Infección de Amor (Love Infection): Online Delivery and Pilot Testing of a Dramatized Story Intervention (Telenovela/Soap Opera) for HIV Prevention Among Latinas in North Carolina

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Study Protocol

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Study Description

The study includes women between 18 to 44 years old. We will enroll 66 participants with the aim of testing the feasibility, acceptability of the IA intervention (four telenovela episodes), assessment of the mechanisms of action (self-efficacy, narrative engagement, and emotional elicitation) and conduct a randomized controlled pilot study to examine the change in primary outcomes (condom use, HIV testing, Pre-exposure Prophylaxis [PrEP*/ awareness and use)* and secondary outcomes (Substance abuse (SA), intimate partner violence (IPV), and depression comparing 33 intervention- and 33 control Latinas at baseline (T1, pre-intervention), T2 (immediately post-intervention, 1 month) and T3 (3 months after the end of the intervention, with no intervening contact with study staff).
Participants will be asked to: (1) attend to a one hour-meeting with the research team to complete a baseline survey and receive an orientation about the use of the telenovela website, (2) access the telenovela website once a week for 4 weeks to watch a telenovela episode and answer some questions about the episode (one hour each week, 4 in total), (3) complete a survey (on their own) one-month after the baseline survey, and (4) complete another survey (on their own) 4-months after the baseline survey. Participants will be interview by the research team using a structured survey in the first meeting (baseline survey) and then they will complete the surveys (1-month and 4-months after baseline) on their own. Participants can request help to complete these surveys (online using zoom or face to face if needed).
If participants request help to complete the follow-up surveys using zoom, we will ask participants to access from a place that is comfortable and provides privacy and encourage the use of headphones if needed. We will ask them to be alone during the meeting and we will conduct the meeting at the participant's preferred time. We will not record the zoom meetings. The research team will also access from a private place and will use headphones if needed. Any disclosure of the participants' responses outside the research will not place them at risk of criminal or civil liability or damaging their financial standing, employability, or reputation since we will not be asking personal questions such as
immigration status, or any financial information. Questions will be about feasibility and acceptability of the intervention, study mechanisms' of action and HIV prevention related questions. (primary outcomes: condom use, HIV testing, Pre-exposure Prophylaxis [PrEP*/ awareness and use* and secondary outcomes: Substance abuse (SA), intimate partner violence (IPV), and depression)

Informed Consent Procedures

Potential participants will be screen by the study team (researcher/research assistant) following a verbal consent script for telephone screening. After the research team explain the study information, they will ask the potential participant if she is interested in the study. Then, a member of the research team will ask the participant if she consents to provide personal information to determine if she qualifies for the study. If a woman meets inclusion criteria, the research team member will make an appointment to meet with the participant at the community center, in a study office that will be located near to the community center or in any other participant's preferred location. The appointment can be remotely via telephone or teleconferencing if needed due to COVID social distancing requirement. In a private

room and at a convenient time for the participant, the research team member will conduct the informed consent process. Then participants will complete the baseline survey and the orientation to the intervention. Women will sign a consent form before participating in their preferred language (English/Spanish).
A copy of the ICF will be given to them. This study will focus on Spanish speaking Latinas, but since some Latinas prefer to read in English, participants will have the option to choose the preferred language for the ICF process and the written consent.

Subjects

We will enroll 66 Latinas ages 18-44 years who report sexual activity with a man in the last 6 months, have internet access from any device, and reside in NC. The research team is bilingual and will be able to assist women if they have questions about the study.

Study procedures will be conducted in English and/or Spanish according to participant's preference. Recruitment and screening will be led by a bilingual (English and Spanish) study personnel. Participants will be asked their preferred language at the time of recruitment. All study materials, including information and consent forms, questionnaires, and recruitment ads, will be translated and available in Spanish. Any direct interaction with non-English-speaking participants will be available in Spanish.

