Pilot and Feasibility Studies

STUDY PROTOCOL

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Juntas Contra el Virus del Papiloma Humano: protocol for a pilot randomized controlled trial of an HPV self-sampling intervention for underscreened Latinas

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Abstract

Background Rates of cervical cancer incidence and mortality are persistently higher among Latina women in the continental United States (US) and women in Puerto Rico (a US territory) compared with non-Hispanic White (NHW) women. Multiple factors contribute to low participation in cancer screening, including structural barriers (e.g., low access to healthcare services, racism/discrimination, lack of culturally and linguistically adequate information), cultural concerns, and low perceived risk and awareness of cervical cancer. Although community-based education and navigation support can be effective in overcoming some barriers to screening, structural barriers and limited access remain formidable challenges to overcome. Emerging technologies supporting self-sampling for high-risk human papillomavirus (HPV) testing may offer a valuable evidence-based strategy for empowering Latina women to engage in cervical cancer screening. Thus, the objective of this study is to assess the feasibility and acceptability of a novel HPV self-sampling intervention for underscreened Latina women.

Methods The study will be a randomized controlled feasibility trial involving 100 Latina women who have not received cervical cancer screening within the recommended guidelines. Participants will be randomly assigned to the intervention condition, which includes a synchronous three-session group cervical cancer educational program delivered virtually along with a mailed HPV self-sampling kit (to obtain self-collected cervical samples for HPV testing), or to a comparison condition that involves receipt of the mailed HPV self-sampling kit with written information about cervical cancer screening and nearby clinics. Study assessments will be obtained at baseline (i.e., study entry) and 1-month post-program. The primary outcome of feasibility will be measured through study enrollment and intervention completion. In addition, acceptability of study materials and the self-sampling procedures will be assessed using self-report surveys at 1-month post-program.

Discussion Provision of a mailed HPV self-sampling kit may present new options for encouraging participation in cervical cancer screening among underscreened Latina women. This study will evaluate the feasibility and acceptability of such an approach, which will inform the subsequent design of a full-scale randomized trial to assess intervention effectiveness on screening behavior.

Trial registration ClinicalTrials.gov no. NCT06439706. Registered 28 May 2024 — retrospectively registered.

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Keywords Human papillomavirus (HPV), Cervical cancer, Screening, Self-sampling, Latinas

Background

In 2024, there will be an estimated 13,820 new cases of cervical cancer and 4360 deaths attributed to this disease [1]. Disparities in cervical cancer incidence and mortality continue to persist across racial/ethnic subgroups in the United States (US). Specifically, cervical cancer incidence rates are 32% higher among Latina women residing in the continental US and 78% higher among women in Puerto Rico (a US territory) compared with non-Hispanic White (NHW) women [2]. US Latinas are also 30% more likely to die from cervical cancer than NHW women [2].

These disparities are alarming given that cervical cancer is a highly preventable disease and can be detected in its early stages — when treatment is most effective — with screening [3, 4]. Yet, despite having one of the highest cervical cancer incidence rates, Latina women in the US are significantly less likely to undergo cervical cancer screening compared with non-Hispanic women [5, 6]. Prior studies have reported multiple factors that contribute to non-screening among Latinas [7]. These include language barriers, lack of access to care or limited clinic hours, racism and discrimination, inadequate knowledge, preference for race/ethnic concordant providers, and cultural concerns regarding modesty [7, 8]. Therefore, innovative strategies that effectively address multiple barriers to cancer screening are needed.

