UTHealth Jane and Robert Cizik School of Nursing
The University of Texas Health Science Center at Houston
Baylor College of Medicine
GIVING LIFE TO POSSIBLE

Title Come As You Are - Assessing the Efficacy of a Nurse Case Management HIV Prevention and Care Intervention among Homeless Youth

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UTHealth The University of Texas Health Science Center at Houston
IRB NUMBER: HSC-SN-18-0993
IRB APPROVAL DATE: 03/09/2021

CONSENT TO TAKE PART IN RESEARCH

Simple Study Title:	NCM4HIV
Full Study Title:	Come As You Are - Assessing the Efficacy of a Nurse Case Management HIV Prevention and Care Intervention among Homeless Youth
Sponsor:	The National Institutes of Health (NIH)
Principal Investigator:	Diane Santa Maria, DrPH, MSN, RN, PHNA-BC, Associate Professor, Cizik School of Nursing at UTHealth Mary Paul, MD, Associate Professor, Baylor College of Medicine
Study Contacts:	Dr. Diane Santa Maria (Principal Investigator): [redacted] Dr. Mary Paul (Principal Investigator): [redacted] Jennifer Torres (Research Coordinator): [redacted]

You are invited to take part in this research study called, "Come As You Are - Assessing the Efficacy of a Nurse Case Management HIV Prevention and Care Intervention (CAYA) among Homeless Youth" conducted by Dr. Diane Santa Maria, of the University of Texas Health Science Center at Houston (UTHealth) Cizik School of Nursing and Dr. Mary Paul, of Baylor College of Medicine.

- This consent form has important information about this study to help to you decide whether or not to take part in this study. Your decision to take part is voluntary.
- The purpose of this research study is to determine whether CAYA works to help youth experiencing homelessness increase the use of HIV prevention strategies.
- If you agree to be in the study, you would be assigned to receive the CAYA intervention OR receive usual care services available to you, take 5 surveys, and be offered HIV & STI testing 5 times throughout the study.
- This study will take place from Fall, 2019 to Winter, 2024. Your participation would be approximately one year (12 months).
- Potential risks include feeling uncomfortable with some the questions and loss of confidentiality.
- There may not be any direct benefits to you, but what we learn from this study will help us develop better HIV prevention interventions for youth experiencing homelessness.
- The only alternative to the study is to not participate in the study.

You may refuse to take part or choose to stop taking part, at any time. Not taking part in this study will not affect the services available to you from UTHealth, the Covenant House Texas, the Salvation Army, the Young Adult Resource Center, Healthcare for the Homeless Program clinics, or any other community service. You may refuse to participate in any session and decline to answer any questions asked or written on any forms or electronic surveys. You may also decline any HIV/STI tests.

If you are interested in participating, please continue to read below.

What is the purpose of this research study?

The purpose of this study is to see how well CAYA works to help youth experiencing homelessness increase the use of HIV prevention strategies. The HIV prevention strategies that youth may use are: taking PrEP and nPEP if needed, getting tested for HIV and other STIs, getting treatment for STIs, using condoms, and not having sex after using drugs or alcohol. The National Institute of Nursing Research (NINR) is paying UTHealth for the work on this study.

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

Who is being asked to take part in this study?

You are being asked to take part in this research study because you are between the ages of 16-25 and are experiencing homelessness or unstable housing. This study is being conducted at UTHealth in Houston, TX. About 450 young people will take part in study activities at the Salvation Army, the Covenant House Texas and other organizations that serve youth experiencing homelessness.

What will happen if I take part in this study?

If you provide written consent and agree to be in this study, we will ask you to:

1) Provide your contact information and take your picture using a Polaroid camera. This information may include phone numbers, email addresses, social media usernames/handles, and family/friend contacts. Your contact information will only be used to contact you for study related activities. The photo will remain in your file and only be used to verify your identity for visits, surveys, and receiving gift cards.
2) Take a baseline survey on an ipad, smartphone, or computer which will ask you about yourself, your experiences with homelessness, and your behaviors related to sex and drug use. The survey will take 30-45.
3) You will also be tested for HIV using a rapid, finger stick HIV test, and other STIs, using a urine and/or blood test. If any of your test results are positive, you can receive treatment and care coordination from the Healthcare for the Homeless Houston (HHH) program or your medical home if preferred. You may also be contacted by the health department to make sure you received treatment. If you test positive for HIV during the study, you will be linked to an HIV care clinic in the Harris Health System or another preferred provider.