Describe the study design. List and describe study procedures, including a sequential description of what subjects will be asked to do, when relevant

The study includes women between 18 to 44 years old. We will enroll 66 participants with the aim of testing the feasibility, acceptability of the IA intervention (four telenovela episodes), assessment of the mechanisms of action (self-efficacy, narrative engagement, and emotional elicitation) and conduct a randomized controlled pilot study to examine the change in primary outcomes (condom use, HIV testing, Pre-exposure Prophylaxis [PrEP*] awareness and use)* and secondary outcomes (Substance abuse (SA), intimate partner violence (IPV), and depression comparing 33 intervention- and 33 control Latinas at baseline (T1, pre-intervention), T2 (immediately post-intervention, 1 month) and T3 (3 months after the end of the intervention, with no intervening contact with study staff).

Baseline survey. If potential participants meet the inclusion criteria, they will be asked to attend to a one hour-meeting with a member of the research team to sign the informed consent, complete a baseline survey and receive an orientation about the use of the telenovela website https://www.infecciondeamor.com/. After participants complete the survey, they will be randomized by a member of the research team to the intervention or control group. The research team member will explain the following activities they have to complete according to the group they will be assigned. If they are randomized to the control group, the orientation to the website will be delayed until they complete the 4-month post baseline survey. The survey will be available in Qualtrics and only the members of the research team will have access to the survey.

- **Intervention group:** 33 Latinas will view four IA intervention episodes, one per week. Participants will receive an email to their preferred email address with a password to access to the episode on the IA's website: https://www.infecciondeamor.com/
    - Each 10-minute episode can be watched more than once during the week and presents a situation with notable HIV risk and ways the characters avoided risk (e.g., condom use) or confronted consequences of poor practices (e.g., HIV infection). The one-week time frame for each episode is needed to provide time to review and reflect about IA's content and modify HIV prevention behaviors. It will also allow Latinas to obtain information and support from the team and referral if needed. This time frame was effective to improve behaviors in our previous studies.
    - After each episode, participants will complete a survey (on their own) on the telenovela website. This post episode survey includes questions about the mechanisms of action of the telenovela. (self-efficacy, narrative engagement, and emotional elicitation)
- **Control group:** A wait-listed control group of 33 Latinas will receive IA in the same manner as the intervention group after completing T3 data collection. Latinas will be informed at recruitment of this group condition and the study randomization. During the three-month waiting time, we will call participants on a monthly basis to encourage participation and refer to services if needed.

Follow-up surveys. Participants will answer a (one-month after baseline) survey, and complete another survey (on their own) 3-months. Participants will complete these surveys (1-month and 4-months after baseline) on their own. Participants can request help to complete these surveys (online using zoom or face to face if needed). We will not record the zoom meeting if we conduct the surveys using zoom. A description of the study measures is provided below.

Infección de Amor website. The PI with a website developer and Dr. Khairat developed the IA intervention delivery website. The website provides: a) access to the four intervention episodes 24/7 from any location or type of device (e.g., cellphone, laptop) since it will be mobile optimized (all the episodes are password protected); b) questionnaires for data collection deployed via Qualtrics; c) a contact section in case participants have technical problems or need to contact the research team; and d) a section with community resources, services, and referrals. We will use secure and private servers and communication channels such as OneDrive to store and to exchange information.
The intervention website is accessible only to study participants in English and Spanish. The intervention participants will access telenovela episodes, available in Spanish or English, at their preferred time and place using a website accessible through any device since it will be mobile optimized. A new episode of IA will be available each week. Women will be instructed to watch an episode as many times as they want during the week, but they need to answer a post episode-viewing survey after viewing it the first time. Also, they will be able to pause or stop the episodes at any time if they need to take a break or stop watching for any reason. Women will be advised to watch the episodes alone. Prior episodes will remain available after a new episode is released. Each episode has an opening that introduces the characters and then the content of the telenovela.

