Official Title:	Can a radical transformation of preventive care reduce mortality by 20% in low SES populations? Preparatory work focusing on AUD/heavy alcohol use, HIV risk, and cardiovascular risk.
NCT Number:	NCT05828849
Study Number:	s22-01584
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NYU Langone Health

Research Subject
Informed Consent Form

Title of Study:	Can a radical transformation of preventive care reduce mortality by 20% in low SES populations? Preparatory work focusing on AUD/heavy alcohol use, HIV risk, and cardiovascular risk. NYULH Study# 22-01584
Principal Investigator:	Ronald Scott Braithwaite Department of Population Health New York University School of Medicine 227 East 30th Street Sixth Floor New York, NY 10016 212-263-4964
Emergency Contact:	Dr. Scott Braithwaite 212-263-4964

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called "subjects". This word is used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this research study is to investigate if a personalized intervention including parts such as navigation (focus on patient outreach efforts, missed and completed encounters), personalization (individual health benefits) and compensation (value health-related costs borne by patients) will help people reduce their chances of dying from preventable causes, including heart attacks, strokes, drinking alcohol, HIV, and other conditions. If you are eligible to participate in the study, we will place you in one of two groups by chance (like flipping a coin). One group (Group A) will receive this intervention and the other group (Group B) will not receive this intervention. If you are in Group A, we will match you with a health guide who will stay in contact with you about your health and help you schedule and attend doctor appointments and other appointments that are important for your health. Your guide will work together with you to make a health plan just for you and then follow up with you about your plan over the next year. Your guide will also provide you with payments for the time that you spend at the appointments and for other expenses while you attend appointments, such as for babysitting. If you are in Group B you

will receive your normal medical care. At the end of the study, we will compare those selected for study procedures (Group A) to a group of people who received their regular medical care without the addition of study procedures (Group B).

3. How long will I be in the study? How many other people will be in the study?

You will take part in the research for 6 months. We will enroll at least 150 participants into the study, by chance, half of them in Group A, and the other half in Group B at Health and Hospitals Corporation of New York Bellevue.

4. What will I be asked to do in the study?

As part of this research, you will have at least three study visits, including one now and then follow-up visits 3 and 6 from now. During the visits, study staff will ask you a series of questions about your health and activities, including, for example, whether you are having difficulty moving around or accomplishing your normal activities. The study team will also collect blood (about 5mL) and urine (or use those already collected during your doctor visit) for lab tests to measure your health; these include test results such as those related to diabetes and cholesterol. Finally, if you are in Group A, you will have an additional visit (shortly after your initial visit i.e., about one to two weeks after your initial visit) to create a health plan with your health guide that includes actions, appointments, and a follow up schedule that works for your availability and preferences.

The following lists the series of visits and activities:

1. **Study entry visit**: study staff will ask you questions about your health and collect blood and urine for lab tests; about 5mL of blood will be taken at the study visit. You will complete a health survey on a computer or tablet. At the end of the visit, you will receive payment for your time. This visit will take around 1 hour to complete.

2. **HIV Testing**
   You are being asked to consent to HIV testing for the purposes of this research. These tests might involve collecting and testing blood and urine. The most common test for HIV is the antibody test, which is a blood test.

   We will conduct an HIV test so we can provide you with treatment if you test positive for HIV. A positive test result means that you have been exposed to the virus and are infected. It does not mean that you have AIDS or that you will become sick with AIDS in the future. A negative test means that you are probably not infected with the virus. It takes the body time to produce HIV antibodies. If you have been exposed to HIV recently, you need to be retested in several months to make sure you are not infected. Your doctor or counselor will explain this to you.

   If you permit the HIV testing and the results show that you have HIV, you will be told this in confidence by your study doctor and be given information about medical follow-up and will talk with you about telling your sex or needle-sharing partners of possible exposure. Additional testing may occur on the sample you provide to determine the best treatment for you and to help guide

HIV prevention programs. You may (or may not) be allowed to participate in this study. Positive results for HIV will be reported to the local health authorities in your country, if required by law.