   Depending on the risk level for in-person contact (due to pandemics such as COVID-19), there may be up to 5 options to complete the HIV & STI testing: in person with study staff at a study site or other partnering agency, in person with study staff at Cizik School of Nursing (6901 Bertner Ave.), at Covenant House clinic, at a Harris Health clinic, or with an at-home test to take under supervision of a study staff via video call. Study staff will be equipped with masks and gloves for all in-person visits. At the time of data collection, study staff will explain which options are available to you. After the first survey, you will be randomized (similar to flipping a coin) to receive the intervention, CAYA, or usual care (called the control group). The usual care includes services usually available to you at the Salvation Army or Covenant House Texas. It is not known whether the usual care will be of benefit. For this reason, some study participants must receive the usual care. This will allow a careful comparison to study the impact of the intervention. There is a 2 out of 3 chance you will receive the CAYA intervention and a 1 out of 3 chance that you will receive the usual services.

   You will be issued a password-protected cell phone to use for 12 months. The study phone will have food, housing, and healthcare resources programmed in the contacts and an app to allow for video calls with the study staff. For the remainder of the study, we will use the study-issued cell phone to contact you about study-related visits and updates. In the event that study staff can no longer reach you on the study cell

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phone, the phone line will be disconnected and study staff will attempt to contact you using the other methods of contact you provide (in step 1).

4) If you are randomized to receive the intervention:

a. You will be asked to attend 6 individual face-to-face sessions with a nurse every 2 weeks in person or via video call During these sessions you would receive personalized education and support for achieving your goals related to HIV prevention strategies. These sessions will be audio recorded and reviewed by research staff and an external counselor to ensure the quality of the sessions. Whatever you choose to share in these sessions will stay confidential, unless you disclose that you intend to hurt yourself or someone else. You will also be screened to determine if you are eligible for PrEP (a medicine to prevent HIV infection).

i. If you are eligible and interested in receiving PrEP, the nurse will connect you with a clinic to conduct necessary lab work and prepare forms to cover the cost of the medicine.

ii. If you are eligible, and decide to begin taking PrEP, your provider will follow standard of care protocol. This will include conducting additional blood tests. You may also be asked to provide a urine sample to assess the amount of Truvada, the medication for PrEP, in your system. This would indicate if you are taking the medication as prescribed, and be sure you are tolerating the medicine.

c. You may be asked to complete more frequent HIV/STI testing than the standard of care.

d. When you receive the study phone you will be asked to download the study app and choose your study goal. During the intervention, you will answer short daily surveys on the app about your behaviors from the previous day including sexual activities, condom use, and substance use. You can check on your goal progression at any time by accessing the app. You will be contacted by study staff if daily surveys are frequently missed to ensure there are no technical malfunctions with the app.

e. After your last face-to-face session, you will be contacted every month by the nurse for 3 months to check on your goal progression and assist with any other needs you may have.

f. You will be asked to participate in an exit survey and may be asked to participate in a brief exit interview after completion of the study to learn more about your experience with the intervention. This exit interview would be audio recorded.

4) If you are randomized to receive the usual care, you will have access to housing, food and clothing needs, basic healthcare, mental health, and substance use treatment referrals that are usually available to you. You will also receive the CAYA intervention after the last survey if you would like to.

5) After the intervention or access to usual care, you will then take 4 more follow up surveys: one immediately after receiving either the last intervention or usual care session, and then one at 3 months, 6 months, and 9 months after you began the program. These surveys will be taken on an ipad,smartphone, computer or other device and will be similar to the baseline survey. You will be offered testing for HIV and STIs every time you take a follow-up survey (about every 3 months). If any of your test results are positive, you will receive treatment and care coordination from the Healthcare for the Homeless Houston (HHH) program or your medical home if preferred. You may also be contacted by the health department to make sure you received treatment. If you test positive for HIV during the study, you will be linked to an HIV care clinic in the Harris Health System or another preferred provider.

6) After the 2nd follow up data collection you will be able to refer eligible peers to participate in the study. For each peer you refer who completes study enrollment, you will receive a $10 gift card (up to 5 referrals).

7) If you decide to begin taking PrEP during the study, you may also be asked to do an additional urine test at the 4 follow up surveys to see if you are taking your pill every day.

What choices do you have other than this study?

The only alternative to the study is to not participate in the study. There will be no penalty for deciding not to participate.

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What are the risks of taking part in this study?

There are both risks and possible benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

If you choose to take part in this study, there is a risk that the CAYA intervention may not be as good as usual care in helping you use HIV prevention strategies. There is also a risk of feeling uncomfortable with some the questions and loss of confidentiality.

What are the benefits to taking part in this study?

If you agree to take part in this study, there may not be any direct benefits to you. What we learn from this study will improve our understanding of developing an intervention for HIV prevention specifically for youth experiencing homelessness. This information will help us develop better interventions.

Can you stop taking part in this study?

You may decide to stop taking part in the study at any time. To withdraw from the study, please contact Diane Santa Maria at [redacted].

