**PATIENT INFORMATION SHEET AND INFORMED CONSENT FORM**

*(for adult subjects and interventional studies)*

1. **Title of study**:

Effectiveness of the PAUSE© Flipchart Compared to Conventional Method Of Premarital HIV Counselling :A Randomised Control Study

2. **Name of investigator and institution:**

Institution:

Department of Family Medicine, UKM

Researchers:

Associate Professor Dr Leelavathi a/p Muthupalaniappen, Principal Investigator, Department of Family Medicine, Faculty of Medicine, Universiti Kebangsaan Malaysia

Associate Professor Dr Aznida Firzah Abdul Aziz, Co-Researcher, Department of Family Medicine, Faculty of Medicine, Universiti Kebangsaan Malaysia

Dr Magaletchumi a/p Chelladorai, Medical Officer, Department of Family Medicine, Faculty of Medicine, Universiti Kebangsaan Malaysia

3. **Name of sponsor**:

UKM Fundamental Faculty Grant (GFFP) and self-funded

**4. Introduction:**

You have been invited to participate in this research because you need to undergo HIV screening

as a precondition for marriage registration. This information sheet explains the details of the research more comprehensively. It is very important that you understand why this research is being conducted and what it entails. Please take enough time to read and carefully consider the information provided before agreeing to participate in this research. If you have any questions or require more information, you may ask any of the research staff involved.

Once you are satisfied that you understand this research and are interested in participating, you will be required to sign the Patient Consent Form on the last page of this information sheet. To participate in this research, you need to provide your doctor with your past medical history and illnesses; if you are not forthcoming you may cause yourself problems in the future.

Your participation in this research is voluntary. You do not have to participate if you do not wish to. You also have the right not to answer any questions you do not wish to answer. You may also withdraw from this research at any time. If you withdraw, any information obtained before your withdrawal will still be used for this research. If you do not wish to participate or withdraw from this research, it will not affect any of your rights and privileges to medical care and services that you would otherwise be entitled to receive.

This research has been approved by the Medical Research & Ethics Committee, Ministry of Health Malaysia.

**5. What is the purpose of the study?**

The purpose of this research is to compare the effectiveness of premarital HIV counseling using the PAUSE© flipchart versus conventional premarital counseling methods and to assess the level of understanding of the PAUSE© flipchart.

Currently, premarital HIV screening counseling is provided by medical or paramedical personnel. The counseling content depends on the counselor's knowledge of the HIV/AIDS guidelines. Therefore, the delivery of these counseling sessions may vary in terms of content, duration and language used as it is not standardized.

The PAUSE© flipchart is designed to be concise and pictorial for easy understanding. This flipchart is designed based on local and World Health Organization (WHO) guidelines. This study will assess the effectiveness and understanding of this tool which will help expand its use nationwide as a more structured and standardized method for delivering HIV counseling. A total of 180 clients from Johor Bahru will be participating in this research. The research will be conducted over 3 months (from 1/12/2023 to 31/3/2024). Your estimated involvement is 30 minutes.

**6. What kind of study products** *[or procedures]* **will I receive?**

If you agree to participate in this research, you will be randomly assigned to one of the counseling groups described below. The chances of you being placed in any treatment group are equal.

Group 1:

Receives conventional counseling, counseling will be given once by the medical practitioner. Counseling duration: 10 minutes

Group 2:

Receives counseling using the PAUSE© flipchart, counseling will be given once by the researcher. Counseling duration: 10 minutes.

**7. What will happen if I decide to take part?**

You will be randomly assigned to a counseling group as described above.

You will be given a questionnaire containing 22 questions related to HIV. You will be given 10 minutes to answer the given questions. You can choose to answer the questions in Malay or English. After completing the questions, you will be given HIV counseling followed by HIV infection screening. After that you will be given the same set of questions to answer again. The questionnaire will be returned to the researcher after the answering time is over.

You do not need to come for follow-up treatment for the purpose of this research.

**8. When will I receive the trial product and how should it be kept?**

You will not receive any research product, but you will be given counseling using the research product.

**9. What are my responsibilities when taking part in this study?**

It is very important that you answer all the questions asked by the research staff honestly and completely and you are expected not to share the details of these questions with others.

**10. What kind of treatment will I receive after my participation in the trial?**

The treatment given depends on the results of your HIV screening test. The HIV screening results and subsequent treatment are not included in the research.

