

**Intensified HIV/TB prevention linking home-based HIV testing, including the option of self-testing, with HIV care: a cluster-randomised trial in Blantyre, Malawi**

**Dr Elizabeth Corbett**

**BC01 HIV testing Stage 2 info**

Place sticker or write ID number here

IP1

**Background**

TB is an infection spread from one person to another through coughing. If a person who has HIV gets infected with TB they are more likely to get sick with it, because their immune system is weak. HIV-negative people often fight infection without needing any treatment. Because of this TB has increased due to HIV in Blantyre.

HitTB is running a study in 28 neighbourhoods. You are living in with home-based HIV testing and counselling services.

**Purpose of the study**

We are looking at early diagnosis of TB, and treatment of HIV-positive people with a drug "IPT" to reduce the risk of TB. The study is being run by researchers from England and Blantyre, with involvement of Blantyre District Health Office and Ministry of Health. It is funded by a British charity (the Wellcome Trust).

**What it will mean if you take part in home-based HIV testing and counselling**

You can only test once in this study, so if you have a partner it is best if you test together --- but both of you will need to sign a form and take one kit each.

You can choose to have the counsellor do the HIV test for you, with counselling before and after the test, or take an HIV test kit home to test yourself ("self-test"). If you want to self-test then we will do a test of understanding --- if you do not fully understand the test then you cannot self-test on your own (although the counsellor can come home with you to help).

You will not have to tell a self-test result to the counsellor, but we do need you to return the packaging and "post" the used kit in an envelope into a locked box (like voting). We will open the box in the HitTB laboratory to count the positive and negative tests. This will stop kits being sold, and allow us to know how many positive self-tests there have been. But we will not know which test came from which person. At the same time you will get post-test counselling with all the information that an HIV-positive person will need, --- even if you are HIV-negative or the counsellor does not know your result.

We recommend that you do trust to tell the counsellor if you are HIV-positive. They will be able to:

1. Check to see if your test really is positive and write it in your health passport
2. Give more support and more effective counselling
3. See if you need to be tested for TB and if you need to start HIV treatment ("ART") by asking you questions about your health
4. Take a specimen of sputum if you do have symptoms of TB
5. Arrange for you to be seen in an HIV clinic by someone working with HitTB who will take blood ("CD4 count") and start you on a drug to fight infections (cotrimoxazole) and to stop you getting TB ("isoniazid preventive therapy")
6. They will also be available for you to ask for advice and help if anything happens to your health or have questions about your HIV care.

The risk of trusting them is that you live close together and may do so for many years after this study has finished, and so there is a small danger of other people finding out. Also you may not be comfortable with meeting them as a neighbour when they know your HIV status.

If you test positive and do not want to trust the counsellor then take a “self-referral” card (*counsellor shows card*) to any of these clinics. The named staff know about the study and will provide you with all these same services and will register you at the HIV clinic.

### **Risks and discomforts**

Having an HIV test is stressful, and some people find it difficult to cope after a positive result. You may be at increased risk of not coping if you decide to self-test and then test positive.

### **Costs and benefits**

Taking part will not cost you anything but we will not pay you for taking part. Knowing your HIV status is a benefit, allowing you to plan your life and get care if needed.

### **Confidentiality**

The counsellor and all of our staff have signed a confidentiality agreement that they will not tell or hint at your HIV status. We will record your name but not result in our HIV test register to show you have had a test --- and mark your health passport. An HIV test register --- just like the ones used in VCT clinics --- will record your study/hospital number but not your name these will have results if you tell the counsellor, but do not identify who you are to anyone who does not know your study/hospital number (*counsellor to show register*). These files will be taken to our offices for our records. These will be held securely, and stored on paper in locked files and entered into a computer file that will be protected with a password and held securely. Dr Corbett will be responsible for keeping your personal information confidential.

### **Voluntary participation and withdrawal**

Your participation is voluntary. You may withdraw from the study at any time without giving a reason and without penalty.

### **The Ethics Committees that have approved the study are**

The College of Medicine Research Ethics Committee, Blantyre, Malawi and the London School of Hygiene and Tropical Medicine , London, UK

### **Questions**

If you have any questions concerning participation in this study, please feel free to ask me. Alternatively you can contact:

Name:

Telephone:

**Intensified HIV/TB prevention linking home-based HIV testing, including the option of self-testing, with HIV care: a cluster-randomised trial in Blantyre, Malawi**

Place sticker or write ID number here

IP1      /

**Dr Elizabeth Corbett**

**BC01 HIV testing Stage 2 consent**

I have read or had read the information sheet about the study which explains the study and what I am required to do.

Please tick if you agree with the following statements

1. I have asked all the questions that I need to and am happy with the answers you have given me and that I have enough information about the study Yes/No
2. I understand that the answers I give will be confidential and that you will not link my name to or tell anyone about what I say Yes/No
3. If I change my mind about participating in this interview that I understand that this will not affect either my right to take part in other aspects of the study or my right to health care in Blantyre Yes/No
4. I understand that if I test positive and tell the result to the counsellor that they will check the result, ask me questions about my health and may take a specimen of sputum to test for TB and that I will be referred to the HIV clinic Yes/No

Participant \_\_\_\_\_  
(Name in BLOCK CAPITALS)

Study Team Member \_\_\_\_\_  
(Name in BLOCK CAPITALS)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date

*If the participant gave verbal consent, please enter the name of person who witnessed the consent here, and their signature:*

Witness \_\_\_\_\_  
(Name in BLOCK CAPITALS)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature