

June 7th, 2025

Title: A Technology-based Psychosocial Intervention to Support Social Engagement and Well-being in Older Adults With HIV

NCT Number: NCT06560970



Research Consent

COPPEHR (Connecting older positive people to enhance health and resilience): A technology-based psychosocial intervention to support social engagement and well-being in older adults with HIV

May 9, 2025

Please read this form or have this form read to you. Take your time to make your decision. Make sure we explain the study to you. Ask us any questions. You may also want to talk about the study with your doctor and family, loved ones, or friends. The choice to join the study, or not, is yours. If you decide to join, please sign and date this form.

Why is this study being done?

You are being asked to join a research study that is being done by Dr. Sara Czaja and Dr. Eugenia Siegler, funded by the National Institute on Aging. We hope to learn if a device (Chromebook/laptop) with access to special programs can reduce social isolation and improve quality of life for older HIV long term survivors. You are being asked to join because you are at least 50 years of age, you live alone, and you have had a diagnosis of HIV for at least 15 years.

Important information for you to think about:

- **What am I being asked to do?** Participate in a research study to determine if a device with access to special programs can help reduce loneliness.
- **How long will the study last?** If you join the research study, it will take 9 months. You will be trained to use the device; you will be using the device for 6 months, and there will be follow up phone calls at the end of the study.
- **Any possible risks or discomforts?** There is a minimal risk of loss of confidentiality. *You may have discomfort answering some questions as part of your participation in the study.*
- **Will this study help me?** There are few direct benefits to you.
- **Do I have to join?** You do not have to be in this study.

If you are now or have been (within the last 6 months) in any other research study, please tell the research team.

What will I be asked to do? If you decide to participate, you will be taught how to use the device in small groups of 6-8 people, and then you will take the device home and

use it as you wish. The training will include modules on Internet etiquette, cybersecurity, and guarding against spam. Those requesting additional (or booster) training will receive it.

The study will pay both for the device and internet access if you do not currently have WiFi (a type of wireless internet service) in your home. You will be randomly assigned (i.e., by chance, like flipping a coin) to either the standard device group or the enhanced device group (i.e., the one with access to special programs). You will have an equal chance of being placed in either of the study groups. The trial will last 6 months. After the 6 months are over, you keep your device, but the study will no longer pay for the internet access.

We will be making follow-up phone calls (called assessments) at 3 and 6 months after the start of trial and asking you questions about mood, loneliness, social isolation, and other quality of life measures.

The research associate will work with you to schedule all study-related appointments.

Regardless of your assigned group, you will be given a device (Chromebook or Laptop or Tablet). It will be connected to the internet for the duration of your study participation, which is 6 months, at no charge to you. You will use it to access study-related materials that are web-based.

The chrome books will be registered to anonymous users in a dedicated Google Workspace, and remotely administered in kiosk mode via Sure MDM/Sure Lock remote device management software. Users will only be able to use a predefined list of applications on the device, which will include Google's Chrome browser, Calendar, Gmail, and Youtube application as well as the Zoom app. Users will not be able to install applications on their own

Using this device for activities including but not limited to visiting websites or installing software, other than those you received training on by study staff, may expose you and your information to be collected by third parties without your knowledge.

Enhanced device group: If you are in this group, you will have access to features that will promote socialization and knowledge about your medical issues.

Standard device group: If you are in this group, you will have access to the internet and use the device as you wish.

For security and privacy reasons, the device provided by the study is solely for your use. We will be monitoring your frequency of use of the device, not which sites you visit. We will only be measuring your use of the device to count the number of times you use the device and the number of times you use each feature of the program. This information helps us to understand which parts of the program were most useful to you and whether the device was useable.

During your time participating in the study, you have to notify us if the device is lost or stolen.

The device is yours to keep at the end of the trial and we will provide resources for it to be reset it to its original manufacturing state.

Assessments: In addition to the study-related activities above, regardless of what group you are in, the study includes 3 assessments (discussed above) with a study staff member either in person at our Weill Cornell offices, or over a videoconference call, or by telephone: one in the start of the study (Baseline), one at 3 months and one at 6 months (at the end of the trial). These assessments are not done on your device and the information gathered is not recorded on your device, but kept separately in a secure file by the study team. Each assessment will last about an hour and a half. Assessments include questions about basic background information, health, loneliness, resilience, social support, and physical health indicators. All the study-related activities and assessments will be conducted in English. In cases where these visits cannot be held in-person, they may be held over videoconference or telephone.

