The Research Study

We are asking you to participate in this research study. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.
The University of Cape Town is doing this project to research maternal mental health in Khayelitsha. The project is called AFFIRM (**AF**rica **F**ocus on **I**ntervention **R**esearch for **M**ental health), which is a collaboration between the University of Cape Town, University of Addis Ababa, Columbia University, Johns Hopkins University, Kings College University, Makerere University, and the Department of Health. It is funded by the National Institutes of Health, USA.

Why is it important?

The study is important because one out of every three women in Khayelitsha experience depression or anxiety when they are pregnant or after having a baby.

What is it for?

This study is looking at ways to provide counselling services and mental health assistance to depressed pregnant women, so that they can learn to manage and cope with maternal distress.
We want to find out how best to use a "task-shifting" approach, which means using community health workers instead of psychologists and psychiatrists, to provide counselling services for depression. We want to develop appropriate and cost effective mental health services for these women, and we hope that the information obtained will help to improve mental health services in South Africa and other countries in sub-Saharan Africa.

Who will be involved?

1. 420 pregnant women at their first antenatal booking at Michael Mapongwana Community Health Centre MOU and Site B Community Health Centre MOU, who show symptoms of depression when assessed on the EPDS.
2. Community Health workers who work in the catchment area of Michael Mapongwana Community Health Centre and Site B Community Health Centre.
3. Registered Nurse Midwives based at Michael Mapongwana Community Health Centre and Site B Community Health Centre, who work with perinatal mothers and/or mental health in Khayelitsha.
4. Service managers at Michael Mapongwana Community Health Centre and Site B Community Health Centre.

How long will it last? The study will run from July 2012 to July 2016.

What will it mean if you participate in the study?

If you agree to participate in this study you will be asked a few screening questions about depression with the EPDS. If you are distressed according to the EPDS, we will continue with an interview which will take approximately one hour. The interviews will ask some sensitive questions and all information you give us will be kept strictly confidential. You can refuse to answer any questions that you feel uncomfortable answering. The information you give us will be used to help us design a cost effective counseling intervention to help mothers who are suffering from depression.

After this, you will EITHER receive 6 counseling sessions when you come for your pregnancy checkups, OR monthly telephone calls from a community health worker to discuss your depression and ways to help to improve it. The sessions will be audio recorded to ensure the quality of the counseling. You will then be asked to participate in three more interviews at: one month before birth,

three months after birth, and twelve months after birth. We intend to conduct the interviews and counseling sessions on the same days you come for your pregnancy and baby check-ups at the clinic so that you will not incur any additional costs. In the interviews after your baby is born we will also ask some questions about your baby. We will inform you if any new findings arise during the duration of the study that may affect your participation.

Is there any disadvantage from participating in this study?

There is the possibility that you may have a mental health problem or that participating in the study may remind you of a time that you had such a problem. The risks associated with worsening of your depression are present whether or not you participate in this study. If you get distressed by a mental health problem or feel suicidal, we will refer you for psychological help. If you have a serious substance abuse problem or psychiatric illness that was not initially picked up at the interview, we will refer you for external assistance and you will no longer be able to participate in the study.

If you receive counseling from us, there a small risk that counselors may breech confidentiality and/or disclose personal information to you or others. We will minimize this risk by careful evaluation of the counselors and through weekly group supervision and monthly individual supervision for them. If you report or the counselors observe any child abuse, we are obliged by law to report this to the Department of Social Development. This means that we will need to give information about your child to the social worker.

Is there any advantage to the study?

We hope that the counselling will improve your mental health and help you to build better ways of coping with depression in the future. We also hope that the information obtained will help to improve mental health services in South Africa and other countries in sub-Saharan Africa.

What alternatives do I have if I don't participate in the study?

If you think you are depressed but you do not want to participate in the study, you can contact one of the organisations listed in the pamphlet we give you, and they can help you.

What if I change my mind later?

You are free to withdraw at any stage from participating in the study and your decision will not disadvantage you in any way. You will need to inform a member of the project if you wish to withdraw, and if you require, we can refer you to relevant local mental and social health services.

Who will see the information that we collected?

All records will be kept completely confidential, and stored electronically at UCT. Your identity will be anonymous and your information will be combined with that of all the other participating women. After the information is analysed, the recordings and transcripts will be destroyed. This information will only be seen by the researchers and investigators.

When we have finished the study, the information that you provide to us could be used by researchers outside of this study. However, your name and personal details will never be given to any of these researchers. They will never be able to identify who you are.

Who to contact if you want to know more, or if you have a problem at any time?

If you want more information on the study before deciding whether or not to participate, or if you participate and later need help or have questions, please contact:
Prof C. Lund, Department of Psychiatry and Mental Health, University of Cape Town,
Tel: 021 685 0120
If you have any questions about your rights and welfare in the research, please contact: The Human Research Ethics Committee, Groote Schuur Hospital. Tel: 021 406 6626

Consent to Enroll **Research ID #**

I, _____ agree to participate in the research study on maternal mental health in Khayelitsha, to help to develop relevant and cost effective ways of helping mothers with depression.

I have received and understood the study information sheet. I have discussed the advantages and disadvantages of participating in the study and I agree to participate in the interviews as stated in the information sheet.

I know I can leave the research study at any time without prejudice and be referred for psychological help if need be.

Signature: _____

Date: _____

Witness
Name: _____

Signature: _____

Date: _____

You may keep the information sheet. The signed consent form will remain in our study files.