Your signature below indicates that your health care provider has answered any questions you have about HIV/AIDS and you have been provided information with the following details about HIV testing:

- HIV is the virus that causes AIDS and can be transmitted through unprotected sex (vaginal, anal, or oral sex) with someone who has HIV; contact with blood as in sharing needles (piercing, tattooing, drug equipment including needles), by HIV-infected pregnant women to their infants during pregnancy or delivery, or while breastfeeding.
- There are treatments for HIV/AIDS that can help an individual stay healthy.
- Individuals with HIV/AIDS can adopt safe practices to protect uninfected and infected people in their lives from becoming infected or being infected themselves with different strains of HIV.
- The law protects the confidentiality of HIV test results and other related information.
- The law prohibits discrimination based on an individual's HIV status and services are available to help with such consequences.
- The law allows an individual's informed consent for HIV related testing to be valid for such testing until such consent is revoked by the subject of the HIV test or expires by its terms.

You may revoke your consent orally or in writing at any time. As long as this consent is in force, your provider may conduct additional tests without asking you to sign another consent form. In those cases, your provider will tell you if other HIV tests will be performed and will note this in your medical record.

Under New York State law, HIV-related information can only be disclosed to people authorized by you by signing a written release. Because the HIV test is needed to conduct this research, it is also necessary to obtain your authorization to share the HIV-related health information with those individuals who are conducting or overseeing the research. Those individuals who may receive your HIV-related information are listed in the "*HIPAA Authorization"* section. Your signature on this informed consent is your authorization that your HIV-related health information can be released to those individuals. This authorization shall be valid for the same period of time that you have authorized release of your other protected health information for this study, and likewise can be revoked at any time.

Under New York State law, HIV-related health information may also be released to the following: health providers caring for you or your exposed child; health officials when required by law; insurers to permit payment; persons involved in foster care or adoption; official correctional, probation and parole staff; emergency or health care staff who are accidentally exposed to your blood; or by special court order.

Under New York State law, anyone who illegally discloses HIV-related information may be punished by a fine of up to $5,000 and a jail term of up to one year. However, some re-disclosures of health and/or HIV-related information are not protected under federal law. For more

information about HIV confidentiality, call the New York State Department of Health HIV Confidentiality Hotline at 1-800-962-5065; for more information regarding federal privacy protection, call the Office for Civil Rights at 1-800-368-1019. You may also contact the NYS Division of Human Rights at 1-888-392-3644.

3. **The 1st follow-up visit:** only Group A will have this study visit. During this visit, you will meet with a health guide to review your lab and health survey results together. These include lab results for cholesterol and diabetes, and alcohol use, and health survey results about your substance use, HIV risk, and overall well-being/quality of life. Working with the health guide you will make a health plan. At the end of the visit, you will receive payment for your time. This visit will take around 1 hour to complete.

4. **The 3-month follow-up visit** will include a follow-up health survey and a satisfaction survey about your experience of being a part of the study. Group A participants will also review and update their health plan with their health guide. At the end of the visit, participants will receive payment for their time. The visit will take approximately 30 minutes to 1 hour to complete.

5. **The 6-month follow-up visit** (the final visit): study staff will ask you questions about your health, and you will again complete a health survey, satisfaction survey, and have lab tests for blood and urine; about 5mL of blood will be taken at the study visit. At the end of the visit, you will receive payment your time. The visit will take around 1 hour to complete.

6.

Any identifiable private information collected and/or used for the purposes of this research will not be used or distributed for future research studies.

Researchers may need to communicate with you about information relevant to the research study. The research team will usually contact you for these purposes by phone, but if you have given the Researchers your email address and mobile/cell phone number and permission to send a text message, the research team may contact you that way.

When the research team sends email messages that include identifiable health information, they will use encrypted messaging (e.g., Sendsafe). When the research team uses texting over mobile/cell phones there is no way to encrypt the message. This means that information you send or receive by text message is unencrypted and could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier. Therefore, text messages carry security and privacy risks.

Below are some important points about texting in this research study.

Text messages are not encrypted, and therefore are unsecure and may result in a breach of your confidentiality.

You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and Bellevue will not cover the cost related to any increased charges, data usage against plan limits or changes to data fees from the research texts

Text messages will only be read during regular business hours. However, if you have a scheduled visit outside of business hours, you may receive a text in relation to this visit outside of regular business hours.

Text messaging should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.

You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number a text message that says, "Stop Research Text."

Your agreement applies to this research study only. Agreeing to other texts from NYU Langone Health, for example appointment reminders, is a separate process. Opting out of other texts from NYU Langone Health is a separate process as well.