We will also be collecting some laboratory data from your medical record at the Center for Special Studies (CSS) at the beginning and end of the study. The data will include information about your cell counts, viral load, and basic laboratory studies from your chemistry and hematologic panels. We will not be drawing your blood or contacting your physicians. This information will be stored securely in a HIPAA compliant database.

Some in-person interviews will be recorded using WCM Zoom service. The data obtained during these interviews will be transcribed through the same WCM Zoom service. Zoom data will be deleted once transcribed. The transcribed data will be de-identified and stored securely in a HIPAA compliant location.

What are the risks? During the assessment, we will be asking questions that are personal and sensitive, and you may feel uncomfortable or embarrassed answering some of these questions. You may skip any questions that you do not wish to answer. You can stop being in the study at any time. We will give you breaks if you feel tired. The study also includes group training sessions, during which we ask that only first names be used to maintain confidentiality among participants. Participating in a group session may include additional risk to privacy. You also have the option to opt-out of these group sessions to avoid this risk. There is a chance that laboratory information could be revealed, but as we are using a secure server, this is extremely unlikely; however the risk of loss of confidentiality is possible. You will also be informed of any new findings that may change your mind to continue in this study.

Using this device for activities including but not limited to visiting websites or installing software, other than those you received training on by study staff, may expose you and your information to be collected by third parties without your knowledge.

Do I have other choices? You may choose not to participate in the study.

New information that may change your decision to join: During the study, Either Dr. Czaja or Dr. Siegler will tell you if there is new information or changes to the study that could affect you, your health, or your desire to stay in the study.

What are the costs? Other than the time that you will take to be in this study, you will have no other costs for your participation.

Who will be in the study? About 68 people will be asked to join the study at Weill Cornell Medicine/New York Presbyterian Hospital.

Will I get the study results? There will be no clinical results from participating in the study.

Risks from Invasion of Privacy:

Every effort will be made to protect your privacy. Included in this form is a HIPAA authorization regarding your privacy rights with respect to your participation in this study. No personal health information will be used/disclosed unless you agree to sign this form.

As part of this study you will be given access to the Google messaging app (Google chat). We strongly encourage you not to share private or health information with other participants when you use this app.

Can being in this study help me? No benefit can be promised to you from your time in the study. However, the results of the study may help investigators in designing future technology-based programs to reduce loneliness and improve health for people living with HIV.

Can being in this study benefit the researchers or WCM/NYP?
No.

How will my information be used and protected? Efforts will be made to protect your medical records and other personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. Records of study participants are stored and kept according to legal requirements and may be part of your medical record. We will take steps to protect all of your personal information, but we cannot promise confidentiality of all research data. Your name will not be used in any reports about this project. Organizations that may request to inspect and/or copy your research and medical records for quality assurance and data analysis include groups such as:

- Weill Cornell Medical College and NewYork-Presbyterian Hospital
- The Institutional Review Board (IRB)
- The Office of Human Research Protection (OHRP)
- Department of Health and Human Services and National Institutes of Health
- National Institute on Aging

We will share your information with a court of law or the government, in the unlikely event this is required by law.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

By signing this consent form, you give permission to access your confidential research information.

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

Will my information be used in the future?

We will keep your information in a library that has information from other research studies. Your information may be used in the future for other research studies. If you agree to this future use of your data, information that identifies you may be kept for a long period of time (longer than 50 years). Some of your information that cannot be linked to you may be placed on scientific databases for others to use without your permission. These may include databases maintained by the federal government. You may decide to have your information removed from the library at any time by contacting the researcher. All your information in the library will be destroyed but information about you that has already been shared cannot be destroyed. In order to be in the main study, you must agree to your identifiable information entering the library for future use.

How will the researchers share my information?

Researchers will share information if it is requested by others for research purposes. This information will be deidentified and not be linked to you.

Will I be paid?

You will receive compensation for participating in this study. You will receive \$30.00 for each of the assessments: the first, the 3rd month, and the 6th month assessment, totaling \$90 for all assessments. If you are not eligible to participate, you will receive \$10.00. This will be given to you in either the form of a Target gift card or ClinCard.

