Community Health Worker And MHealth to ImProve Viral Suppression (CHAMPS)

NCT04562649
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Columbia University Consent Form

Protocol Information

TITLE: Community Health Workers And MHealth to Improve Viral Suppression (CHAMPS)

PROTOCOL NO.: R01NR019758
WIRB® Protocol #20202675
AAAT2430

SPONSOR: National Institute of Nursing Research (NINR)

INVESTIGATOR: Rebecca Schnall, PhD, MPH, RN-BC, FAAN
560 West 168th Street
New York, New York 10032
United States

STUDY-RELATED PHONE NUMBER(S): Dr. Rebecca Schnall
(212) 342-6886
(212) 305-8198 (24 hours)

General Information

Consent Number: CF-AABZ8377
Participation Duration: 12 months **Anticipated Number of Subjects:** 300 **Key Information:**

The purpose of this research study is to assess the effectiveness of an existing community health workers' (CHW) intervention through the use of a mobile health (mHealth) approach and determine if it helps people living with HIV (PLWH) improve their quality of life.

- The procedures in this study are to complete a survey and a blood draw every six months. Some participants will receive a pill bottle dispenser, access to a mobile application (app), and participate in sessions with a community health worker (CHW).

- The time frame for your involvement in the study is 12 months.

- The Introduction section below provides details about the study, and the full schedule for visits is in the Procedures section.

- Risks for the study include physical discomfort from the blood draw and feeling uncomfortable completing some questions in our survey or knowing that, although unlikely, there is potential risk for loss of confidentiality. There may be other risks of taking part in this research study that we don't know about. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study. Detailed information of all the known risks can be found in the Risks section.

- There may be no direct benefits for participants in the study.

- It is your choice if you want to be in this study. The alternative is to not participate. If you decide to take part in the study, it should be because you really want to volunteer. You can choose to withdraw at any time during the study. If you choose not to volunteer you will not lose any services, benefits, or rights you would normally have.

- If you are interested in learning more about this study, please read the details below.

Contacts

Contact	Title	Contact Information
Rebecca Schnall	Principal Investigator	Phone: 212-342-6886 or (212) 305-8198 (24 hours) Email: rb897@cumc.columbia.edu

Detailed Information on Research

Introduction

The purpose of this form is to give you information to help you decide if you want to take part in a research study. This consent and HIPAA authorization form includes information about:

- why the study is being done;
- the things that you will be asked to do if you are in the study;
- any known risks involved;
- any potential benefit;
- options, other than taking part in this study, that you have; and
- the way your health information will be used and shared for research purposes.

The study staff will discuss the study with you. If at any time you have questions about the study, please ask a member of the study team. Take all the time you need to decide whether you want to take part in this research study.

The purpose of this research is described below in the 'What is Involved in This Study?' section of this consent and HIPAA authorization form.

This consent and HIPAA authorization form is written to address a research subject.

What is Involved in this Study?

Rebecca Schnall PhD, MPH, RN-BC, FAAN at the Columbia University School of Nursing and Scott Batey, PhD, MSW, LiCSW, PIP at the University of Alabama at Birmingham Department of Social Work are conducting a research study to assess the effectiveness of an existing community health workers' (CHW) intervention through the use of a mobile health (mHealth) application (app) to determine if it helps people living with HIV (PLWH) improve their quality of life.

If you agree to be in this study, the following will happen:

At the time of enrollment, you have a 50/50 chance of being assigned to either the intervention or control group. You will be randomly assigned to one of the two groups which are described below. Comparing these two groups is investigational.

All participants will complete a survey and provide a blood sample at the first (baseline) visit, at a 6-month follow up, and at a 12-month follow up to measure HIV viral load and CD4 count. The blood draw at Baseline will also be tested for genotyping. The purpose of the genotype testing is to show a person's risk or susceptibility for Alzheimer's disease, but is not directly determinant of your risk of developing Alzheimer's disease. You may wish to obtain professional genetic counseling prior to signing the consent form. Any positive result from the genotype testing is an indication of your risk or susceptibility for Alzheimer's disease and you may wish to consider further independent testing, consult your physician, or pursue genetic counseling. We will also look at inflammatory cytokines (IL-1beta, IL-2, IL-4, IL-6, IL-8, IL-10, IL-13,TNFalpha, and CRP), estrogen, FSH and also conduct a GSA chip and qPCR. If these test are not completed at Baseline, then they will be completed at 12 months.

