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Overview

Firstly, we'd like to thank you for participating in the CETA study. At this stage you would have already received CETA sessions from our study team back in 2023 and would have also completed your 3 and 12 months follow up assessments. I would now like to tell you more about the final phase of this study we are conducting. I am going to give you information about why we are doing this work and what you will be asked to do if you choose to participate in this phase of the study. We will read this form with you. If there are words or information that you do not understand or if you have any questions about this study please feel free to ask your questions at any time. It is important you fully understand this information and can make an informed choice about being in this final phase .

We are asking you to be part of the final phase of the CETA research study. You are already enrolled in this study and hopefully remember receiving CETA sessions from our counsellors and we would now just like to understand a little bit more about your experience of receiving those sessions.

Why are we doing this final part of the study?

In order to try and address the impact that violence can have on an individual's health we tested the CETA counselling intervention to see if this could help them improve their mental health and give them the tools to deal with their exposure to and experience of violence. You have been selected to participate in this final phase of the CETA study as you received at least 5 CETA sessions during 2023. We would now like to get an in-depth understanding of your experiences and perceptions of CETA and if the skills and tools that you were taught have helped you in the time since completing the intervention. This will help us understand the results from the main study and guide how the CETA intervention might be delivered in the future.

If you agree to participate in this final study phase, we would like to complete the informed consent process with you now. We will then make arrangements for you to join a focus group discussion with up to ten other participants who have also experienced CETA.

What happens in this phase of the study?

If you agree to take part in this phase and consent to participate, we will want to ask you some more questions relating to your experience with CETA, your perceptions of the intervention and how it might have influenced your knowledge and skills in accessing healthcare and information. We will do this in a focus group discussion with about 6-10 other people and may follow the focus group with individual questions for about 10 people. We anticipate that the FGDs will take approximately 60-75 minutes of your time and for those asked to complete the in-depth interview this may take 30-45minutes of your time. You are free to withdraw your participation at any time.
We would also like to audio record this discussion so that we can refer back to this to make sure that we did not miss

any points. These recordings will only be used to check the information that has been collected and will not be

shared with anybody outside the study team. We will need to ask for your written consent to record this focus group discussion. If you agree to participate in this phase of the study we will ask you to sign a consent form that confirms that we explained this additional research to you and that you are willing to participate. We will also ask that you complete a separate consent that confirms you are will for the discussion to be audio recorded.

Risks and discomforts of participating in this study

During the interviews and focus group discussions, we will be asking questions about your experiences with the CETA intervention and asking you to share these experiences with others in the group discussions. Although we will try to be sensitive when asking questions, we acknowledge that some questions may cause some people to feel uncomfortable or might cause some distress. If this happens. you can stop answering questions or withdraw from the discussion at any time. If you become very distressed or uncomfortable during the FGD or the interview, we will connect you with our study supervisors and a trained psychologist who are trained to provide appropriate support. South Africa also has numerous hotlines and programs to support victims of abuse, rape and violence. These include:

1. The Tears Foundation which have a 24/7 hotline for anyone experiencing Gender-Based Violence or Domestic Abuse, which is accessible in all 9 provinces in South Africa (Dial *134*7355# https://www.tears.co.za/gbv-domestic-abuse/)
2. People Opposing Women Abuse (POWA) offer counselling (face to face) and legal support as well as some short-term sheltering (011 642 4345 https://www.powa.co.za/POWA/get-help/)
3. Child Line offer counselling support to abused and abandoned children and their families – for any woman who has concerns for their children. They offer a 24/7 line (0800 055 555 or 011 484 1070 https://childlinegauteng.co.za/)
4. LifeLine South Africa have a dedicated 24/7 counselling line for victims of IPV/domestic violence/gender abuse (0800 150 150) as well as a counselling hotline (0861 322 322; http://lifelinesa.co.za/)
5. Stop Gender Violence Helpline provides anonymous, confidential, telephonic counselling and referrals (0800 150 150 or dial *120*7867# or https://lifeline.co.za/stop-gender-violence/index.html
6. The South African Depression and Anxiety Group (www.sadag.org) offer a mental health helpline (011 234 4837), a substance abuse helpline (0800 12 13 14 or SMS 32312), and suicide crisis line (0800 567 567 or 0800 456 789)

How do we keep your information safe and confidential?