The Principal Investigator (PI) can stop the study at any time. The PI may stop your participation in the study if the study is stopped, you do not meet all the requirements of the study, or the study is not in your best interest.
If you stop participating in this study, the information already collected about you will still be used in the data analysis. However, no further information will be collected without your permission.

While taking part in this study, the study team will notify you of new information that may become available and could affect your willingness to stay in the study.

What happens if you are injured during the study?

In the event of injury resulting from this research, the Harris Health System is not able to offer financial compensation nor to absorb the costs of medical treatment. However, necessary facilities, emergency treatment and professional services will be available to you, just as they are to the general community.

What are the costs of taking part in this study?

There is no cost to take part in this research study. You will receive gift cards in the amount of:

- $20 for the baseline survey and $20 for STI testing
- $20 for the immediate post-intervention follow up survey and $20 for STI testing
- $25 for the 3 month follow up survey and $20 for STI testing
- $35 for the 6 month follow up survey and $20 for STI testing
- $40 for the 9 month follow up survey and $20 for STI testing

You would receive up to $240 for completing all surveys and STI testing follow ups.

You will receive a METRO bus/rail tickets to cover the cost of transportation to and from data collection survey locations if needed. If you are randomized to the CAYA, you will also receive METRO bus/rail tickets to cover the cost of transportation to and from the sessions if needed.

What information are you collecting from me?

We will be collecting two types of data, or information, from you:

1) The information you provide on the surveys. The survey asks about yourself, your experiences with homelessness, and your behaviors related to sex and drug use. Your survey responses will not be connected to your name or other personally identifiable information. This information will NOT be included in your medical records.

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2) Your HIV & STI test results. We may access your medical records to determine your test results. Your test results will be kept confidential, however, if your test results are positive, we are required by law to report it to the health department. We will also attempt to contact you to discuss treatment options available to the general community.

How will privacy and confidentiality be protected?

Your privacy is important and your participation in this study will be kept confidential. However, absolute confidentiality cannot be guaranteed.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

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

The Certificate of Confidentiality does not prevent the researchers from disclosing, without your consent, information that they are required by law to disclose to government authorities. For example, researchers must comply with laws requiring the reporting of suspected child abuse and neglect and communicable diseases.

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine, UTHealth, and the Harris Health system to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Specific information concerning HIV
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Billing or financial records

The health information listed above may be used by and or disclosed (released) to the following:

- The study sponsor or its representatives, including companies it hires to provide study-related services • UTHealth and its representatives
- Other Institutional Review Boards and/or affiliate institutions where approval must be obtained and its representatives
- Regulatory and Government health agencies (such as the Food and Drug Administration, Department of Health and Human Services etc.) in the US or other countries (e.g. European Medicines Agency)
- Office of Human Research Protections (OHRP)
- Member of the research team
- Researchers at other centers taking part in the study
- Data safety monitoring board/committees that are responsible for the safety of research subjects

- Other health care providers involved in your care
- Hospital or other accrediting agencies

Use or Disclosure Required by Law

Baylor College of Medicine, UTHealth, and the Harris Health system are required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine, UTHealth, and the Harris Health system to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research does not involve treatment. Baylor College of Medicine, UTHealth, and the Harris Health system may not condition (withhold or refuse) treating you on whether you sign this Authorization.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, regulatory agencies such as the U.S. Department of Health and Human Services, Baylor College of Medicine, the Data and Safety Monitoring Board, UTHealth, and the Harris Health system may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to:

Mary E. Paul MD
[redacted]

Diane Santa Maria, DrPH, RN
[redacted]

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

A Data and Safety Monitoring Board appointed by UTHealth will have access to the research records including your health information.

Whom can I contact if I have questions about the study?

The investigators, Dr. Diane Santa Maria, Dr. Mary Paul, or someone they appoint in their place will try to answer all of your questions. You can contact the study team: Diane Santa Maria at [redacted] and Mary Paul at [redacted] during the day and after hours to discuss problems, report injuries, voice concerns, obtain information in addition to asking questions about the research.

The Committee for Protection of Human Subjects at the University of Texas Health Science Center and Baylor College of Medicine has reviewed this research study. You may contact them for any questions about your rights as a research subject, and to discuss any concerns, comments, or complaints about taking part in a research study at [redacted].

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.
The investigator, Diane Santa Maria, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: Diane Santa Maria at [redacted] or Mary Paul at [redacted] during the day and Jennifer Torres at [redacted] after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The BCM IRB office number is [redacted]. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Would you like us to notify you when you may be eligible for future studies? Please check one below.

_____Yes, please contact me in person or by phone for future studies.

_____No, please do not contact me for future studies.

Printed Name of Subject	Signature of Subject	Date	Time
Printed Name of Person Obtaining Informed consent	Signature of Person Obtaining Informed Consent Date Time	Date	Time

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