Participants will receive reminders about their participation using an automated notification system from Qualtrics. We will send up to three automatic reminders each week to participants who have not accessed an episode in a specific window period and completed the post episode survey or if the participant has not access to the website in one week. If a woman does not complete the episode in one week or does not access the website in one week, the research team will contact the participant (e.g., emails, calls, or text messages) to her preferred email or phone. The research team will discuss with her any impediments to her participation, how to watch the missed episode, and resume with the following episodes. Women will be able to pause or stop the episodes at any time if they need it. Prior episodes will remain available after a new episode is released if women would like to review them.

Procedures for Minority Retention and Potential Challenges. For each video episode, participants will have a one-week window to view and will receive reminders using an automated notification system from Qualtrics when the end of the viewing-window is approaching. The website will track if participants watched the whole episode. We will also provide information about HIV prevention at the end of each episode and a link to the technical support and referrals sections if needed. Other retention strategies will include: 1) updating contact information frequently; 2) requesting contact information of at least two friends or relatives in case we cannot contact the participant; 3) contacting the woman by email or cell phone (we will ask permission in the informed consent for contacting them); 4) providing compensation for their time, internet use, and transportation; and 5) automated notification system messages for special occasions (e.g., holidays). We will also be flexible in scheduling enrollment and data collection appointments. We will monitor attrition in both conditions. We will discuss potential issues with Latinas and community centers, and if needed, establish a community advisory board of three Latinas of the same age as those participating in the study to ask for their advice.
We will use unencrypted messaging to send participants information about the date/time of the baseline survey and follow-up surveys. If participants have not completed the electronic surveys, we will also use text messaging and unencrypted email to request electronic survey completion. We will also use it to send reminders of the telenovela episodes and post episode surveys.

Team Training

All study personnel will be adult, bilingual, and will receive training in human subjects and a 3-5 day training about study procedures and their specific functions in the study (e.g., website access, use of Qualtrics, and Microsoft excel). We will have monthly team meetings with all personnel to discuss study progress. The PI will supervise staff, talk with RAs daily-to-weekly during the intervention period, participate in recruitment, conduct baseline questionnaires, and coordinate all study implementation activities. Also, two RAs recruit participants, administer baseline questionnaires, and track participation. The RAs will: a) monitor Latinas' website access; b) track number of times they watch the episodes and support with referrals; and c) contact the PI if needed. A section of the platform will provide direct contact with the research team if they need technological assistance.

Potential risks

Participants will have access to watch the intervention online individually 24/7 from their preferred location. They will be asked to watch the intervention in a comfortable and private place since some of the content (e.g., IPV, substance use) can be sensitive for them or other people (e.g., their children) if they allow them to watch. Participants will have a contact section on the online platform in case they have questions, they need referrals, or they want to talk about issues that may arise while they are watching the telenovela. If they are watching the telenovela and they experience stress or anxiety, they will be instructed to call a person from the team who will be available to listen to them and refer them to proper services if needed. The person from the team will notify the PI about the situation and how it should be managed. A protocol will be created by the research team to manage these situations. The PI will train the research assistant (RA) on how to manage these situations, how to support women, and help them feel comfortable. Latinas will be instructed that they can stop their participation at that moment and that this situation will not affect their ability to continue in the study. The research team will treat Latinas with respect and will be sensitive if they express that they feel or voice embarrassment with the intervention content. The team will explain to them that this will not affect their ability to continue in the study.

If a potential breach of confidentiality occurs, which could be related with someone finding out that a participant is involved in the study or if a study member unintentionally disclosures confidential information about the participants. Efforts will be made to avoid these situations, by not revealing any information about participants to any people external to the research unless requested by authorities. Participants will be requested to keep their randomization to the groups (intervention or control) confidential. In addition, all the team members will have their Human subject training up to date and will receive a training to avoid situations that can lead to breach in confidentiality.

During enrollment in the study and the study, Latinas may run across other Latinas that are joining the study from their community. We will reinforce during the informed consent process that their participation and information provided to the study will remain confidential and will not be shared outside the study.

A password protected linking file with the identifiers will be stored in a different physical location from the research data. Only the research team will have access to this file. All the paper records with this information will be storage in a locked office at the School of Nursing at the University of North Carolina at Chapel Hill and will be store separate from the research data. Zoom sessions will not be recorded.

