puertorriqueñas heterosexuales. El currículo de la intervención se perfeccionó a través de una colaboración académica-comunidad entre Taller Salud, el Campus de la UPR- Cayey, y la UCC-Escuela de Medicina, que fue auspiciada en 2012-13 por PRCTRC. La colaboración ha sido fundamental para validar el impacto de utilizar el arte como una herramienta para facilitar las habilidades de negociación sexual y prácticas sexuales más seguras entre las mujeres adultas que tienen relaciones sexuales con hombres y que participan en la prevención del VIH. **Métodos:** En este artículo se describe el proceso de implementación de Arte con Salud basado en las tres etapas del modelo de investigación participativa asociada a la comunidad (Community Partnered Participatory Research- CPPR por sus siglas en inglés): visión, valle y victoria. Presentamos las barreras y lecciones aprendidas encontradas durante la implementación de una intervención del ensayo controlado aleatorio por una asociación académica-comunitaria dirigida a abordar las disparidades de salud del VIH/SIDA. **Resultados:** Algunos de los desafíos, incluidos la necesidad de canales de comunicación eficaces entre las partes, así como los obstáculos financieros e institucionales incluyendo el manejo del tiempo. Algunas de las soluciones identificadas incluyen: el establecimiento de metas para asegurar el financiamiento, reuniones quincenales, y la inclusión de los estudiantes de pregrado para asistir en la implementación de la intervención. Estas soluciones ayudan a construir confianza entre la comunidad y socios académicos. Como resultado de esta colaboración, se reclutaron 86 participantes y se han sometido un total de 5 estudios de investigación competitivos. **Conclusión:** La colaboración

académica en la comunidad es esencial para construir una infraestructura sólida de investigación que aborda las complejidades de la educación para la prevención del VIH entre los grupos de mujeres puertorriqueñas.

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