Participants in the intervention group will:

- be given a CleverCap Lite device which is a smart pill bottle to use over the course of the 12-month study
- Have access to a mobile application (app) which will remind you to take your medication, track physical activity and provide other information to help manage HIV care. The study may need to help you set up a mobile app on your phone that you will access using a login name and password. The app will send daily reminders about your health over the course of participation.
- Participate in 10 sessions with a community health worker (CHW) over the course of a six-month period. You will have the option to participate in most CHW sessions in person or via the app.

Participants in the control group will be provided standard health care which includes mental health services, case management, referral to clinical care and a brief educational session to improve adherence with HIV care.

For both groups, we will obtain information from your medical records, such as information regarding health care utilization.

During the course of this research we would like to send you text (SMS) messages for appointment reminders (for example, “Your study visit will take place at [time] on [date] at [address].”), and notifications to call us (for example, “Please call the office at (212) 305-8198.”). Using text messaging makes it easier to get into contact with you and provide you with study information during your participation.
If you agree to receiving messages from us, please enter your cell phone number here:

_____

The study will take about 3 hours for the baseline visit, and 2 hours for the 6-month and 12-month visit, including the blood draw.

Technical Difficulties

If you have any technical difficulties using the CleverCap Lite device, or the app, please contact our study staff: at 212-305-8198 or at sonwellness@cumc.columbia.edu.

Permission for Future Contact

The researchers may want to contact you in the future. This study has the potential for revealing information about mobile app for HIV prevention and treatment.

We would like to contact you to solicit your participation in any research associated with the current study or other future studies. Please initial below to show whether or not give permission to us to contact you in the future.

_____ (initial) I give permission to be contacted in the future for research purposes.

_____ (initial) I do NOT give permission to be contacted in the future for research purposes.

Risks

General risks

There may be risks or discomforts if you take part in this study. These include: physical discomfort from the blood draw and feeling uncomfortable completing some questions in our survey. There may be other risks of taking part in this research study that we don't know about. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study.

Blood Draw

Risks of having blood drawn are soreness and/or a black and blue mark at the site from where the blood is drawn.

Sometimes, people feel uncomfortable at the time of the blood draw. Occasionally people feel lightheaded or faint. There is also a small risk of infection whenever blood is drawn.

Loss of confidentiality

A risk of taking part in this study is the possibility of a loss of confidentiality. Loss of confidentiality includes having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your confidentiality. Their plans for keeping your information private are described in the Confidentiality section of this consent form.

Benefits

There may be no direct benefit to you for participating in this study. Although it can not be guaranteed, you may benefit from improved self management of your HIV by being in this study. Our goal is for the information gained from this study to contribute to the development of knowledge in health information technology acceptance and use for health management.

Alternative Procedures

The alternative is not to participate. You are free to refuse to participate or to withdraw from this research at any time.

Confidentiality

What about Confidentiality?

Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised. Additionally, your individual-level data will not be shared through unrestricted- or controlled-access repositories. Despite all of our efforts, unanticipated problems such as a stolen computer may occur, although it is highly unlikely.

Access to your health information is required to be part of this study. If you choose to take part in this study, you are giving us the authorization (i.e. your permission) to use the protected health information and information collected during the research that can identify you. The health information that we may collect and use for this research may include medical history that may be considered sensitive. The health information that may be collected, used or disclosed includes:

- All health information collected during the research described in this consent and authorization; and
- Health information in my medical records that is relevant to the Research. This may include medical information that may be considered sensitive, including: HIV status, history of drug use or alcohol abuse; and mental health information.

Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care that is needed for this research purpose.

Any research information that is shared with people outside Research Columbia University Medical Center and New York-Presbyterian Hospital will not include your name, address, telephone number or any other direct identifier unless disclosure of the information is required by law or you have authorized the disclosure.

Your data, blood samples, questionnaire responses, health information and app data will be assigned a code number, and separated from your name or any other information that could identify you. The research file that links your name to the

code number will be kept in a locked file cabinet, an encrypted data file, and/or a password-protected computer and only the investigator and authorized study staff will have access to the file. Your participation in this research study will be documented in your electronic medical record and can be viewed by authorized personnel from Columbia University Irving Medical Center, Weill Cornell Medical Center and New York-Presbyterian Hospital and its affiliated institutions, because these institutions share the electronic medical record system. Study monitors and others who provide oversight of the study may also need to access this record.

