

**INFORMED CONSENT FOR PATIENTS –Enhanced Usual Care  
(Control Arm)**

**A cluster randomized controlled trial of a brief psychological intervention for  
common mental disorders delivered by lay health workers**

**Version 3.2, Dated 18 August 2014**

**PRINCIPAL INVESTIGATOR:**

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**CO-INVESTIGATOR:**

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**INTRODUCTION:**

You are being asked to take part in the research study named above. This study is being conducted in randomly selected city health clinics in Harare. The doctor in charge of the study is Dr. Dixon Chibanda.

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 feel free to ask us if there is anything that is not clear or if you would like more information. Once you understand the study, and if you agree to take part, you will be asked to sign this consent form or make your mark in front of someone. You will be offered a copy to keep.

**Please note that:**

- Your participation in this research is entirely voluntary;
- You may decide not to participate or to withdraw from the study at any time without losing the benefits of being treated at this clinic.
- If you decide not to participate in this study, you can still join another research study later, if one is available and you qualify.

**PURPOSE OF THE STUDY:**

Over the past 6 years we have identified a large proportion of people suffering from common mental disorders (kufungisisa) coming to the local clinics in Harare. Most people come to the clinic for conditions such as hypertension, diabetes; HIV/AIDS just to mention a few, however, these people often have kufungisisa and are not aware of it. The purpose of this study is to identify people with kufungisisa and then inform them of their condition and advise them on what is routinely available for this condition. Treating kufungisisa is important because if left untreated it may affect other existing conditions such as hypertension, diabetes, and HIV/AIDS. Earlier studies carried out in Zimbabwe show that when kufungisisa is not treated it may affect the outcomes of other chronic conditions commonly attended to at primary health care level. In this study we will provide you with information in the form of a pamphlet about kufungisisa and what can be done about it. We will be in touch with you at least once a week for the next 8 weeks and then we will follow-up your progress after 3 months, and six months.

**STUDY PROCEDURES:**

If you agree to join this study and if you are selected for the trial you will be asked a series of questions about your socio-demographic details. You will then be asked to answer a few more questions related to how you are feeling and your economic support systems. A trained researcher will administer these questions. These questions will take about 30-45 minutes to administer. After this you may or may not be selected to participate in the study depending on whether you meet the study inclusion criteria. If you meet study inclusion criteria you will be referred to a research team member who will provide you with information about kufungisisa and explain what it is and what you can do about it. If the research team finds that you are unwell and need to be referred you will be referred to an appropriate health facility for further care if you cannot be helped at this clinic. You are free to utilize this City Health Clinic as you have always done for other health related problems. The research team members may contact you so we need to know the best way to reach you such as home visits or phone call. We are inviting people aged 18 and over to respond to these questions (age must be verified by national ID).

**POTENTIAL RISKS /BENEFITS:**

There may be no other direct benefits to you by participating in this study though we believe this study will benefit the clinic community as a whole by increasing knowledge and awareness about treatment for depression.

You will not be subjected to any risk in this study. If you find any question posed by the interviewer is sensitive you can decline responding to that question. You will not be compelled to answer all the questions.

**REIMBURSEMENT:**

To thank you for taking part you will be given refreshments during the interview and your transport costs using public transport will be reimbursed at the rate of \$3.

**CONFIDENTIALITY:**

Your identity will be secured by assigning you a number before the meeting and only using that number through the record keeping. The only exception to this would be if you will be identified to have a serious mental health problem. In that situation, the study team leader at this clinic will discuss it with you and if needed, refer you to specialist medical care. Care will be taken to keep your situation confidential among other clinic members.

**ALTERNATIVES TO PARTICIPATION:**

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this form to keep and be asked to sign consent form once you are enrolled. If you decide to take part you are still free to not answer any question that you are not comfortable with at any point in the interview and you can withdraw at any time without giving a reason. Please note that you will not be compensated for your time in participation of this study when you withdraw

**PERSONS TO CONTACT FOR PROBLEMS OR QUESTIONS:**

If this study has harmed you in any way or if you have any problem or doubt about this study you may clarify from the interviewer or directly contact Dr Dixon Chibanda at the University of Zimbabwe Dept of Psychiatry, telephone +263 712 204 107 or If you ever have questions about your rights as a research participant you may call the Medical Research Council of Zimbabwe, at 04 791792 or 0712 433 164-7 (offices located corner Tongogara/Mazoe Street in Harare).

NOTE: You are not giving up any of your legal rights by signing this informed consent document.

**SIGNATURE PAGE**

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English

**STATEMENT OF CONSENT**

Thank you for considering taking part in this research. The person organizing the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

- I understand that if I decide at any time during the research that I no longer wish to participate in this project, I can notify the researchers involved and withdraw from it immediately without giving any reason. Furthermore, I understand that I will be able to withdraw my data up within two weeks of the interview date.
- I have read the informed consent or had it read and explained to me. I understand the information and I voluntarily agree to join this study.
- This page of the Informed Consent Form is stamped by the Medical Research Council of Zimbabwe to indicate it has been approved by the MRCZ.
- I consent to my interview being recorded.

Please tick or initial

**Participant's Statement:**

\_\_\_\_\_  
Name Signature Date

**Witness:**

\_\_\_\_\_  
Name Signature Date

**DELETE IF NOT APPROPRIATE**

**Investigator's Statement:**

I \_\_\_\_\_

Confirm that I have carefully explained the nature, demands and any foreseeable risks (where applicable) of the proposed research to the participant.

Signed \_\_\_\_\_ Date \_\_\_\_\_

