



Staff
RESEARCH CONSENT FORM

Protocol Title: The CASA Study: Care and Support Access Study for implementation of a palliative approach with HIV treatment

Study No.: HP-00058180

Principal Investigator: Carla S Alexander MD (410) 328 7129

Sponsor: Patient Centered Outcomes Research Institute (PCORI)

What you should know about this study:

You are being asked to join a research study. This consent form explains the research study and what is required. Please read it carefully and take as much time as you need. Please ask questions at any time about anything you do not understand. You do not have to join this study, participation is voluntary.

The principal investigator for this study is Dr. Alexander. You should ask her or a member of the study team, to explain any information in this informed consent that you do not understand. Once you understand the study, you can decide if you want to take part in it. Your decision to participate or not to participate is entirely voluntary. If you choose to take part, we will ask you to sign this form. We will give you a signed and dated copy of this consent form for your records.

If you are an employee or student, your employment status or academic standing at UMB will not be affected by your participation or non-participation in this study.

PURPOSE OF STUDY

Why is this research being done?

Since the identification of the HIV virus, much has been learned about HIV disease and the prognosis, or life expectancy, for people able to adhere with their antiretroviral medications and outpatient follow-up visits, is now what it would be for that person based upon his current age.

In Baltimore and other US cities, HIV positive young men who have sex with men (YMSM) have not been easily kept in outpatient care to successfully manage their HIV disease. Multiple approaches, such as outreach workers or support networks, have been employed to try to keep these YMSM on treatment but no one has examined what changes might be made to the manner in which the health delivery team offers care to this group of young men.



This research is testing the impact of offering new care strategies to staff of the HIV clinic where YMSM receive their care. The study will document your own response to the training in order to improve the educational sessions and you may be offered the opportunity to complete a full interview regarding your observations of the impact upon yourself and the clinic of the training content. There will be on-going surveys of YMSM to describe the current population of YMSM in Baltimore over a period of 18 months. The study intends to determine if the training for staff members makes any change in the perceived care delivery by the patients. The post educational evaluations will ask about the ease of understanding and applying the skills being taught as well about your own response to the stress of integrating new skills while continuing to give HIV care and treatment.

The skills being introduced represent a palliative approach to care meaning that the you will focus upon issues from the point of view of the patient, or in a patient-centered manner. The specific patients being studied are YMSM because they are at high risk for being lost to follow-up across the trajectory of their illness.

This research is being done to advance our understanding of an HIV population that has been difficult to engage and retain in usual outpatient HIV clinics to see if we might identify targets for future interventions for this population. The study also intends to improve care delivery that can positively impact mental health and quality of life outcomes for YMSM.

We expect to enroll 204 patient participants at 2 HIV clinics and up to 25 staff members from each of 2 clinics.

Background

There are 1.1 million people living with human immunodeficiency virus (HIV) disease in the US with almost 20% of those infected being unaware of their infection. Although HIV Disease is now considered a manageable chronic illness with a normal life expectancy for those who start medications early and do not miss doses of antiretrovirals (ART), only 14% of persons living with HIV (PLWH) have documented viral control meaning that 86% remain at risk for spreading the virus. Baltimore, Maryland ranks fifth in HIV infection rates among US cities and men who have sex with men (MSM) continue to bear the greatest burden of HIV infection. Young men who have sex with men (YMSM) face multiple mental health and other challenges that may make them at higher risk for other illness or early death. HIV will continue to be spread in Baltimore unless we can reduce the overall pool of those with virus that is not controlled.

As a chronic illness, health professionals caring for HIV patients must now focus beyond the surrogate markers of CD4 cell count and HIV PCR (viral load) measurements to quality of life as perceived by the patient. Being able to “connect with” patients is one method for promoting engagement and retention in care. Many HIV clinics offer support groups and have outreach workers to assist people living with HIV (PLWH) in staying in care. Little attention has been paid to assisting the clinical staff of an HIV clinic to adjust their approach to care management in a manner that may enable these patients to remain in care. Any change to health delivery may



appear to be time-consuming, or an added burden, and clinicians may not take time to acknowledge that the PLWH is suffering from physical or mental symptoms.