Please make sure to keep the research team updated if your mobile/cell phone number changes during the study.

_____ Yes, I agree to receive texts from this research group.
_____ Initial here
Cell phone number:_____

_____No, I do not agree to receive texts from this research group.
_____ Initial here

5. What are the possible risks or discomforts?

There are minimal risks in taking part in this study. Please find them listed below.

Side Effect of Having Blood Taken:

- Fainting or feeling faint. Tell the study staff right away if you feel faint.
- Redness, pain, bruising, bleeding, or infection at the needle site.

Risks related to Health Plan Intervention:

- Group A subjects may find it stressful to think about their health or change their lifestyle. If you feel uncomfortable about any follow up visits or interactions, please alert the PI using the contact information above. Please also be aware that you can stop participating at any time.

Risks related to Survey Procedures:

- Both Group A and B may also find some questions on the surveys and assessments difficult or uncomfortable to answer. You may skip any question you feel uncomfortable answering or stop participating in the study at any time.

Breach of Confidentiality:

- There is also a possibility of loss of confidentiality from collecting data about you and your health, such as your name or birthdate. We will minimize this risk by storing your identifiers separately from the research data and limiting access to your data.

Risks related to using text message communications:

- In this study you may receive texts over mobile/cell phones and this method of communication may result in a breach of your confidential information because text messages to mobile/cell phones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier.

Risks For Standard of Care Procedures You May Undertake for Routine Care (Not Research Activities)

Risks related to cognitive behavioral therapy (CBT) treatment:

- You may feel emotionally uncomfortable at times during the therapy sessions

Risks related to antiretroviral treatment (ART) if you test positive for HIV and are offered treatment:

- You may experience side effects to ART including allergic reactions, with symptoms such as fever, nausea, and vomiting or rash

Risks related to medicated assistant treatment:

- You may experience side effects that include nausea, constipation, frequent urination, sexual dysfunction, and addiction.

Risks related to taking polypill for those with CV risk:

- Possible side effects included a cough, muscle aches and stomach irritation.

Risks related to diabetes treatment:

- For those with diabetes diagnosis, treatment for this condition may cause side effects including hypoglycaemia, nausea, gastrointestinal disturbance, including diarrhea and constipation, abdominal pain, allergic skin reactions, and liver inflammation.

6. Can I be in the study if I am pregnant?

If you become or you think you have become pregnant during the study, you must tell the principal investigator right away and must tell your obstetrician or other health care provider caring for you during your pregnancy that you took part in this study. If you become pregnant, you can still be a part of this research study as this research only involves survey administration and the interventions as described above. You will be followed up to the end of the study and will continue to receive care through your personal doctors at H+H per standard of care. The principal investigator may ask you to provide information about the outcome of your pregnancy.

7. What if new information becomes available?

During the course of this study, we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will let you know as soon as possible if such information becomes available.

8. What are the possible benefits of the study?

This study could benefit you by improving your health and increasing your life expectancy. For example, if you are in Group A, having a health guide could make it easier to understand your current health and to plan and take actions that improve your health. Having a health guide could also make it easier to book, remember, and attend appointments. Receiving payment for your time could also help you prioritize your health without worrying about the money you could make doing other things with that same time. If we find that taking part in this study helps you and others like you, many more people in the future could also benefit from being offered the same strategies used in this study.

9. What other choices do I have if I do not participate?

You can choose not to participate and still receive your standard of care. Your decision to participate will not interfere with your future care, payment for your routine health care outside of the study care, or your eligibility for health care benefits.

10. Will I be paid for being in this study?

If you attend all study visits, you will be paid a minimum of $148.00 if you are assigned to Group A (approximately 37.00 per visit for 4 visits) and a minimum of $105.00 if you are assigned to Group B (approximately 35.00 per visit for 3 visits) for participation in the study. This includes transportation costs, and costs associated with time needed for participation in the study. If you choose to leave or are withdrawn from the study for any reason before finishing the entire study, you will be paid for each visit that you complete. Payment for each visit will be given via a gift card.

In order to receive payments for your participation in research, you may need to provide your Social Security number. This is because NYU Langone Health is required to report to the IRS any amounts that are paid to research participants that are equal to or greater than $600.00, and you may be taxed on these research payments above $600.00. If you receive payments in any amount by a check, you will need to provide your Social Security number or Alien Registration number and will be asked to complete an IRS W-9. If you do not have either of these numbers or are not willing to complete the IRS, you may be in the study but will not receive any payment.

