

Appendix 06: Information and Informed Consent for participants in the Stepping Stones and Creating Futures Intervention Trial.



Version 4: 7 November 2015

Invitation to participate in the study

Good day, we invite you to participate in a research study exploring the impact of a combined Stepping Stones and Creating Futures intervention on the lives of young people. This information leaflet will help you to decide whether you want to participate. Before you agree to this, you should fully understand what is involved if you decide to participate in this study. If you have any questions that this leaflet does not fully explain, please do not hesitate to ask the researcher. This study is being jointly conducted by the Health Economics and HIV/AIDS Research Division (HEARD) at the University of KwaZulu-Natal, the Gender and Health Research Unit at the Medical Research Council and Project Empower.

What does “giving informed consent” mean?

- *It means that you understand what this study is all about and that you freely agree to participate in this study*
- *That you understand all the things that we will ask you to do as part of this study and you are happy with them*
- *That you know that you don't have to agree to participate in this study and that no one will be cross with you if you don't want to participate in this study*

What is the nature and purpose of this study?

This study explores if a combination of two programmes: Stepping Stones (a gender and sexual health curriculum) and Creating Futures (a livelihood strengthening curriculum), can help young people to have healthy sexual behaviours and also help them to start at an early age to think responsibly about their lives and ensure that they follow a productive life and create good relationships with other people in their community.

Explanation of Procedures to be followed.

We aim to test this curriculum with young people between the ages of 18-30 who live in informal settlements in eThekweni district and do not have a long-term job. We are asking you to participate in this study because you fall in this age group. If you agree to participate in this study, you will be one of approximately 1280 participants (640 males and 640 females) from 32 communities. All participants will participate in this study for a period of two years. During this time, participants will be interviewed three times.

If you decide to take part, we will invite you to participate in the following activity:

- As a first stage you are being asked to participate in a one hour interview in which your answers to questions will be recorded using a cell phone (mobile phone) working as computerised hand-held device. We hope you will agree to three of these interviews at three different times during the next two years. These interviews will help us to determine the usefulness of the combined intervention and how we can improve it. In the interview you will be asked about your background, experiences of violence, relationships, peer pressure, gender attitudes and norms, alcohol and drug use, sexual behaviour, your mental health, HIV, your beliefs and how you make a living. This interview will be repeated after 12 months and 24 months and we will ask you again if you are still happy to do the interview. Signing the consent form will mean that you are agreeable to the three data collection time periods.
- Participants in this study will come from 32 communities around eThekweni. These communities will be grouped into two groups. Sixteen communities will get the intervention immediately. The other 16 communities will only get the intervention two years later. This will be determined through a process called randomization where communities will be allocated into the two groups by chance. This process is like tossing a coin to decide which communities get the intervention and which ones do not. This means that all communities have an equal chance of getting the intervention immediately. The communities which get the intervention will hold workshops twice a week and these workshops will last for about 3 hours. The majority of workshops are single sex, although at times you will be brought together with others. In total there are 21 workshops. At the end of the study (in 2 years' time), the intervention will also be given to the other 16 communities which did not get the intervention.
- Your community _____ was randomly allocated to receive the intervention now/in two years [DELETE AS APPROPRIATE]
- In order to collect information from you we will ask you to answer questions on a cell phone (mobile phone). The researcher will give the cell phone to you and you will answer the questions on your own, and when you are done you will return the cell phone to the researcher. You will not write your name in the cell phone as you will be given a unique code, and only authorized researchers will be able to link this code to you. However, the document that links codes to people's names will be kept in a secure and password protected computer and separately to where the data (information given by participants) is kept. In this way, the researcher that is with you will not know how you have answered the questions. The questionnaire will take approximately one hour each time. If you need help answering the questions you can ask the research for help.
- If you are in the intervention arm (receiving Stepping Stones and Creating Futures) you will also be asked to complete a short questionnaire during one of the sessions about whether you had to make choices about coming to sessions (e.g. instead of going to look for work) and whether you spent any other money related to this. This will be done with paper and pencil and will take approximately 10-15 minutes to complete. The same code will be used to link your answers to the other questions you have been asked.

- Also, if you are in the intervention group, you may have fieldworkers come and observe sessions to understand how the intervention is delivered. The fieldworkers are interested in watching how sessions run, what goes well, and what is challenging. They will take notes and may participate in sessions. They are primarily interested in the people running sessions, but they may make notes about what you say and do. However, we will not use your name when they are typed up.
- For the study to be able to maintain contact with you for the next two years, we ask that you provide us your home address, cell phone number and the cell number of two close friends or family members. This information will be kept in a password protected computer and will only be used to make contact with you. When the study is completed, this information will be destroyed.

Will any Procedures Result in Discomfort or Inconvenience?

You might not be comfortable with some questions in the questionnaire (cell phone), or issues discussed in the workshop, if your community gets the intervention. If that happens, please feel free not to answer questions that you are not comfortable with. There will be no negative consequences or criticism if you do not to answer questions or withdraw from the study at any time.

Are there any Risks or Costs involved for me?