We will try to ensure that all the information collected through the FGDs and IDIs does not include any personal identifiers (such as names) and that it remains anonymous. Only your unique study ID will be used for the purpose of these questions. We will also store your information in ways we think are secure. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. We will do everything that we can to ensure that your confidentiality is maintained and inform focus group participants that anything discussed in the group should not be shared outside of the room. However, we cannot guarantee that this will always be the case. (More information about how we will ensure your confidentiality and data sharing is given at the end of this form).

You should know that we are required by law to report certain information if we are made or become aware of these situations, this includes information about child abuse or neglect; elder abuse; specific reportable diseases; harm to others or if we believe your life is at risk from violence from a known party.

Potential benefits of being part of this study

We know that CETA may help with feelings of sadness, anxiety, relationship problems and healing from trauma. We do not yet know if this counseling has helped you specifically or others who received the intervention, but asking about your experiences with the intervention and how you found it will help us better understand results from the study. You may personally not receive any benefit from participating in this phase of this study but the feedback you give may help those individuals and communities who receive CETA in the future.

What are your rights if you participate in this study?

Your participation in this research is completely voluntary. That means that it is your choice to join or not. You are not required to join this final phase study, and if you do join the study, you do not have to answer any questions that you are not comfortable with. You can also decide to stop at any time.

By consenting to be in this final phase you do not waive any of your legal rights. Giving consent means that you have heard or read the information about this study; that you agree to participate. You will be given a copy of this form and the signed consent form to keep if you wish.

You can choose not to take part in this study phase. If you decide not to take part or withdraw from this study phase at any time, you will not suffer any penalty or lose any benefits to which you are entitled, and it will not affect your care at this or any other clinic in any way. You will still get the services you need if you don't join the final phase of the study.

Will it cost me anything to be in this study?

If you are enrolled in this study phase, you may have costs associated with travel to come for the FGD and IDI. You will receive R400 Rand for your transportation costs and time. You will not incur any costs for your participation in the study.

If you think that you have been injured by being in this study, please let the investigator know right away. Use the phone number below. You can get treatment for the injury at any healthcare facility you choose. While there is no program to provide compensation for the cost of care for research related injury or for other expenses, the study team maintains a list of resources for accessing additional mental health care and will help support you in accessing those services. You are not giving up any of your legal rights by signing this form.

Who to Contact

If you have questions about this phase of the study you may ask them now. If you agree to join the study, you can contact the persons listed below at any time if you have any questions.

For questions about the study, please contact:
Sophie Pascoe or Sithabile Mngadi-Ncube, Health Economics and Epidemiology Research Office, Johannesburg
Telephone: +27 (0) 10 001 7930 ext.2661 or Email: spascoe@heroza.org or smngadi@heroza.org

If you want any information regarding your **rights as a research participant, or complaints regarding this research study**, you may contact Prof. Paul Ruff, Chairperson of the University of the Witwatersrand, Human Research Ethics Committee (HREC), which is an independent

committee established to help protect the rights of research participants at (011) 717 2301 / EthicsRegulatory@witshealth.co.za.

More information about confidentiality and data sharing:

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health in the United States. All studies funded by the National Institutes of Health that involve identifiable information are covered by a CoC. The CoC provides how we can share research information. Because we have a CoC, we cannot give out research information that may identify you to anyone that is not involved in the research except as described below. Even if someone tries to get your information in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information.

If you agree to be in this study, we may share your answers with the following groups of people:

- People who do the research or help oversee the research.
- People from Federal and state agencies, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
- Any people if you give us separate permission allowing us to give them your answers.

If you agree to be in the study and sign this consent form you give designated officials from the Human Research Ethics Committees at the University of Witwatersrand in Johannesburg, South Africa and the Institutional Review Boards at Boston University, Johns Hopkins University and Columbia University in the US and the US National Institutes of Health permission to look at your consent form and study records. They are ensuring that everything happening in this study is ethical. They would only review the electronic study records to ensure that your privacy and integrity is being maintained and protected and would only require your personal data in exceptional circumstances to respond to a formal complaint or for a compliance audit. In compliance with the South African Protection of Personal Information (POPI) Act your name will NOT be recorded by those parties outside of South Africa to ensure your confidentiality.

We might share your answers further but only where we have removed personal identifiers. There still may be a chance that someone could figure out information is about you. Such sharing includes:

- Publishing results in a medical book or journal.
- Adding results to a Federal government database (which is required by our funders).
- Using research data in future studies, done by us or by other scientists.

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.