The following individuals and/or agencies will be able to look at, copy, use, and share your research information: - The investigator, Columbia University Medical Center, New York-Presbyterian Hospital, and the study staff and other medical professionals who may be evaluating the study

- Authorities from Columbia University and New York-Presbyterian Hospital, including the Institutional Review Board
- ('IRB')
- The Office of Human Research Protections ('OHRP')
- The sponsor of this study, National Institute of Nursing Research/NIH/DHHS, including persons or organizations working with or owned by the sponsor
- Other government regulatory agencies (including agencies in other countries) if the sponsor is seeking marketing approval for new products resulting from this research.
- The US Food and Drug Administration (FDA)

Your authorization to use and share your health information does not have an expiration (ending) date.

Once your health information has been disclosed to a third party, federal privacy laws may no longer protect it from further disclosure.

You may change your mind and revoke (take back) this consent and authorization at any time and for any reason. To revoke this consent and authorization, you must contact the Principal Investigator, Rebecca Schnall at rb897@cumc.columbia.edu or 212-342-6886.

However, if you revoke your consent and authorization, you will not be allowed to continue taking part in the Research. Also, even if you revoke this consent and authorization, the Researchers and the Sponsor (if applicable) may continue to use and disclose the information they have already collected.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate 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 action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the agency which is funding this project 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 from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. You should also know that this Certificate does not protect you from our responsibility to report certain communicable diseases, suspected child abuse, or danger of physical or mental harm, to appropriate agencies or authorities.

What about my Privacy?

Every effort will be made to keep your personal information confidential. However, we cannot guarantee total privacy.

Your data, questionnaire responses, and blood samples will be given a code number, and separated from your name or any other information that could identify you. The research file that links your name to the code number will be kept in a password protected database and/or locked file cabinets. Only the Investigators and the study staff will be able to see this file. The technical platform is designed to be a safe and secure environment as much as possible, for data input, data sharing, synthesis, storage, and retrieval. Your participation in this research study will be documented in your electronic medical record. This record can be viewed by authorized personnel from Columbia University Irving Medical Center, Weill Cornell Medical Center and New York-Presbyterian Hospital and its affiliated institutions, because these institutions share the electronic medical record system. Study monitors and others who provide oversight of the study may also need to access this record.

If information from this study is published or presented at scientific meetings, your name and other personal information about you will not be used.

Compensation

You will receive up to $150 after finishing the 12-month study. You will be given $40 at the baseline visit for completing the survey and blood draw, $50 at your 6-month visit for completing the survey and blood draw, and $60 at your 12month visit for completing the survey and blood draw.

Additional Costs

There are no costs to you for taking part in this study.

Voluntary Participation

Participation in this research is voluntary. You are free to decline to be in this study, or to withdraw from it at any point. Your refusal to participate, or early withdrawal, will not result in penalty or affect any benefits to which you are otherwise entitled nor will it affect the care provided by members of your care team.

Additional Information

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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.

Questions or Concerns About Research

If you have any questionsconcerns or complaints about the study, you may contact: Dr. Rebecca Schnall at (212) 342-6886 or (212) 305-8198 (24 hours) or rb897@cumc.columbia.edu.

If you have any questions about your rights as a research participant, or if you have questions, concerns or complaints about this study, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

OR

Human Research Protection Office,
Institutional Review Board
Columbia University Medical Center
Address: 154 Haven Avenue, 1st Floor; New York, NY 10032
Telephone: (212) 305-5883
Email: irboffice@columbia.edu

An Institutional Review Board is a committee organized to protect the rights and welfare of human subjects involved\ in research. More information about taking part in a research study can be found on the Columbia University IRB website at: http://www.cumc.columbia.edu/dept/irb.

Statement of Consent

Statement of Consent and HIPAA authorization

I have read the consent and HIPAA authorization form and talked about this research study, including the purpose, procedures, risks, benefits and alternatives with the researcher. Any questions I had were answered to my satisfaction. I am aware that by signing below, I am agreeing to take part in this research study and that I can stop being in the study at any time. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be given a copy of this consent and HIPAA authorization form to keep for my records.

Signatures

Participant Signature Lines

Study Participant

Print Name_____ Signature_____

Date_____

Research Signature Lines

Person Obtaining Consent

Print Name_____ Signature_____

Date_____