Apart from the time you may spend participating in the research or attending workshops there are no costs to you in participating in this study.

If during the course of the study you find information that disturbs you emotionally, please inform the researchers or facilitators. With your permission, you will be referred to a professional counselor who is part of this study at no cost to you.

Possible Benefits of this study.

There are no direct benefits for you in participating in this study. However, some of you may find the information you get in this study useful. For example, young people who participated in a similar study in Durban found the combined intervention of stepping stones and creating futures very useful in their lives. Similarly young people in the Eastern Cape said they benefited from participating in Stepping Stones workshops. The information we are collecting in this study may be helpful in telling us whether the curriculum we are testing is useful for promoting good sexual behaviour for young people and enable them to think seriously about their lives and take responsibility for it.

What are your rights as a participant?

Your decision to participate in this study is completely voluntary. You can refuse to participate or stop at any time without giving any reason and this will not affect your relationship with the researchers or your community.

Compensation

Your participation in this study is entirely voluntary; there is no reward to be given to you for participating in this study. But we will compensate for your time and inconvenience as follows. All people who agree to the study will receive R100 for completing the questionnaire.

- If your community was chosen to receive the intervention you will receive nothing else. During the workshop refreshments (snacks and drink) will be provided. At 12 months you will receive R150 for completing the questionnaire and at 24 months R300 for completing the questionnaire.
- If your community was not chosen to receive the intervention immediately you will receive an additional R200 (total received R300) approximately the value of the Child Support Grant. At 12 months you will receive R450 for completing the questionnaire and at 24 months R600 for completing the questionnaire. You will also at 24 months be offered the chance to participate in the intervention.

If you incur travel expenses related to the study we will compensate you for this.

Your community is in the intervention/control [DELETE AS APPROPRIATE] community. As such you will receive R550 / R1350 [DELETE AS APPROPRIATE] over the two years as compensation.

Confidentiality

Questionnaires will be self-administered, meaning that you will read and answer the questions yourself on the cell phone without the researcher reading the questions to you or hearing your answers. This will be held in a private place to ensure that there is no other person who can see the answers you give in the cell phone (questionnaire). You will be identified by means of a coded number, and no personal information will be linked to this number. Information you enter onto the cell phone cannot be linked to you once we have uploaded it. In answering questions on the cell phone we do not collect sufficient information that could result in a prosecution for any illegal acts that you may have committed and reported on the questionnaire.

During the workshops you may discuss issues about your life that you do not wish to have shared outside of the workshop. While we cannot maintain confidentiality of people involved in these workshops, one of the first workshop sessions ensures that the group has a shared understanding of confidentiality during workshops and agrees rules about what can and cannot be shared. If during a workshop the person running the workshop feels you may be about to provide too much information (such as an intention to harm someone else in the future) they will warn you not to reveal any further information. If you did continue to tell them about this, we may be required to report the information to the authorities (e.g. Police or Social Workers).

If a fieldworker is watching a session and taking notes we will make sure that when they get written up, all names are removed and so anything you say will remain anonymous in the future.

Before we write the results of this study, we will ensure that your names and any other thing that would identify you as participant in this study are removed. Therefore Data (information) that may be written into a report or reported to scientific journals will not include any personal information that can identify you as a participant in this research.

Has the study received ethical approval?

This study has been approved by the South African Medical Research Council and University of the KwaZulu-Natal and Ethics Committees. These ethics committees will continue to see if this study is being done in a safe way until the study is completed. I have copies of approval letters from the ethics committees that show that the study was approved by them. I can give it to you if you wish to have one.

If you have any questions about the study or something that you are not happy about, please feel free to contact the Chairperson of the South African Medical Research Council Ethics Committee Prof. Danie du Toit at 021 938 0341 or email: adri.labuschagne@mrc.ac.za and the administrator of the University of KwaZulu-Natal Humanities and Social Sciences Ethics Committee Phumelele Ximba, at this number: 031-260 3587 or email: ximbap@ukzn.ac.za

Information and contact person

If you have any questions or concerns about this study please contact the researchers below.

- Andrew Gibbs, HEARD : 031 260 7737
- Ms Laura Washington, Project Empower : 031 310 3564

INFORMED CONSENT FORM.

I hereby confirm that the person asking me to participate in this study has given me information to my satisfaction. He or she explained to me the purpose, things that are involved, risk and benefits and my rights as a participant in the study. I have also received the information leaflet for the study and have had enough time to read it on my own, ask questions and I am happy with the answers I have been given regarding participation in the study. I have been told that the information I give to the study will together with other information gathered from other people, be written into a report and scientific publications. This will be done without my name, personal details and any other information that may identify me as a participant in the study.

I am aware that it is my right to refuse participation in this study without experiencing any harm. I hereby, freely and voluntary give my consent to participate in the study.

Participant’s name.....(Please print)

Participant’s signature.....Date.....

PERSON OBTAINING CONSENT

I have fully explained everything about the research to the participant and am satisfied that the participant demonstrated understanding of the research and is giving consent voluntarily.

Researcher’s name.....(Please print)

Researcher’s signature.....Date.....