Do I have to join? Can I quit the study? It is your decision whether to join this study or not. You have the right to choose not to join or to stop your participation at any time. Your decision to join in this research or stop participating will not affect your regular care nor your relationship with Weill Cornell Medicine, your doctors, or other employees. You may withdraw from the study by contacting the primary investigator, Dr. Sara Czaja via phone (646) 962-7141 or email at AgingBehavioralRsrch@med.cornell.edu.

You will be told about new information that may affect your health, wellbeing, or participation in this study.

The investigators, physicians or sponsors may stop the study at any time or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, if you need additional or different medication, or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

What if I have questions?

If you have any questions, concerns, or complaints about the research, please contact:

Dr. Sara Czaja
Division of Geriatrics and Palliative Medicine
420 E. 70th Street, Rm LH-311, NY, NY 10021
646-962-7141
AgingBehavioralRsrch@med.cornell.edu

If you have questions regarding your rights as a research participant, about what you should do in case of any injury or illness because of your study participation, or if you want to get information or give feedback, please contact the WCM Institutional Review Board (IRB) at:

WCM IRB, (646) 962-8200, irb@med.cornell.edu

Website: <https://research.weill.cornell.edu/irb>

You may also submit questions or complaints without giving your name by calling (866) 293-3077 or visiting <http://www.hotline.cornell.edu/>.

HIPAA Authorization for Use and Disclosure of Your Protected Health Information

As part of this study, we will be collecting health information about you and sharing it with others. This information is “protected” because it identifies you.

Protected Health Information (PHI)

By signing this Consent Document, you are allowing the following people to use or release your protected health information for this study: researchers and their staff.

This information may include: age, sex, HIV-related variables, general medical information. We will use this information to: see if there is a relationship between health status and benefit from the COPPEhR system. The health information listed above may be used by and/or released to: researchers and their staff.

In addition to the people listed in this form, there is a chance that your health information may be shared outside of the research study and no longer be protected by federal privacy laws. Examples of this include releases to law enforcement, legal proceedings, health oversight activities and public health measures.

Right to Withdraw Your Authorization

Your permission for the use and disclosure of your health information for this project shall not expire unless you cancel it. Your health information will be used or disclosed as long as it is needed for this project. However, you may stop your permission at any time by notifying the WCM Privacy Office in writing. To do this, please send a letter to:

Privacy Office
1300 York Avenue, Box 303
New York, NY 10065
Email: privacy@med.cornell.edu

If you have questions about this and would like to discuss them, please call (646) 962-6930.

Please note that the research team does not have to destroy or retrieve any of your health information that has already been used or shared before your withdrawal is received.

If you have questions about the privacy practices of the institution, you can request a Notice of Privacy Practices from your provider.

Where to address your questions or concerns about your personal data

If you want to make a request relating to the rights listed above or if you have any concerns about how your personal data is being handled, please contact the researcher listed at the end of this form. You may also contact the WCM Data Privacy Committee at dataprivacy@med.cornell.edu. Include your name, reasons for the request, and any other information that you find important.

Will I be able to see or copy my information? During this study, you will be able to see or copy your protected health information as described in this form per Weill Cornell Medicine policies. During your participation in this study, you will have access to your research record and any study information that is part of that record.

Refusal to Sign

If you choose not to sign this consent form, and permission for the use and disclosure of your PHI, you cannot be in the research study. Your decision to sign this consent form or stop participating will not affect your regular care, benefits, nor your relationship with Weill Cornell Medicine, your doctors, or other employees.

Please check one of the following:

- ☐ I agree to be [audio and/or video] recorded.
☐ I do not want to be [audio and/or video] recorded.

☐ **YES**, I give permission for my data and information to be kept for future unknown research. I understand that my data and information will be kept indefinitely. I also give permission for my data and information to be **shared** with other qualified **researchers** for future research.

☐ **NO**, I do not give permission for my data and information to be kept or shared for future research.

Participant Signature

I agree to participate in this research and allow my information to be used in this research. My questions have been answered. I will get a signed copy of this form.

Name of Adult Participant

Signature of Adult Participant

Date

Participant Medical Record Number: _____

Researcher Signature (to be completed at time of informed consent)

I confirm that the research study was thoroughly explained to the participant. I reviewed the consent form and answered all questions. The participant appeared to have understood the information.

Name of Research Team Member

Signature of Research Team Member

Date