Confidentiality of the data

Confidentiality will be protected through a coding mechanism. The names of all participants will be removed from the data and a code number assigned. Each participant's identifying data will be separated from the study data, and the PI will keep key identifying code numbers and the participant identification in a locked file cabinet that only the PI and the RAs will have access.

Qualtrics will be used for the study measures, and this online questionnaire platform is password protected. The study questions will be accessible online to the RAs/participants through the use of a link. Data will be reported in an aggregate form without identifying information by site or individual.

All research personnel study personnel will be trained in IRB guidelines to maintain the security and confidentiality of the data. Latinas will be made aware of the precautions that the research team will take in keeping their data confidential. All identifying information will be destroyed at the earliest possible time following completion of the study. Publications arising from the study will not contain personal information. All data will be analyzed by groups, with no potential for individual participants to be identified.
In addition, the telenovela website does not have any personal information from participants, all the data is collected through Qualtrics and is password protected. Access to the episodes on the website only is possible if participants receive a password with access to a specific episode. Only the research team members will have access to the information collected in Qualtrics. We will use secure and private servers and communication channels such as OneDrive to store and to exchange information. Zoom meetings will be used to conduct the interviews using structured surveys in the 2 meetings. We will not record zoom meetings.

We will create a one drive folder to storage the study information and only the team members will have access if needed. We will also have a Qualtrics account with the survey information that only the research team will have access.

We will ask HIV status as an inclusion criteria of the study. For aim 2 we will HIV related prevention outcomes including sexual behavior, condom use, HIV testing, Pre-exposure Prophylaxis [PrEP] awareness and use, substance abuse (SA), intimate partner violence (IPV), and depression, and other sensitive information.

We will use an eligibility form for this study that will be enter in Qualtrics, which has protected access and only the research team members will have access. All the information will be kept in the UNC one drive if we need to download the file during the study and only the research team members will have access. We will keep this information until one year after the research is conducted. We will refer participants in case they experience any distress while answering the surveys.

Recruitment
The sample will consist of 66 Latinas ages 18-44 years who report sexual activity with a man in the last six months, have access to the internet from any device (e.g., cellphone, laptop), and who resides in NC. We refer to Latinas as women who self-identify as having Latino ancestry. Latinas positive for HIV will be excluded given our focus on primary prevention.

Recruitment strategies will include talking to women in the community face-to-face, using posters/flyers and/or brochures, and snowball sampling. The PI has used these strategies successfully in previous studies with Latinas. To increase the intervention's future scalability and reduce contact with the project staff, we will add online recruitment using Facebook Ads, found

effective in other studies with Latinas. One month before enrollment, the research assistants (RAs) will begin recruitment efforts in the two El Futuro community centers and place Spanish and English posters, brochures in waiting rooms and online using Facebook Ads. Also, posters will be hung in areas where Latinas gather in the community (e.g., churches, community centers, coffee shops).
For the online recruitment, we will use Facebook ads (which are part of Facebook). The PI will create a password protected account. The account will post the study poster automatically with the study contact information during one month. If a participant is interested she will need to call the study phone number. No contact information from participants will be requested online. The post option will not be available online to talk with participants.
Potential participants will be screened by the study team (researcher/research assistant) following a verbal consent script for telephone screening that includes the inclusion criteria for the study.. We will conduct the two meetings at a convenient time for the participant in a private room and their preferred language using COVID precautions on-site (e.g., temperature check, symptoms assessment, facial mask). After the research team explain the study information, they will ask the potential participant if she is interested in the study. Then, the researcher/research assistant will ask the participant if she consents to provide personal information to determine if she qualifies for the study.

Data monitoring

Our data safety and monitoring plan will take steps to minimize the risk of breach of confidentiality, including procedures to prevent unauthorized use of study data. Names will not be attached to any research instruments or digital files, and all participant data will be identifiable only using the sequentially assigned Study ID number. All investigators have experience collecting data with HIV risk populations.

