Official Title: Understanding and Developing a Network-based Social Support Intervention to Improve Retention in Human Immunodeficiency Virus (HIV) Care and Antiretroviral Therapy Adherence for Adolescents Living With HIV

NCT04077047

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CONSENT FORM FOR iENGAGE PROGRAM (ADULT 18+ YEARS)

Social determinants of engaging youth with lifelong illnesses in health care (Short Title: iEngage)
Cape Town Protocol Version 2.0: 23 April 2024
Consent Form Version 2.0: 02 April 2024

Study Implementers: Desmond Tutu Health Foundation, University of Cape Town & Wake Forest University School of Medicinein Winston-Salem, North Carolina (USA)
Study Sponsors: USA National Institute of Mental Health
Principal Investigators: Professors Tiarney Ritchwood and Linda-Gail Bekker

Introduction
Good day, I am …….. and I am working on a collaborative project between the Desmond Tutu Health Foundation and Wake Forest University School of Medicine focused on testing the safety and usefulness of a new program called iEngage. The goal of the iEngage program is to improve life for youth living with lifelong illnesses. To do this, we are leading a research study with up to 60 participants from this and neigbouring communities to participate in the iEngage intervention. This research is sponsored by the National Institute of Mental Health in the United States. This is a consent form. It gives you information about the research study. Please take your time in deciding if you want to be part of this study. Talk to people you trust such as your friends, family, or doctor if it helps you to decide. You can ask questions at any time. We will give you a copy of this form to keep. You do not have to participate in this research study. It is your choice. Just tell us if you do not want to take part in the study. If you decide to be part of the study but change your mind later on, that is okay. You may leave the study at any time. Your decision to take part or not take part in this study will not impact your healthcare.

Why is this study being done?
We are doing this study to better understand the safety and usefulness of a new program called iEngage. The goal of iEngage is to help youth in treatment for a chronic condition to stay in care and take their medication.

What would I have to do if I agree to take part in the study?

1. Take part in the iEngage program which will include a pre-enrolment meeting and four in-person sessions at Phillipi Village or another private setting. Each session will last *approximately 60-90* minutes and will be led by a facilitator who discuss topics such as living with a chronic condition, ways to manage these conditions alone and with support, goalsetting, and social support.
2. Participate in the session as a pair with a youth (individual, aged 15-25 living with a chronic condition) and 1-2 treatment buddies (individuals aged 18 years old or older who provide support to the youth and are aware of their chronic condition).
    a. <u>If you are the primary participant or Youth:</u> You will be asked to invite 1-2 SN Members to participate in the program with you.
    b. <u>If you are a social network member or treatment buddy:</u> You will be asked to participate in sessions with the youth and facilitator.
3. As part of this study, we will also collect information about your experience in the intervention and your knowledge, attitudes, and behaviors. We will do this through survey(s) and interview(s) before, during, and/or after the intervention.

Who is allowed to be part of this study?
Youth or a SN Member is allowto take part in this study if:
    a. You are living with a chronic condition (Youth)
    b. You are 15-25 years old.
    c. You are the support person for someone living with a chronic condition and participating in the intervention (treatment buddy).
    d. You are 18 years old or older.

Do I have to take part in this study?

No, you do not have to take part in this research study. It is your choice. If you agree to take part and change your mind later on, that is okay. You may leave the study at any time. Your decision to take part or not take part in this study will not impact your healthcare.

What if the study questions or activities upset me?
If you feel uncomfortable or do not want to be part of any of the activities, or if any of the questions make you uncomfortable or anxious, we ask that you to let the staff member know so that we can find a way to assist you. This will not affect your participation in the study.

What happens if a participant is hurt taking part in this study?
Because the study is low risk, it is very unlikely that you could be injured as part of the study. There is no program for compensation either through the listed institutions or the US National Institutes of Health (NIH). You will not be giving up any of your legal rights by signing this consent form.

What are the benefits of being in this study?
You may not directly benefit from taking part in this study. If you are living with a chronic condition, it may help you to remain in care for that condition and/or improve adherence to any medications you take to manage your condition. You may also have the indirect benefit of helping with this research program; this research may help youth in your community, as well as others, stay in treatment, leading to lower rates of some lifelong conditions.

What are the risks of being in this study?
The risks to being part of this study are very small but no study is without any risk. If being part in this study causes you distress, please let a member of the team know and we will refer you to a counselor with whom you can talk further. You may also stop participating at any time.

Why you may be asked to leave the study:
We may ask you to leave the study early if:

- The study is cancelled by either the sponsors or the Institutional Research Ethics committee or other review committee. These committees watch over the safety and rights of study participants.
- You or your network member misses 2 or more scheduled sessions.

Alternatives to being in the study
Other than not being part of the study, there is no alternative.

Cost to you
There are no costs to be part of this study.

Will what I say be kept confidential?
All efforts will be made to keep research records confidential. All the research records will use a code number, not names. Research records are stored in a locked room at the University of Cape Town and securely online. However, we cannot guarantee absolute confidentiality. Data from this study will be stored at the University of Cape Town and a copy will travel with the principal investigator to the United States with all identifiable information removed.

Names will never be used in any publication or presentation about this research study. You will never be required to disclose your health condition, publicly.

The research records may be reviewed by the U.S. National Institutes of Health (NIH), other government and regulatory authorities, the Human Research Ethics Committee (HREC) of the University of Cape Town in South Africa, the Institution Review Board of Wake Forest University School of Medicine, study staff and authorized representatives of these organizations. The information you share with us during the study will not be shared to anyone outside of the study team unless you ask us to share it.

Do I get paid for taking part in this study?
You will be paid R200 or the equivalent in a combination of cash, vouchers, and or gift cards for attending sessions 1-4. You will also receive R20 or the equivalent in a combination of cash, vouchers, and or gift cards for transportation or be given the cost of transportation for each in-person session you attend.

Who should I contact for further information?
If you have questions about this study, you may contact the principal investigator, Dr. Millicent Atujuna at [redacted] or speak with our research assistant, Nqaba Nkomana [redacted] or [redacted]

Who can I call for information about my rights as someone who is helping with research?
This study protocol has been approved by the University of Cape Town's Human Research Ethics Committee (HREC), the Western Cape Province, and Wake Forest University School of MedicineInstitutional Review Board. All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research participant, you may contact, anonymously if you wish, the University of Cape Town's Human Research Ethics Committee. Please phone [redacted] to be directed to Dr. Mark Blockman, who is the chair of this committee.

For the participant
Your signature on this consent form means you:
(1) have read the information about the study
(2) were given the chance to ask questions;
(3) agree to be part of the research study

Please confirm that you give permission or do not give permission for the following:

We would like to save your contact information for potential participation in future research studies. We are not asking you to agree to take part in another study at this time, but may contact you to see if you might be interested at a later date. **Could we contact you at a later date to see if you might be interested in taking part in future studies?** Please know that you may change your mind about being contacting for new studies at any time.	☐ Yes, you may contact me about future studies. ☐ No, I do not want to be contacted about future studies.

Participant
_____ _____ **Participant name and surname** (print) Signature of participant _____ _____ Date (DD/MM/YYYY) Time
Study staff
_____ _____ **Staff obtaining consent name and surname** (print) Signature of staff obtaining consent _____ _____ Date (DD/MM/YYYY) Time
Witness (only include if person signing is not able to read/write)

_____	_____
Witness name and surname (print)	Signature of witness
_____	_____
Date (DD/MM/YYYY)	Time