Novel developments in self-collection devices have resulted in the ability for women to safely collect and send their own cervicovaginal samples for human papillomavirus (HPV) DNA testing. Studies have demonstrated that self-collection or "self-sampling" yields similar results to clinician-collected samples [9, 10]. Importantly, studies with other populations and conducted in other countries report that offering self-sampling for HPV testing can be successful in improving participation in cervical cancer screening among underscreened women [11–15]. The ability to obtain one's own sample at a time and place that is convenient for them is a key advantage of self-sampling [16], particularly among women who report that they were unable to complete clinic-based screening due to transportation barriers or inflexible clinic hours [17]. In the US, several studies have offered HPV self-sampling using community health workers or direct mailed kits [18–22]. Key findings from these studies suggest that HPV self-sampling is deemed to be acceptable to US women. However, it is unclear from the prior studies whether the convenience of offering a mailed self-sampling kit would be sufficient to overcome the multiple barriers to screening encountered by US Latina women or whether additional education and addressing women's beliefs would be needed to motivate participation and engagement in self-collection of samples for HPV testing. Thus, the objective of this pilot study is to assess the feasibility and acceptability of an HPV self-sampling intervention presented in two formats: (1) a virtually delivered cervical cancer educational program combined with a mailed HPV self-sampling kit (i.e., an enhanced HPV self-sampling intervention) and (2) a mailed HPV self-sampling kit with written information about cervical cancer screening and nearby available clinics.

Methods

Design and setting

This is a two-arm randomized pilot study with data collection at baseline (i.e., study entry) and 1-month post-intervention (see Table 1). The study will be conducted at Fox Chase Cancer Center located in Philadelphia, PA, USA. Study participants will be recruited from the surrounding region, including Pennsylvania, New Jersey, and New York.

Participants

Individuals will be eligible for the study if they are as follows: (a) self-reported Hispanic/Latina ethnicity; (b) assigned female sex at birth; (c) aged 30–65 years, consistent with guidelines for HPV DNA testing for cervical cancer screening [23]; (d) able to speak and read English or Spanish; (e) able to access a computer or other device with an Internet connection; and (f) overdue for cervical cancer screening (e.g., no cytology-based screening within the past 3 years or no high-risk HPV testing either alone or in combination with cytology in the past 5 years).

Potential participants are excluded if they belong to groups that have different US Preventive Services Task Force (USPSTF) recommendations for the frequency of screening [23]. These groups include individuals with a prior diagnosis of cervical cancer or abnormality (e.g., dysplasia), those who have had a hysterectomy or removal of the cervix, or those with a compromised immune system (e.g., living with HIV). We will also exclude women who self-report that they are pregnant or are within 3 months after a pregnancy based on instructions for use of the HPV self-sampling device [24].

Participant recruitment will be conducted through Latino-serving organizations, via social media, and based on recommended recruitment strategies from our pilot study's Community Advisory Board (CAB) members. Our CAB members will also help foster awareness of the study across their networks. Informed consent will be obtained by the study coordinator prior to any study procedures.

Table 1 SPIRIT diagram for the *Juntas* study

	Study period						
	Enrolment	Allocation	Post-allocation				
			Kit mailed	~ 1-week time frame			Follow-up
Time point	$-t_1$	0 day	1 day	Session 1	Session 2	Session 3	~ 30–40 days
Enrolment							
Eligibility screen	X						
Informed consent	X						
Baseline assessment (see below)	X						
Allocation		X					
Interventions							
Enhanced HPV self-sampling Intervention			X	X	X	X	X
Mailed HPV self-sampling kit			X				X
Assessments							
Sociodemographic characteristics	X						
Knowledge	X						X
Community & environmental factors	X						X
Outcome expectancies	X						X
Feasibility							X
Acceptability							X

Interventions

Enhanced HPV self-sampling intervention condition

After providing informed consent and completing the baseline assessment, participants who are randomized to this condition will be scheduled to participate in a virtual group led by a bilingual health educator. The materials and content to be covered in these virtual sessions were developed to address factors from the Population Health Frameworks conceptual model [25–27] and principles from health behavior change models [28–30] and based on input from our prior focus-group participants and CAB.

Cervical cancer education The education sessions will be delivered virtually by a bilingual staff member in a small-group format. The educational content will be presented in three sessions; each session will be conducted as a live class lasting approximately 1–1.5 h each. There will be separate groups for Spanish-speaking and English-speaking participants. The sessions will be scheduled to occur approximately 2–4 days apart, with the goal of completing all three sessions within 1 week. Intervention content will include information on cervical cancer incidence among US Latinas and risk factors for cervical cancer, including the role that HPV plays in causing cervical cancer (Session 1); cervical cancer screening, including clinic-based screening guidelines, the benefits of screening, and available sites offering low- or no-cost screening (Session 2); and strategies for promoting healthy lifestyles (Session 3). Table 2 presents the learning objectives for each session. All materials will be available in English and Spanish.