Data Gathered During Screening. We will assess potential participants' eligibility for the study using a series of screening questions, which will not include any personal identifying information. We will destroy any and all notes taken during screening after we verify that each participant is eligible for the study.

Informed Consents. Pen-and-paper data collection methods will be used to conduct the informed consent process with participants. A copy of the signed informed consent will be given to them. If we use zoom for the baseline survey, we will use the electronic version of the informed consent and a copy will be sent to the participants' preferred email address. This informed consent will be available in Qualtrics and only the research team will have access. Printed copies of the informed consents will be store in the Principal Investigator's locked project office at the School of Nursing. Any printed information that might identify participants will be transported in a sealed folder when necessary and kept in a locked cabinet in the PI's office, which will be accessible only to essential

Surveys. Quantitative survey data will be gathered via electronic (using Qualtrics). Pen-and-paper data collection methods will be used in case that we have Qualtrics or internet related issues. Printed copies of the surveys will be store in the Principal Investigator's locked project office at the School of Nursing.

Data will be linked to participants' sequentially assigned Study IDs, but it will not be linked to their Unique IDs or to any personal identifiers. Any identifying information, including the participants' name and number used to set up appointments, will be kept separate from data at all times. Unique IDs and participant contact details will be written down and kept in a separate locked cabinet in the PI's office.

Qualtrics will be used to collect information from the surveys. Only the research team will have access to Qualtrics. Participants will receive a unique link in their preferred email address that will give them access to the follow-up surveys. Data will be de-identified for the analysis and files will be saved in a password-protected computer in the Principal Investigator's locked project office.

When Zoom is used to conduct the surveys, we will not record the meeting and all the information will be saved in Qualtrics. To protect participants' confidentiality, we will have the following guidelines to maintain security and safety of Zoom meetings:

1. We will password protect any online meeting. We will set up a unique password for each meeting. All participants will be required to enter the password to join the meeting.
2. Participants will only be allowed to join the meeting after the host (either the PI, co-Is or project coordinator) has arrived. In addition, we will use the waiting room feature of Zoom to keep participants in a waiting area until the host is ready for them.
3. We will lock down the meeting once every expected participant has arrived. This lock down will prevent others from joining, even if meeting IDs or access details have been leaked.
4. For each meeting, a randomly generated meeting ID will be created. Meeting IDs will be sent to participant's email or through text messaging.

Intervention website. The intervention website will not have any personal information from participants. Participants will access to the episodes using a password.

Monitoring. The PI will provide ongoing supervision and training to essential study staff at weekly meetings, which will also ensure continued compliance with data safety protocols. The Investigator will also discuss human subjects' issues at weekly meetings.
Participants in human subjects' research inevitably give up some privacy to share data about their individual experiences; however, we believe our data safety and monitoring plan will minimize the risks of any further breach of privacy or confidentiality. The Investigators will be responsible for ensuring that study protocols for maintaining confidentiality are followed.

Statistical Analysis Plan. For Aim 1 and Aim 2 data, we will conduct descriptive analyses of the outcome measures (e.g., the mean and standard deviation for continuous variables and frequency and proportion for categorical variables). To examine the intervention effect on HIV prevention in Aim 2 data analysis, we will adopt multiple mixed-effects models to analyze the data. Specifically, we will include behavioral outcomes (e.g., substance abuse) as the dependent variable. In contrast, the treatment assignment status (intervention or control), age, education level will be included as the fixed effect terms. The subject-level cluster effect following a normal distribution with a mean zero will serve as the random effect term. We will also consider

different covariance structures among repeated measurements and conduct model selection to determine the optimal model and covariance structure for the data, as in our early published work. Alternatively, if the model does not converge, we will adopt an ANOVA model to investigate the intervention efficacy at each measurement time point. Though the intervention efficacy will be evaluated across several different outcomes in the Aim 2 data analysis, multiple comparisons will not be adjusted since our goal in this pilot study is to collect preliminary data to design future R01 study and proposal submission.