Informed Consent

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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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants- Patients

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IRB Study # 21-3214
Title of the Study: Love Infection: Feasibility, Acceptability and Pilot Testing of an HIV Prevention Telenovela Intervention

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CONCISE SUMMARY

The purpose of this study is to assess the feasibility, acceptability, mechanism of action and pilot test an online telenovela intervention Infección de Amor (Love Infection, IA), an intervention designed for HIV prevention among Latinas. The study's goal is to help Latinas to prevent HIV infection. Participants will be 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.

Participants will be asked to: (1) receive an orientation about the use of the Infección de Amor (IA) telenovela website and access the telenovela website once a week for 4 weeks to watch a telenovela episode and answer some questions about the episode (half hour each week, 2 in total), (2) attend to a one hour-meeting with the research team to complete a baseline survey, (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 complete a structured survey in the first meeting (baseline survey) with a member of the research team and then they will complete the follow-up surveys (1-month and 4-months after baseline) on their own. Participants can request help to complete these surveys with the help of the research team (online using Zoom or face to face if needed). The moment that participants will access the IA intervention will depend on the group to be assigned by the research team (intervention or control group).

What are some general things you should know about research studies?

You are being asked to take part of this study. To join the study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There are no anticipated serious risks related to participating in this study, the risk is minimum. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this study is to test the feasibility, acceptability, mechanism of action and pilot test the online telenovela intervention Infección de Amor (Love Infection, IA), an intervention designed for HIV prevention among Latinas. The total sample of this study is 66 Latinas. The study's goal is to help Latinas to prevent HIV infection.

We will include 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 because the intervention is culturally tailored to the HIV prevention needs of this group of Latinas.

You are being asked to be in the study because you meet the following criteria:

- Self-identified as a Latina
- Fluent in English or Spanish
- Between 18 and 44 years old
- Report sexual activity with a man in the last 6 months
- Have internet access from any device
- Reside in NC

Are there any reasons you should not be in this study?

You should not be in this study if:

- You are unwilling to be part of the study
- You do not read, speak, or understand Spanish or English
- You do not have access to internet

How many people will take part in this study?

Approximately 66 people will take part in this research study, which will consist of 66 Latina women.

How long will your part in this study last?

Your participation in this study will last about four months. Depending on your availability, we will conduct 3 surveys, one at the beginning of the study (baseline survey), one month later, and the last one 4 months after the baseline survey. Each survey has a duration between one hour to one hour and a half.

We will also ask you to access to the intervention website to watch one telenovela episode each week (4 in total) and review the website sections (e.g., homepage, Q&A, resources in the community) and answer some questions after each telenovela episode. We do not think this will require more than one hour per week (4 hours in total).

After the baseline survey, women will be randomized (e.g., flip of a coin) in two groups: intervention or control. The moment that you will access the telenovela (IA intervention) will depend on the group to be assigned by the research team (intervention or control group):

Intervention group: After the baseline survey, if you are selected to be in the intervention group, you will begin watching the telenovela (IA intervention) the following week. After you complete the four episodes (one-month approximately) you will complete the one-month post baseline survey and then the four-month baseline survey.

Control group: After the baseline survey, if you are selected to be in the control group, you will watch the telenovela (IA intervention) after you complete the one-month post baseline survey and then the four-month baseline survey. The telenovela (IA intervention) is the same as in the other group.

What will happen if you take part in the study?

If you are eligible and provide the informed consent, we will ask you to do the following (the order of the activities may vary according to the group you will be assigned; both groups will have the same activities in a different order):

Intervention group

1. Complete a baseline survey (one to one and a half hour) that will include questions about your lifestyle practices, including sexual behaviors, drug and alcohol use, experience of violence, and knowledge about safer sex.
2. Receive an orientation to the Infección de Amor Telenovela Website.
3. Access to the intervention website once a week to watch one telenovela episode each week (4 in total) and answer some questions about each episode (one hour per week)
4. Complete 2 follow-up surveys (one-month post baseline survey and four-month post baseline survey) that will have questions about your lifestyle practices, including sexual behaviors, drug and alcohol use, experience of violence, and knowledge about safer sex. The estimate duration is between one hour to one hour and a half for each survey.

Control group

1. Complete a baseline survey (one to one and a half hour) that will include questions about your lifestyle practices, including sexual behaviors, drug and alcohol use, experience of violence, and knowledge about safer sex.
2. Complete 2 follow-up surveys (one-month post baseline survey and four-month post baseline survey) that will have questions about your lifestyle practices, including sexual behaviors, drug and alcohol use, experience of violence, and knowledge about safer sex. The estimate duration is no more than one hour to one hour and a half for each survey.
3. Receive an orientation to the Infección de Amor Telenovela Website.
4. Access to the intervention website once a week to watch one telenovela episode each week (4 in total) and answer some questions about each episode (one hour per week)

A bilingual member of the research team will help you to complete the baseline survey and the follow-up surveys (if needed) using an online survey system.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. You might benefit by learning how to protect yourself from becoming infected with HIV or other sexually transmitted infections.