HPV self-sampling kit Participants will be mailed a self-sampling kit that has been utilized in prior studies involving self-collected cervical samples for HPV testing [31–33]. The kit will include a detailed instruction

Table 2 Session topics and learning objectives

Session 1: *Juntas* intervention + understanding cervical cancer & HPV
Learning objectives
• To increase knowledge and information about HPV and cervical cancer
• To understand the scope, objectives, and content of the *Juntas* intervention
• To understand the roles and responsibilities of peer navigators/*navegantes*
• To understand factors associated with cervical cancer screening among Latinas
Session 2: Prevention is essential for maintaining health
Learning objectives
• To understand strategies for screening, prevention, and care among Latinas
• To understand the barriers to care experienced by Latinas
Session 3: Sustainability & healthy lifestyle
Learning objectives
• To understand cancer treatments and steps post-screening
• To deepen understanding of sustainability and living a healthy lifestyle
• To increase knowledge and information about comorbidities related to HPV
• To increase the ability to educate families and the community about HPV and sexual health

card, available in English and Spanish, on how to collect a sample and return it to the study coordinator. As in prior studies, all women will also be encouraged to complete clinic-based screening [34].

Mailed HPV self-sampling kit comparison condition

Participants in this condition will receive a mailed self-sampling kit after completing the baseline assessment, along with instructions on how to collect and return the sample using the postage-paid mailer. In other countries, mailed self-sampling kits have been provided in an effort to increase participation among unscreened women [35, 36]. While this offers a low-cost, low-intensity approach to increasing screening, it is also associated with suboptimal uptake, with rates of 23–32% participation. Because studies have identified a lack of knowledge about screening as a key barrier, we believe that the inclusion of a dynamic educational program (such as the program contained in our enhanced HPV self-sampling intervention) will increase participation in HPV self-sampling more so than simply providing a mailed kit with written information and materials.

Sample analysis and management of positive test results

Self-collected samples received by the study team will be sent to collaborating labs for testing of high-risk HPV subtypes using a PCR-based multiplex HPV assay integrated with the mass spectrometry system MALDI-TOF (MassArray matrix-assisted laser desorption/ionization time of flight), which has been previously validated [37, 38]. Test results will be reviewed by clinical members of the study team. Subsequently, the bilingual study coordinator will contact each participant who provided a sample with her test result and reiterate the importance of obtaining clinic-based screening. Participants who test positive for a high-risk HPV subtype will receive referrals for a follow-up exam and be navigated to clinical care.

Study measures and outcomes

The primary outcome is to assess study feasibility and acceptability in preparation for a large-scale effectiveness trial.

Primary outcomes: feasibility and acceptability

- Feasibility will be assessed by tracking the following: the number of eligible participants required to enroll the sample size and the rate of intervention completion (i.e., the number of participants who attend at least one session in the enhanced intervention arm). Completion is defined as attending one or more sessions. We will also assess uptake as the number of participants who return a self-collected sample to the study coordinator. Further, we will track the rate of recruitment, including the ability to recruit participants within a specified time frame and the recruitment success for each of the recruitment venues and strategies. The research team will also monitor and document any adverse events or unintended consequences associated with the intervention or study procedures. Given the nature of our study, we will also evaluate the level of engagement and collaboration with key stakeholders (e.g., number of community partners and healthcare providers engaged in the pilot study, attendance at the CAB meetings, level of engagement in CAB meetings) involved in the study.
- Acceptability of self-sampling will be assessed among all participants at the 1-month follow-up only. Participants who returned a sample will be asked to rate the acceptability of self-collection using items adapted from prior studies [18, 39, 40]. Among participants who do not return a self-collected sample, we will assess the reasons for nonparticipation. Acceptability of the virtually delivered educational intervention will be assessed among enhanced intervention participants only at the 1-month follow-up time point. All participants will be asked to provide feedback regarding their overall satisfaction with the program and suggestions for improvement. These

measures collectively provide insights into the feasibility and acceptability of the intervention, helping to inform its potential scalability and effectiveness in broader settings.