The educational presentations in this study are derived from standard palliative care (PC) that have been used in international settings to improve care for patients with HIV disease. This type of care has been referred to as “Care and Support.” It recognizes the importance of developing a trusting relationship between the patient and the clinical team. The goals include improving team care by use of multidimensional patient assessment that incorporates communication skills, symptom management, and goal setting to assist patients facing major life transitions. PC also recognizes that care providers may be stressed by many aspects of care delivery including having to care for patients with multiple psycho-social or spiritual problems not always addressed by routine medical care. Internationally, PC has been shown to improve patient outcomes even in early HIV illness.

Intent of the Study

The overall research question of this study is: “Does early implementation of a palliative approach to care delivery for PLWH, specifically YMSM in inner city Baltimore, improve individual outcomes compared to delivery of standard HIV outpatient care alone?”

The intent of the study is to offer you an experience in team building and in integrating care delivery skills that may improve your own ability to improve long-term outcomes for a known challenging population in Baltimore in terms of engagement and retention in care. These care delivery methods have been used successfully in other settings and in our international HIV work. We call this the CASA approach (care and support access). The study is grounded in implementation science meaning that we will use accepted quality improvement methods to introduce new skills.

Your qualification for the CASA Study

You have been selected by leaders of your clinic using selection criteria prepared by the Research Team. The Research Team asked for a minimum of one person representing each of the following disciplines: physician, nurse practitioner, nurse, social worker or counselor, outreach worker and administrative staff. The requirements were that the staff members are familiar with care delivery activities of your clinic, be someone others look to for leadership, and preferably have teaching or supervisory experience.

How many people will be in this study?

There are 2 sets of participants in this study: YMSM attending one of 2 HIV clinics and your group, members of the staff who care for those patients. There will be up to 102 patients enrolled at each clinic. You will be one of up to 50 staff members to be enrolled between the 2 clinics.



PROCEDURES

What would I have to do?

You would be a member of the multidisciplinary CASA Team to be trained at your clinic; input from your discipline is critical to the success of this study. You will attend the initial training followed by on-site clinical team meetings of 1.25 hours to be held every other week for approximately 18 months where you will meet with an Expert Coaching Team (ECT) to review progress of the patients enrolled in the study and how your team is able to introduce aspects of the initial training into clinic “flow.” The CASA Team and the ECT will be expected to identify content for quarterly in-service education for all staff members of your clinic to share what you have learned with the rest of the staff.

The study takes place over 2 years during which time 204 total HIV positive young men who have sex with men (YMSM) will be enrolled in the study at 2 clinics. These patients will receive usual care at each clinic but the goal of the study would be to introduce aspects of the initial training into the clinical delivery of care. The study will determine whether introducing new skills has an impact upon outcomes of YMSM who attend the clinic.

The initial training is meant to reflect how education is commonly introduced for outpatient settings. Part 1 contains didactic topics and problem-solving for the CASA Team from your clinic. The timing of this training will be planned with the directors of your clinic. Part 2 occurs every other week, when an expert coaching team (ECT) will come to your clinic for a 1.25 hour meeting to discuss progress of patients and of the study. Part 3 is quarterly in-service educational presentations open to all staff members to hear updates regarding the study. Each of these sessions will be planned by the CASA Team and the ECT. The methods for introducing this content to the whole clinic will be those used in continuous quality improvement. You will be asked to complete usual pre- and post-educational evaluation forms to assist in refining the curriculum. You will use a unique identifier on these evaluation forms to compare your responses over time but your responses will not be individually identified.

This study differs from other educational evaluations because we will measure the impact of participating in the training. We will ask for your evaluation of each part of the training. We will also ask you how taking the training has impacted your usual work. Later, after the training, we will ask selected YMSM and staff members to participate in a structured interview. There will be a separate consent form for this part of the study. The intent of the interview is to give more depth to the understanding of the impact and effectiveness of the training.