What are the possible risks or discomforts involved from being in this study?

The risk for being in this study includes the possibility that your identity is revealed. We will take special precautions to ensure your privacy is maintained. However, you might get tired or stressed from answering questions, some of which are personal. You can take a break at any time. Also, you do not have to answer any questions that you do not want to answer. You may feel uncomfortable talking about sensitive or personal information. If you should become upset during any part of the study, a registered nurse or other licensed clinician will be contacted and will speak with you. The registered nurse or licensed clinician will be able to assess your needs and, if needed, refer you to the appropriate health services. We do not think there are any additional risks to you from participating in this study. There may be uncommon or previously unknown risks. You should report any problems to the research staff.

If you choose not to be in the study, what other treatment options do you have?

You do not have to be in this research study in order to receive treatment. If you decide not to be in this study, you will still be able to receive regular standard of care treatment as directed by your health care provider(s).

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?

The initial survey will be conducted face to face in a private place. If you need help with the follow-up surveys you can meet with a member of the research team face to face and conduct the survey in a private place or request to use Zoom for the surveys. If you decide to conduct the follow up surveys in a place of your choosing (e.g., your home using Zoom) it will be your responsibility to ensure privacy within the setting so that you may answer all questions as freely as possible. When you watch the telenovela episodes and answer the post episode questions on your own it will be your responsibility to ensure privacy within the setting so that you can watch the telenovela as freely as possible. If you cannot watch the telenovela or answer the post episode questions at a comfortable place for any reason, we will arrange a location for you to come and watch the telenovela and answer the post episode questions without interruptions.

Only members of the research staff who directly work on the project and the principal investigator will have access to the information you provide during the surveys. You will be assigned an ID number that will be used to help link your data and your contact information. Your consent, name, and contact information will be saved in a separate file in a separate folder

with password to protect your identity and privacy. De-identified information collected from this study may be used for future research without additional consent.

You will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

The research data will be digital and saved in a password protected encrypted network through the University of North Carolina computer system. These data will be destroyed after the research is complete.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use. The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will you receive anything for being in this study?

You will be receiving a small incentive to compensate you for your time: $30 dollars for each survey ($90 dollars in total) and $10 dollars for watching each telenovela episode ($40 dollars in total) and answer some questions about each episode. The study has minimum risk.

Payments for the intervention group will be provided: (1) at the end of the first survey ($30), (2) after you complete the telenovela episodes, answer the questions about each episode, and the second survey ($40 dollars for watching the telenovela episodes and $30 dollars for the survey, $70 dollars in total), and (3) at the end of the four-month after baseline survey ($30 dollars in total).

Payments for the control group will be provided: (1) at the end of the first survey ($30), (2) at the end of the second survey ($30 dollars for the survey), (3) after you complete the third survey and watch all the telenovela episodes and answer the questions about each episode ($30 dollars for the survey and $40 dollars for watching the telenovela episodes, $70 dollars in total).

If you decide to withdraw from the study prior to finish the described activities, you will be compensated for the study activities they have completed up to that point. Any payment provided for participation in this study may be subject to applicable tax withholding obligations.

Will it cost you anything to be in this study?

It will not cost you anything to be in this study.

What if you are a UNC student?

You may choose not to be in the study or to stop being in the study before it is over at any time. This will not affect your class standing or grades at UNC-Chapel Hill. You will not be offered or receive any special consideration if you take part in this research.

What if you are a UNC employee?

Taking part in this research is not a part of your University duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

Who is sponsoring this study?

This research is funded by the North Carolina Translational and Clinical Sciences Institute (NC Tracs). The researchers do not have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Use of unencrypted messages

The study team would like to call you or message you by text messaging or e-mail, however you may say "no" to receiving these messages and still participate in this study. If you say "yes", messages may contain personal information about you and may be sent or received by the study team's personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team. This information may include information such as reminders and notifications to contact the study team.

If you wish to stop receiving unprotected communication from the study team or have lost access to your device, please notify the study team using the study contact information on the first page of this consent form. After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving unprotected communication, you will no longer receive un-encrypted (un-protected) messages specific to this study.

_____ Yes, I consent to the study team utilizing the following (cell phone number, text messages email) to send communication: (List e-mail, cell-phone #)_____
_____

_____ No, I do not consent to receive un-protected communication from the study team.

Future Studies:

We may conduct future studies related to your participation in this research. If we do conduct these studies, we would like your permission to contact you at that future time to see if you would be interested in participating in future studies. If we have difficulty finding you, we might contact your emergency contacts to find you.

I agree that you may contact me and/or my emergency contacts regarding my further interest in any future studies related to this study.

☐ Yes

☐ No

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

Signature of Research Participant | Date

Printed Name of Research Participant

Signature of Research Team Member Obtaining Consent | Date

Printed Name of Research Team Member Obtaining Consent

Signature of Witness if applicable; e.g. literacy issues, visually impaired, physically unable to sign, witness/interpreter for non-English speaking participants) | Date

Printed Name of Witness