Secondary outcomes

- *Knowledge* about HPV and cervical cancer will be captured at baseline and 1-month follow-up using items drawn from the NCI Health Information Trends Survey (HINTS) and our prior research [41–43].
- *Outcome expectancies* about cervical cancer and screening will be assessed at baseline and follow-up using 15 items answered on a 5-point Likert-type scale ranging from 1 "strongly disagree" to 5 "strongly agree". Example items include the following: "I believe that cervical cancer screening can detect cervical cancer early and prolong life" and "Having a Pap test will be embarrassing for me" (reverse scored) [44–46]. Self-efficacy in obtaining screening will be assessed using three items (e.g., "I am confident about my ability to obtain cervical cancer screening"). These items were adapted from established measures of health-related self-efficacy [29] and utilized in our prior studies [22, 44, 45]. Responses to the items will be summed to create a composite score of positive outcome expectancies with respect to screening, similar to prior studies [22].
- *Community and environmental factors*: Sociocultural environment (e.g., family and community support for screening) will be assessed at baseline and follow-up using items including "My family will support me if I decide to get screened for cervical cancer" and "People from my community are supportive of screening for cervical cancer". Physical environment barriers will be measured using items from our prior studies that assess factors such as language or access difficulties (e.g., "My doctor's office is not open when I get off from work"; "I do not have transportation to the doctor's office or clinic to get a Pap test") These items were adapted from prior studies [41, 45].

To characterize the pilot study sample, we will capture *sociodemographic characteristics* at baseline only. These variables will include race, ethnicity, age, education level, marital status, employment status, and English language reading/speaking ability. Prior cervical cancer screening behavior and healthcare access (including health insurance and regular healthcare provider) will also be assessed.

Procedures

After providing informed consent, participants will be asked to complete the baseline survey using a REDCap link. Following the completion of the baseline survey, participants will be randomized (1:1) — using a randomization schedule provided by the study biostatistician — to receive either the mailed HPV self-sampling kit with written materials alone ($n = 50$) or in combination with a three-session group education workshop led virtually by a Latina health educator ($n = 50$), both of which are described above. Study staff will mail each participant an HPV self-sampling kit with written instructions on how to collect a sample, as well as a postage-paid, pre-addressed envelope for returning the sample. Samples can be stored at room temperature and returned via US mail. Samples that are received by the study team will be submitted for HPV DNA testing. Test results will be reviewed by study team members and returned by letter sent via US mail. Those participants who test positive for a high-risk HPV subtype will also be contacted by telephone by a study staff member who will review the test result with the participant and recommend follow-up clinical care. Approximately, 1 month following the mailing of the HPV self-sampling kit, participants will be sent a link to complete the follow-up survey in REDCap.

All study data will be collected electronically using REDCap, a software application designed to build online surveys and databases. REDCap provides numerous safeguards against confidentiality breaches and is designed to comply with national regulations governing the protection of participants' health information. Upon completion of assessments, data are automatically uploaded to a secure, password-protected cloud database; participant assessment data are not linked to identifying information. Data gathered from REDCap may be seamlessly imported into statistical software packages for subsequent data analysis.

Data analysis

The sample will be characterized using descriptive and exploratory analyses. Measures will be quantified and described using standard statistics (frequencies, proportions, means, standard deviation [SDs], etc.). To provide information regarding potential attrition bias, we will examine the baseline comparability of participants who do and do not complete the study. Factors predictive of successful completion of the study will be identified via logistic regression. We will use proportions and 95% confidence intervals [CI] to assess uptake.

The primary objectives are to assess the feasibility and acceptability of the HPV self-sampling interventions.

We will define the study as feasible if sufficient proportions of women who contact the team (a) enroll in the study and (b) complete one or more sessions of the enhanced HPV self-sampling intervention. We will declare a larger study feasible if two conditions are met: (1) 50% or more of eligible participants consent (i.e., screen no more than 200 eligible participants to get 100 enrolled) and (2) 50% or more of the 50 who consent and are randomized to the enhanced HPV self-sampling intervention condition complete at least one session. We focus one feasibility criterion on the enhanced intervention arm as this arm is expected to be more burdensome to participants than the mailed HPV self-sampling arm. The operating characteristics of our feasibility rules are provided in Table 3.