Biospecimens collected for the purposes of this research (even if identifiers are removed) will not be used for commercial profit.

11. Will I have to pay for anything?

You will not have to pay for any part of the research or for participating in the research study. All costs will be covered by the research study.

You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay. If you have health insurance, the cost of these services will be billed to your insurance company. If your insurance does not cover these costs or you do not have insurance, these costs will be your responsibility. The study will pay for out-of-pocket medical copays that you may be responsible for when you do have a medical visit as part of the study if you are in the intervention or (Group A). Routine medical care costs will be your responsibility if you are not part of the study (Group B).

12. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the Principal Investigator as soon as possible. The Principal Investigator's name and phone number are listed at the top of page 1 of this consent form. We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for NYU Langone Health to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

13. When is the study over? Can I leave the study before it ends?

This study will end after all subjects have completed all study visits, and all study information has been collected. This study may also be stopped, or your participation ended at any time by the study sponsor if:

- The Principal Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed the study visit schedule for appointments related to the study.
- The study sponsor, the Principal Investigator, or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your routine health care outside of the study care, or your eligibility for health care benefits.

14. How will you protect my confidentiality?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at Bellevue Hospital. In compliance with NYU Langone Health policies and procedures and with HIPAA, the only research staff that can access this information are those who need your information as part of their job. Any information we collect about you that makes it easy to tell who you are will not be shared or used outside

of this study or for any future research studies. Additionally, study staff will protect your identity by using a study number (instead of your name) for all information collected about you for the study, so it is unlikely anyone will be able to identify you from our records.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including to securely document any medical services you receive, and so that other members of the Bellevue Hospital community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

Certificate of Confidentiality
To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information 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, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

By agreeing to be in this research and signing below, you are giving your consent to share research information with others at NYU Langone Health. This means that your research information, including lab results, X-rays, MRIs, information about the investigational drug used in this study, may be included in your NYU Langone Health electronic medical record.

What is an Electronic Medical Record?
An Electronic Medical Record (EMR) is an electronic version of your medical chart within Bellevue Hospital. An EMR is simply a computer version of a paper medical record.

If you are or have been a patient at Bellevue Hospital in the past, you have an EMR at Bellevue Hospital. Information from your research participation will be added to this EMR.

If you have never been a patient at Bellevue Hospital, you may not have an EMR at Bellevue Hospital. In connection with your participation in this study, an EMR will be created for you. The purpose of your EMR at Bellevue Hospital will be to facilitate this research study and allow the researchers to maintain information arising from your participation in this research study. The creation of this EMR is a requirement of your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility, for example, your name, the name of your primary doctor, the type of insurance you have, your date of birth and other health-related information.

What may be placed in the EMR?
Information related to your participation in the research (e.g., laboratory tests, research-related notes, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by Bellevue Hospital.

This information will be accessible to other members of the Bellevue Hospital workforce that are not part of the research team. Information within your EMR may also be shared with others who Bellevue Hospital has determined may appropriately have access to your EMR (e.g., Health Insurance Company, disability provider, etc.).

Will I have access to research-related information within the Electronic Medical Record
The 21st Century Cures Act allows patients increased access to their EMR. If you agree to participate in this study, this means that any research-related information placed in your EMR will be available to you immediately.

As a research participant, this means that you have immediate access to any research-related information that is placed in your EMR before the researchers have had an opportunity to review the information.

The research-related information that will be available to you immediately are as follows:

Results that may be placed in the medical record: laboratory tests, research-related notes, imaging studies, and clinical procedures.

Access to research-related information within your EMR can be found through Bellevue Hospital's patient portal.

15. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your

permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed below. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: National Institute on Alcohol Abuse and Alcoholism (NIAAA)
- Governmental agencies responsible for research oversight (e.g., the U.S. Food and Drug Administration or FDA).
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- H+H personnel responsible for the support or oversight of the study at Bellevue Hospital.

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, contact the Principal Investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

16. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU Langone Health IRB Office number is (212) 263-4110. The NYU Langone Health IRB is made up of doctors, nurses, non-scientists, and people from the community.

17. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns, or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

A description of this clinical trial will be available on http://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 site at any time.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date