Study Design. This is a quasi-experimental design, sometimes called a “before and after” study, to obtain information from both PLWH and staff before and after an educational intervention. Following the training sessions that occur about month 14 of the study, the CASA Team will receive bi-weekly, on-site coaching and with the Expert Coaching Team and will develop quarterly all-staff in-service education reflecting what you have learned and how it might be integrated with your clinic.



WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible to attend the training sessions and to complete pre- and post-evaluations for each session. All answers are confidential and connected to you by a unique code only to protect confidentiality. You will be able to complete the evaluation forms with privacy. These will be given to the monitoring and evaluation staff of the study, the Psychosocial Research Unit on Health, Aging and the Community at New York University Colleges of Dentistry and Nursing. If you are selected for the structured interview, there will be a separate consent form that will be developed in response to findings during the study.

POTENTIAL RISKS/DISCOMFORTS:

Foreseeable risks to participants are twofold:

- 1) There is a potential loss of confidentiality. All members of the Research Team take this seriously and are trained in methods for protecting your confidentiality and privacy. The loss of confidentiality will be minimized by storing data in a secure location in a locked office and locked cabinet and all electronic data will be password-protected.
- 2) The second possible risk is that something you read or discuss in relationship to this study may cause you to worry. If this happens the staff is trained in methods for recognizing any distress this might cause you and there is a “safety protocol” in place that will allow us to get you to an appropriate counselor or other staff member experienced with this type of issue. You are also free to contact Dr. Alexander directly relative to this occurrence. Her telephone number is at the top of the consent form.

In any study, there may be risks that are not yet known.

POTENTIAL BENEFITS

There is no guarantee that you will receive direct benefit from participation in this study. We hope that you will find the training interesting and of use in your daily work. You may develop insight with regard to your own behaviors and care delivery skills.

If this study is successful in assisting clinic personnel to integrate skills that may improve the clinic experience or individual clinical outcomes for what is considered to be a difficult to engage and retain population, there may be a societal benefit for other clinics in attempting to retain patients in care.

ALTERNATIVES TO PARTICIPATION

This is not a treatment study. Your alternative is to not take part. If you choose not to take part, there will be no adverse effects and your employment at University of Maryland, Baltimore will not be affected.

COSTS TO PARTICIPANTS

Questionnaires for this study are completed at the same time as the educational intervention. It will not cost you anything to take part in this study.



PAYMENT TO PARTICIPANTS

Your participation in the CASA education is considered on-the-job training. Near the end of the study, we will select representative members from the staff to complete an in-depth interview about the experience with the CASA training. If you are selected and complete an interview, you will be paid \$25 in cash.

Confidentiality and Access to Records

Efforts will be made to limit your personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of UMB who have a role in study oversight. Study records will be considered confidential, and your name will not be used in reports or publications. Study records can be reviewed by the sponsor- Patient-Centered Outcomes Research Institute (PCORI), its monitors, auditors or other representatives.

The data from the study may be published. However, you will not be identified by name. People designated from the University of Maryland Medical institutions where the study is being conducted and the sponsor (PCORI) and its representatives will be allowed to inspect research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. Refusal to take part or to stop taking part in the study will involve no penalty, loss of benefits, or impact on employment. If you decide to stop taking part, or if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator **Dr. Carla Alexander MD at 410 328 7129.**

There are no adverse consequences (physical, social, economic, legal, or psychological) of your decision to withdraw from the research. You may be asked to sign and date a document should you decide to withdraw for documentation purposes.

If you withdraw from this study, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

You will be told of any significant findings which develop during the study which may affect your willingness to participate in the study. If you are an employee or student, your employment



status or academic standing at UMB will not be affected by your participation or non-participation in this study.

CAN I BE REMOVED FROM THE RESEARCH?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include failure to follow instructions of the research staff or failure to attend adequate sessions that might interfere with the research outcomes. The sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.

The research described in this consent form has been classified as not greater than minimal risk by the IRB of the University of Maryland, Baltimore (UMB). The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is not greater than minimal risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.

If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staff of the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
[410-706-5037](tel:410-706-5037)



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.

If you agree to participate in this study, please sign your name below.

Participant's Signature

Date: _____

Investigator or Designee Obtaining Consent Signature

Date: _____