**11. What are the potential risks and side effects of being in this study?**

This study carries minimal risk. Illustrations may cause discomfort and increase anxiety in some people.

**12. What are the benefits of being in this study?**

This research may or may not bring any direct benefit to you. All information obtained from this research will help improve counseling methods for other clients who will undergo premarital HIV screening.

**13. What if I am injured during this study?**

If you sustain injuries due to your participation in this research, you should contact your research doctor. If physical/bodily injury or disease results directly from the research product in this research, the sponsor will pay all reasonable treatment costs required. However, the sponsor will not be responsible for medical expenses for pre-existing illnesses or treatments that you were already undergoing, or any problems arising from your own negligence or intentional misconduct, or negligence or intentional misconduct by your research doctor, the research site/location/centre, or any third party involved.

However, you do not waive any of your legal rights to seek compensation even if you have signed this form.

**14. What are my alternatives if I do not participate in this study?**

You will be given conventional counseling and will undergo HIV screening as currently available.

**15. Who is funding the research?**

This study is partially funded by UKM Fundamental Faculty Grant (GFFP).

Any other procedures and treatments not required by this research but are part of your daily treatment are your own responsibility or that of your insurance. You will also be given a 5 ringgit token of appreciation.

**16. Can the research or my participation be terminated early?**

The research doctor or sponsor may terminate this research or your participation at any time if necessary for your safety. If this research is terminated prematurely, you will be informed of the reasons. You may be asked to attend one final follow-up visit for this research.

Conditions under which a subject's participation may be terminated:

Subject is unable to comply with study rules

Any disciplinary issues

Criteria for subject withdrawal:

Unable to comply with study rules

Problems understanding the content of the PAUSE© flipchart and questionnaire

**17. Will my medical information be kept private?**

All your information obtained from this research will be stored and handled confidentially, in accordance with relevant regulations and/or laws. If the results of this research are published or presented to the public, your identity will not be revealed without your prior consent. Certain parties such as individuals involved in your medical research and treatment, trained auditors and monitors, the sponsor or its affiliates, governmental or legal authorities, may review and make copies of your medical records as applicable and necessary.

All data related to this research will be archived for analysis, but your identity will not be revealed at any time.

With your permission, your regular treating doctor will be informed of your participation in this research.

**18. Who should I call if I have questions?**

You may contact the research doctor for this study (Dr Magaletchumi) at 03-9171001 if you have any questions about this research or if you suspect you have sustained injury as a result of this research and want information about its treatment.

MEDICAL RESEARCH & ETHICS COMMITTEE,

MINISTRY OF HEALTH MALAYSIA

National Institutes of Health Complex (NIH),

No.1, Jalan Setia Murni U13/52,

Seksyen U13 Setia Alam,

40170 Shah Alam, Selangor.

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**INFORMED CONSENT FORM**

Title of Study:

Effectiveness of the PAUSE© Flipchart Compared to Conventional Method Of Premarital HIV Counselling :A Randomised Control Study

By signing below I confirm the following:

 I have been given oral and written information for the above study and have read and understood the information given.

 I have had sufficient time to consider participation in the study and have had the opportunity to ask questions and all my questions have been answered satisfactorily.

 I understand that my participation is voluntary and I can at anytime free withdraw from the study without giving a reason and this will in no way affect my future treatment. I am not taking part in any other research study at this time. I understand the risks and benefits, and I freely give my informed consent to participate under the conditions stated. I understand that I must follow the study doctor’s (investigator’s) instructions related to my participation in the study.

 I understand that study staff, qualified monitors and auditors, the sponsor or its affiliates, and governmental or regulatory authorities, have direct access to my medical record in order to make sure that the study is conducted correctly and the data are recorded correctly. All personal details will be treated as STRICTLY CONFIDENTIAL

 I will receive a copy of this subject information/informed consent form signed and dated to bring home.

 I agree/disagree\* for my family doctor to be informed of my participation in this study.

*(\*delete which is not applicable)*

**Subject:**

|  |  |
| --- | --- |
| Signature: | I/C number: |
| Name: | Date: |

**Investigator conducting informed consent:**

|  |  |
| --- | --- |
| Signature: | I/C number: |
| Name: | Date: |

**Impartial witness:** *(Required if subject is illiterate and contents of patient information sheet is orally communicated to subject)*

|  |  |
| --- | --- |
| Signature: | I/C number: |
| Name: | Date: |