Our co-primary endpoint will be acceptability. We will summarize acceptability using means, standard deviations, and proportions of a dichotomized acceptability variable. We will report acceptability for each study arm. The primary purpose of measuring acceptability is for quality improvement purposes with respect to a subsequent larger study. We hence do not provide a sample size justification for acceptability. We will also describe secondary outcomes in each study arm using means, standard deviations, and proportions as appropriate for continuous or categorical variables.

Sample size justification

We chose our sample size of 100 as it provides reasonable probabilities of declaring the study a feasibility success under the assumptions given in Table 3.

Discussion

Community-engaged screening interventions have demonstrated effectiveness in reaching underscreened women [47–49], yet persistent structural barriers to healthcare, such as limited operating hours, inconvenient locations, structural racism and discrimination, lack of insurance, and transportation challenges, continue to hinder access for many Latina women [7, 8]. Overcoming these barriers remains challenging. However, offering a novel option that empowers women to self-collect a sample for human papillomavirus (HPV) testing holds promise as a potential solution. By providing Latina women with the opportunity to collect their own samples, this approach circumvents traditional barriers to healthcare access, thereby improving participation rates in cervical cancer screening programs [50]. Additionally, self-collection offers Latina women greater autonomy and control over their health decisions [51], potentially leading to increased engagement with screening initiatives and ultimately reducing cervical cancer morbidity and mortality rates within this population.

The intervention described in this paper was developed and adapted in conjunction with input from our Community Advisory Board (CAB) comprised of Latina women with broad-ranging expertise in healthcare, public health, and social policy. They emphasized the need to highlight the benefits of HPV testing and address critical barriers to testing (e.g., knowledge, stigma), as well as the imperative for robust protocols for navigating those who test positive for high-risk HPV. By incorporating the perspectives and recommendations of our CAB members into the intervention design, we have ensured the creation of a culturally responsive and community-centered approach [52]. This approach has the potential not only to increase cervical cancer screening uptake among Latinas [53] but also to cultivate empowerment, resilience, and improved health outcomes within the community.

The data obtained from this pilot study will serve as a foundational resource for shaping the design and implementation of a future full-scale, community-based randomized trial aimed at evaluating the effectiveness of the intervention on screening behaviors. In summary, the

Table 3 Promising and discouraging population rates and decision rules for declaring study feasible

	Promising population rates	Discouraging population rates	Sample decision rule for declaring study feasible under full accrual[a]
% of women who consent (i.e., screen no more than 200 eligible participants to enroll 100 patients)	55%	40%	≥ 50% ($n \geq 100$)
Probability of declaring enrollment feasible	*93%*	*< 1%*	
% of intervention arm participants (e.g., ≥ 25/50) who complete study	55%	40%	≥ 50% ($n \geq 25$)
Probability of declaring completion feasible	*80%*	*9.8%*	

[a] Probabilities of declaring a future study feasible are defined in terms of hypothetical repeated sampling under promising and discouraging rates and calculated using the binomial distribution. In the event that accrual is less than expected, we will investigate the hypothesis that the feasibility rates are consistent with the 40% discouraging (i.e., null) hypotheses stated using one-sample binomial exact statistics

proposed intervention, which includes a mailed HPV self-sampling kit, offers a safe and promising approach to enhance participation in cervical cancer screening among underscreened Latinas. This intervention has the potential to significantly impact future screening guidelines and contribute to improved health outcomes in underserved communities.

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Authors' contributions
CYF, MCC, and OM conceived and designed the study. BE created the randomization scheme and developed the statistical analysis plan. CYF, MCC, PK, SP, ML, YC, GMS, and OM will implement the study procedures. CYF created the first draft of the manuscript. All authors reviewed, edited, or approved the final manuscript.

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Data availability
De-identified data to be collected during the pilot study can be made available after completion of the study upon reasonable request.

Declarations

Ethics approval and consent to participate
FCCC IRB provided approval on September 5, 2023 (IRB no. 23–1027). This study will be conducted in accordance with the ethical standards of the Declaration of Helsinki. All eligible participants will be required to provide informed consent prior to participating in the study.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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